JAASP

RESEARCH PAPER

The National Immunization Committee (Nic), A Philippine Nitag (National Immunization Technical Advisory Group)

Romeo C. Ongpoy, Jr.[1, 2, 3]

[1]College of Pharmacy, De La Salle Health Sciences Institute;

[2]Regulatory, Clinical & Quality Department, PerkinElmer Instruments (Phils.) Corp.

[3]Graduate School, Centro Escolar University – Mendiola

Keywords

NITAG
NIC
Immunization
Vaccination

Correspondence
Romeo C. Ongpoy, Jr,
College of Pharmacy, De La Salle Health Sciences Institute;
Regulatory, Clinical & Quality Department, PerkinElmer Instruments (Phils.) Corp.
Graduate School, Centro Escolar University – Mendiola

E-mail: rongpoy@gmail.com

Abstract

The NIC has been established for 31 years in the Philippines and has been instrumental for translation of immunization science to policy. This paper describes and to some extent compares the committee with other NITAGs in terms of the WHO-UNICEF process indicators as well as the 4 main factors in health policy making generally being addressed by NITAGs; this was made possible through DOH documents, interview with EPI (Expanded Program on Immunization) personnel, and exhaustive literature review on the NITAGs of other countries. About this study, it was found out that generally NIC is compliant with the said process indicators and health policy factors with few recommendations on the committee representation, guidelines clarity, meeting frequency, conflict of interest processes and development of in-house experts.

Introduction

The NIC is an external advisory group to the EPI office of the Department of Health (DOH). This committee was created through the Ministry Order number 327-A series of 1986 and serves to provide direction and technical support on policies and plans pertaining to immunization and provide an avenue for coordinating all aspects of the Philippine immunization program [1]. One of the achievements of the NIC is its support to the eventual elimination of Polio in the country back at 2000 and its current efforts to finally eradicate measles as well as the maternal and neonatal tetanus, the latter being on its final validation stage as of the present.

Through the years NIC has been instrumental in the milestones of the Philippine vaccination (see Table 1).

The major role of the NIC is to provide sound, evidence-based advice on matters related to vaccines and vaccination, including promoting and maintaining the health of the people through effective, efficient, timely and equitable delivery of immunization services which may be achieved through their specific responsibilities. The national EPI Manager through the support of his EPI staff also serves as the secretariat to the NIC and performs routine activities like coordination of meeting logistics, drafting reports, writing minutes of meeting and communications to the rest of the NIC members like the NNCI (National Consultative Council of Immunization) in Honduras [2].

The Philippine NIC does not have a handbook like the Australian ATAGI (Australian Advisory Group on Immunization) [3] where the immunization schedules are listed but promotional/educational materials are available such as printed cardboards and the same information are also being disseminated largely at social media. An internal Manual of Procedures for National Immunization programs is also being followed by the EPI which has just been released last 2015.

The Philippine NIC gives out its recommendation after concerns are being presented to them. This recommendation will then be approved by the EPI after a quorum of around 6 people has been achieved, a technical working group further reviews the approved recommendation. Key organizations in the DOH are being asked to prepare, or in vaccine demands, purchase like in NCPAM (National Center for Pharmaceutical Access and Management) that then makes the vaccine available so that when the secretary of health signs the approved guidelines, the program as well as the policies and regulations are in place (see Figure 1). The process has some similarities to the ECIP (Experts Advising Committee on Immunization Program) in China [4] and the ACIP (Advising Committee on Immunization Practice) in Thailand [5].

NIC ↓	Makes recommendations
EPI ↓	Reviews NIC recommendations (approves or disapproves)
TWG ↓	Drafts guidelines
DOH Secretary	Final approval by signing and further review of the guidelines

Figure 1: The Role of NIC in Immunization Policies

This paper was made possible through interview with on EPI personnel and aims to give information and to some extent compare on how the Philippines manages its NITAG through the NIC so it may serve as a learning for other governments to further improve their processes, for the vaccine companies to understand the pharmaceutical systems behind immunization and for the Philippines to open its processes for constructive points of view. Moreover, for the Filipinos to be informed about the government processes that keep them healthy.

Table 1: Milestones of Vaccination in the Philippines

Year	Milestone
1976	EPI was launched in the Philippines with the introduction of BCG (Bacillus Calmette-Guerin) to school entrants
1979	DPT 2 (Diphtheria-Pertussis-Tetanus) was introduced nationwide
1980	OPV (Oral Polio Vaccine) and TT 2 (Tetanus Toxoid) was given nationwide
1983	Measles vaccine was introduced nationwide
1984	DPT 3 was added and childhood immunization targeted to 0-12 months
1986	Philippines adopted the UN General assembly's commitment to Universal Child Immunization
1991	National Plan of Action for Polio Eradication took effect
1992	Start of Hepatitis B immunization
1993	First National Immunization days, National Plan of Action for Neonatal Tetanus elimination took place and Measles elimination approved. Also the start of vaccine independence initiatives
2000	Philippines was certified Polio-free
2006	Hepatitis B birth dose was introduced nationwide
2009	Introduction of Measles-Mumps-Rubella vaccination to 12-15 years old started
2013	Pentavalent vaccine was introduced
2014	HPV (Human Papilloma Virus), PCV (Pneumococcal Conjugate Vaccine) and Rotavirus vaccination in pilot studies were conducted
2015	Introduction of IPV (Inactivated Polio Vaccine) and school-based MRTD (Measles-Rubella-Tetanus-Diphtheria) adolescent vaccination

2.The NIC And The Who Process Indicators

According to the World Health Organization (WHO) and UNICEF (United Nation's Children Fund), there are 6 process indicators pertaining to the characteristics and functioning of the NITAG. These are legislative or administrative basis for the advisory group, formal written terms of reference, diverse expertise/representation among core members (in terms of pediatrics, public health, infectious disease, epidemiology, immunology or other healthcare professionals), number of meetings per year, circulation of the agenda and background documents at least one week prior to meetings and mandatory disclosure of any conflict of interest [6]. These indicators will be used to describe the Philippine NITAG in this article based on its organizational nature.

2.1. Legislative or Administrative Basis for the Advisory Group

The NIC was created since 1986 under the Ministry Order number 327-A series of 1986. Since then it has underwent administrative changes over the years and most of these changes are in relation to its membership constitution which was changed to a group of 12 in May 16, 1997 [7], added with 3 more members in July 26, 1999 [8], underwent membership restructuring again in August 1, 2002 from the 15 members [9], reconstituted to 16 members in January 24, 2007 [10] and re-composed to a group of 9 in March 15, 2016 with another 6 Technical Working Group (TWG) members in its latest amendment [1]. In this said amendment, roles and responsibilities of the NIC, its composition, EPI manager responsibilities, TWG composition and TWG responsibilities were described.

In policy formulation, drafting of the technical documents are being conducted by a TWG composed of a chairperson, a co-chairperson and 4 members who are all medical doctors with an EPI staff as the secretariat. Epidemiology, disease burden and cost effectiveness are the main thrusts for policies with cost effectiveness studies usually being conducted by experts outside DOH there were no specific mention of vaccine safety and efficacy but NIC explores other measures available for disease prevention before acquiring vaccines. There is also no mention of programmatic issues like evaluation of current programs on immunization, vaccine supply and vaccine presentation to the public.

In other countries like Australia, funding determination is being done by a Pharmaceutical Benefits Advisory Committee, the NIC funding determination is being affected by the DBM (Department of Budget and Management) and there are also no advisory bodies outside DOH like a National Center for Immunization Research and Surveillance [3]. The broad stages in the preparation of a recommendation statement are not detailed and written like in Canada where there are written procedures that involves knowledge synthesis, synthesis of the body of evidence on benefits and harms, considering quality of evidence and the magnitude of effects observed and the translation of the evidence. There is also no recommendation grading like that of the Canadian National Advisory Committee on Immunization (NACI) as well as recommendation or statement templates [11]. There are however vaccine guidelines of the NIC that may be downloaded online through the DOH website. Implementation surveillance are also part of these guidelines where at times an impact study is being conducted only in one area for at least 2 years to determine possible outcomes.

2.2. Formal Written Terms of Reference

The contract of the NIC members are not yet being stabilized like the terms of office and compensation in the US setting [12], member dismissal procedures like that of Korea [13] or the membership criteria, observer membership status and competency building training/courses in China [4]. Table 2 summarizes the terms of reference of the NIC, Table 3 the national EPI manager and Table 4 that of the TWG.

2.3. Diverse Expertise/Representation Among Core Members

In a European NITAG publication [14], professional expertise among member countries that are mostly represented in order of the most common is clinical medicine with 22 EU countries representing it in their NITAG, next is epidemiology with 21, pediatrics with 20, public health with 18, microbiology (including virology) with 17 and immunology and vaccinology with 16 each. Other expertise includes health economics, general practice, regulatory authority, ministry of health, social sciences, well-baby clinics, university faculty, ethics, health insurance system, lay members,

occupational health, non-government organizations, school health medicine and travel medicine. In the Philippines, the current composition includes the Assistant Secretary of Health under the Office for Technical Services as the Chairperson with the Co-chairperson in the Director of Women, Men and Children's Health Division. Core members are represented by the representatives of the National Institutes for Health in the University of the Philippines, the Philippine Pediatric Society (PPS), Pediatric Infectious Disease Society of the Philippines (PIDSP), Philippine Medical Association (PMA), Philippine Society for Microbiology and Infectious Disease (PSMID), Child Neurology Society of the Philippines (CNSP) and the National Adverse Event Following Immunization Committee (NAEFIC). According to the DOH and UNICEF [6], a preferable expertise of the core members should be pediatrics, public health, infectious diseases, epidemiology, immunology or other healthcare professionals. It can be seen that pediatrics are overly represented by 3 organizations representing it while there are no representation from epidemiology, immunology and other allied health professionals like nurses and pharmacists in the US [12] and nurses in Canada [11] and Korea [13].

In the Australian setting, very extensive relations to drug organizations may be seen like the Australian Drug Evaluation Committee (ADEC), Adverse Drug Reactions Advisory Committee (ADRAC) and Pharmacy Benefits Advisory Committee (PBAC) and in Korea their FDA while in the NIC, there is no relationship with most drug agencies and even with professional organizations like the Philippine Pharmacists Association (PPhA) and the Philippine Nurses Association (PNA), affiliated organizations are only physician based. NIC membership is through appointment by DOH officials [8] and there is no defined appointment process like that of Korea [13] and Canada [11] where a mention of CV and other basic requirements are submitted. Previously, there were subcommittees in the NIC but in the current re-organization of the NIC, it does not exist anymore like in Thailand where a subcommittee each in vaccine research and development, vaccine production, vaccine quality control and immunization practice may be observed [5] or like in UK where a subcommittee may be organized should a need arise like in their HPV (Human Pappiloma Virus) vaccine advice development [15] or in India where there are disease specific working groups in addition to a creation of a subcommittee should need arise.

Table 2: NIC Terms of Reference

1. Conduct policy analyses, review of data and evidences to provide sound, evidence-based technical advice and recommendations for the development of dynamic, sustainable and appropriate immunization policies, guidelines, strategies and approaches related to all immunization programs and activities, including decisions for consideration on introducing new vaccines in routine immunization service delivery
2. Review the latest position papers, studies, international guidelines, and recommendations from international agencies and bodies such as the World Health Assembly, Strategic Advisory Group of Experts, Technical Advisory Group for Immunization, World Health Organization and US Centers for Disease Prevention and Control, etc. for possible adoption in the country policies and plans for EPI
3. Provide advice to the national government and the EPI TWG on strategic and annual work plans for the control of vaccine preventable diseases through immunization
4. After careful review, the NIC shall endorse communication and IEC materials that will aid in promoting awareness and demand for immunization and participation to reporting of accomplishments, including reporting of vaccine-preventable diseases (VPDs) among decision-makers, stakeholders, health workers and the community
5. Facilitate/advocate for provision of resources and logistical assistance necessary for program implementation
6. Advise the national authorities on effective means to monitor and evaluate the immunization program for a more quantifiable measure of impact of immunization and other relevant interventions
7. Promote collaboration with and engagement of the local, regional, national and international organizations and institutions to support the implementation of plans and strategies to achieve country's goals for control, elimination and eradication of VPDs
8. Advise on appropriate research and development of new vaccines and vaccine delivery technologies for the future
9. Support and provide guidance to TWG/committees formed as hoc as the need arise. Accomplishments and progress of such ad hoc groups will be reviewed during regular meetings to assess impact t the immunization program.

2.4. Number of Meetings Per Year

The NIC meets twice a year every 3rd Thursday of March and September. Refreshments, documents, printing, copying, etc. are covered to facilitate the work of the members and this number of meetings are minimal compared to other countries like Honduras that meet 3 times a year [2] or in Canada where there are 3 meetings a year with 2 days in each of the meetings [11] and not as defined as China where meetings are the main activities to carry out different mechanisms which includes plenary meetings, including all members; working group meeting, involving some advisory members; and correspondence meeting, which involves the circulation of written papers and documents on matters to resolve that usually needs opinions and specific field surveys and supervision [4]. In the US, the members of the public may also be permitted to attend meetings and to speak or file written statements as meetings are posted online 15 days before the meeting date [12] contrary to India where close-door are observed with observers that may attend per invitation [16]. The NIC does not also have rules that will dismiss members who weren't able to attend 2 meetings in a row like in Korea [13].

NIC informs the members of the agenda 1 month before the meeting. In the meeting guidelines, the process is not as mature as Australia where common meeting aspects like venue, duration, etc. are no longer the focus of guidelines but the process of vaccine recommendations [3] which is also the case in Thailand [5] and not as result-oriented as China where written policies, disease control programs and technical proposals are evident after the meeting. However very procedure-oriented and defined meeting processes are a good reference like in Canada where aside from minutes of the meeting, there is also a summary of discussion document [11]. The US however has the most transparent system where minutes and recommendations are made public and available onsite within 90 days every meeting [12].

2.5. Circulation of the Agenda and Background Documents

NIC meets the criteria of WHO-UNICEF where meetings and background documents should be available at least a week before since NIC protocol is 1 month prior. Dissemination is usually through email and to some extent, faxed. Invitation of outside experts may be made for issues that are not of the expertise of any of the members. Invitation may be vital as there is no research experience requirement to be an NIC member.

Table 3: National EPI Manager Terms of Reference

1. Convene the NIC on a regular basis
2. Prepare the venue, logistics, materials and other administrative requirements for the NIC meetings
3. Responsible for documenting, filing and disseminating minutes of the meetings, including agreements, next steps and pending issues
4. Prepare formal presentation of NIC recommendations with supporting documents to and for consideration by the DOH Secretary and/or Executive Committee
5. Update the NIC on any relevant and current issues, trends and progress on EPI and VPD surveillance
6. Organize, coordinate and document the meeting proceedings of both the NIC and its different TWGs

Table 4: TWG Terms of Reference

1. Review existing immunization policies and guidelines for possible changes based on scientific evidence
2. Prepare and review technical documents, plans and proposals for presentation, approval and/or official endorsement of the NIC
3. Review and provide technical assistance to the Secretary of Health, regional health offices and partners especially program updates
4. Discuss, propose and advocate for activities requiring external support and resources
5. Review technical proposals for internal and external resource mobilization
6. Disseminate policies and guidelines approved by the committee to the sub-national levels and partners
7. Review technical content and appropriateness of information, education and communication (IEC) materials for immunization program
8. Monitor, document and report status of program indicators, implementation progress and accomplisments

2.6. Mandatory Disclosure of Conflict of Interest

NIC like other NITAGs considers conflict of interest and in NIC, working in a drug company is one. There is no processes though like a temporary resignation in Honduras [2] or an annual declaration like in Australia [3] and

Canada [11] and a screening procedure like that of Thailand is not also present like their call for decision if owning a stock in a vaccine company is significant to membership [5]. In the US, even immediate family member that is directly employed in a vaccine company is considered a conflict of interest [12]. NIC like in most Asian countries has fewer guidelines for conflict of interest [6] that can also be seen in China [4], Korea [13] and India [16].

2.7. THE NIC AND THE IMMUNIZATION POLICY MAKING FACTORS

NITAGs affect immunization policy making processes and in most countries, 4 main factors are being addressed by the NITAGs, these are disease burden in the country, severity of the disease, vaccine effectiveness or efficacy and vaccine safety at population level in which data may be gathered through JRF (Joint Reporting Form) from the WHO in which NIC also complies. Members are trained in some NITAGs before and during the role like in US where face-to-face and distance training may be conducted [12] and in Canada where continuing professional development credits are assigned [11] which will help in formulating recommendations for policy making but currently not yet practiced in the NIC.

3.1. Disease Burden of the Country

Morbidity and mortality are usually the basis for recommending vaccines onwards policy. Seriousness and extent of the disease burden are also taken into consideration especially the problems currently encountered locally, nationally and even regionally. To some extent globally as evidenced by purchases of prophylactics to dreaded diseases.

3.2. Severity of the Disease

Health technology assessment, in combination with epidemiological and behavioral analysis which include mathematical modelling has been increasingly used like the cost-utility analysis of HPV and cervical cancer by Guerrero at al [17]. The researchers though and the data sources are still from outside NIC.

3.3. Vaccine Effectiveness

The TWG does therapeutic committee work on vaccines qualification as well as targeting specific risk groups like the impact study on rotavirus in a small population first and in utilizing the cervical cancer study [17] for policy development. Cost effectiveness studies are the usual basis but there are also efficiency studies in vaccination. However, an official analytic framework document with a schematic diagram or any document which details analytic procedures from searching of evidence to conversion to policies are not available at the NIC.

3.4. Vaccine Safety at Population Level

Vaccine safety including effectiveness is usually based on WHO utilized resources and documents like guidelines that are also used by the NIC. Vaccines funding are affected by the DBM which determines supply and availability to the population. A Philippine immunization schedule though is available and well disseminated at health facilities and even online that may also help in promoting safety. Impact studies are also conducted after 2 years of vaccine administration which may include acceptability, efficiency and surveillance.

DISCUSSION

The Philippines generally has a functioning NIC that caters to the needs of the public but like other NITAGs, there are still room for improvements. One thing that needs to be taken into consideration is the representation of different expertise in the NIC, more representation is being given on pediatric and there is no representation in the field of immunology, epidemiology and other health professionals. An affiliate organization may be added like Food and Drug Administration (FDA), PNA and PPhA especially when nurses conduct immunizations and pharmacists will soon administer immunizations as well [18]. Second, official documents may be formally written with schematic representations for the process like in formulation of recommendations in Australia [3] and Thailand [5], the clear relationships with other organizations like budget, medicines, etc. like in China [4] and again in Australia [3] and the transparency of the US where publication and public participations are encouraged [12]. Third, as compared among the NITAGs referred to in this paper, the NIC is the one with the least meetings annually, more concerns and pro-active efforts may be discussed in these meetings and if feasible, meeting frequency should be increased. Fourth, the conflict of interest must have a formal process of declaration and action to ensure protection that recommendations from the NIC are solely for public betterment. Lastly, in-house experts

must be developed like in health economics and in vaccinology as this will minimize outsourcing that may be costly. Overall, the WHO-UNICEF process indicators are mostly met as well as the 4 main factors addressed in the NITAGs as to policy making by the NIC.

Acknowledgements

The author acknowledges the help Dulce C. Elfa MPH RN of the Expanded Program on Immunization, Department of Health for serving as the main resource person for this paper and to Rommel Salazar DrPH RN of the College of Nursing, De La Salle Health Sciences Institute for his advices on the research methodology

Competing Interest

The author declares no competing interest

Funding

This research was conducted as part of the requirement in the Parenteral Therapy subject of Mr. Ongpoy at CEU Graduate School for the PhD Pharmacy Program through the scholarship granted to him by the Philippine Council of Health Research & Development (PCHRD), Department of Science and Technology (DOST)

References

DOH Personnel Order 2016-0968 Department of Health Philippines. Reconstitution of the National Immunization Committee (NIC). March 15, 2016.

Molina-Aguilera, Ida Berenice, Mendoza-Rodriguez, Lourdes Otilia, Palma-Rios, Maria Aparicia, Valenzuela-Castillo, Renato. An Overview of the National Consultative Council of Immunization in Honduras. Vaccine. 2010; 28S: A64-A67.

Nolan, Terry. The Australian Model of Immunization Advice and Vaccine Funding. Vaccine. 2010; 28S: A76-A83.

Zheng, Jingshan, Zhou, Yuqing, Wang, Huaqing, Liang, Xiaofeng. The Role of the China Experts Advisory Committee on Immunization Program. Vaccine. 2010; 28S: A84-A87.

Muangchana, Charung, Thamapornpilas, Piyanit, Karnkawinpong, Opart. Immunization Policy Development in Thailand: The Role of the Advisory Committee on Immunization Practice. Vaccine. 2010. 28S: A104-A109.

Duclos, Philippe, et al. Progress in the Establishment and Strengthening of National Immunization Technical Advisory Groups: Analysis from the 2013 WHO/UNICEF Joint Reporting Form, Data for 2012. Vaccine. 2013; 31: 5314-5320.

DOH Department Order 250-1997 Department of Health Philippines. Reconstituting the Natonal Immunization Committee (NIC). May 16, 1997.

DOH Department Order 305-1999 Department of Health Philippines. Addendum of Department No. 250-1997 dated May 16, 1997 and Department Order No. 53 Fs. 1999 dated February 9, 1999. July 26, 1999.

DOH Department Order 208-2002 Department of Health Philippines. Reconstituting the National Immunization Committee. August 1, 2002.

Department Personnel Order 2007-0323 Department of Health Philippines. Reconstituting the National Immunization Committee (NIC) Members. January 24, 2007.

Ismail, Shainoor, Langley, Joanne, Harris, Tara, Warshawsky, Bryna, Desai, Shalini, Farhang-Mehr, Mahnaz. Canada's National Advisory Committee on Immunization (NACI): Evidence-Based Decision-Making on Vaccines and Immunization. Vaccine. 2010; 28S: A58-A63.

Smith, Jean Clare. The Structure, Role, and Procedures of the U. S. Advisory Committee on Immunization Practices (ACIP). Vaccine. 2010; 28S: A68-A75.

Cho, Hee-Yeon, Kim, Chang-Hoon, Go, UnYeung, Lee, Hoan-Jong. Immunization Decision-Making in the Republic of Korea: The Structure and Functioning of the Korea Advisory

Committee on Immunizing Practices. Vaccine. 2010; 28S: A91-A95.

Nohynek, H. et al. National Advisory Groups and their Role in Immunization Policy-making Processes in European Countries. Clinical Microbiology and Infection. December 2013; 9(12): 1096-1105.

Hall, Andrew. The United Kingdom Joint Committee on Vaccination and Immunization. Vaccine. 2010; 28s: A54-A57.

Jacob John, T. India's National Technical Advisory Group on Immunization. Vaccine. 2010; 28S: A88-A90.

Guerrero, Anna Melissa, Genuino, Anne Juliene, Santillan, Melanie, Praditsitthikorn, naiyana, Chantarapornchit, Varit, Teerawattananon, Yot, Alejandria, Marissa and Toral, Jean Anne. A Cost-utility Analysis of Cervical Cancer Screening and Human Papilloma Virus Vaccination in the Philippines. BioMed Central 2015; 15(730): 1-17.

Ongpoy, Romeo C. Level of Preparedness of the Filipino Pharmacists as Providers for Adult immunization. ASIO Journal of Pharmaceutical & Herbal Medicines Research (ASIO-JPHMR) 2016; 2(1): 4-8.