



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



152nd SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 17-21 June 2013

Provisional Agenda Item 4.5

CE152/14 (Eng.)

1 May 2013

ORIGINAL: ENGLISH

EVIDENCE-BASED POLICY-MAKING FOR NATIONAL IMMUNIZATION PROGRAMS

Introduction

1. National immunization programs (NIPs) have been an unparalleled catalytic force for reducing morbidity and mortality (1–2). Almost four decades after the Directing Council of the Pan American Health Organization (PAHO) created the Expanded Program on Immunization (EPI) through Resolution CD25.R27, these national programs continue to extend their reach by protecting against more vaccine-preventable disease pathogens with the arrival of new, innovative, life-saving vaccines (3–4). However, these newer vaccines are considerably more expensive than traditional vaccines, and their introduction into national immunization programs in the Region imposes greater resource requirements (5).
2. Given that national budgets for immunization are slow to expand relative to the needs of the programs, the scarce resources available must be used as efficiently as possible, and mechanisms should be sought to protect them (6). Resource allocation decisions should be data-driven to ensure positive, equitable, and sustainable outcomes. Likewise, arguments for increasing national immunization budgets must be strongly grounded in evidence given the many other existing public health priorities. The use of evidence to inform broader health sector policy was discussed during the 28th Pan American Sanitary Conference in Policy Document CSP28/11, *Health Technology Assessment and Incorporation into Health Systems* (7). In the same vein, the 65th World Health Assembly endorsed the Global Vaccine Action Plan, calling for the use of evidence, in particular economic evidence, in national decision-making processes around new vaccine introduction (8). This global plan calls upon Member States to incorporate evidence assessment into their immunization policy-making with the aim of maximizing health impact and efficient resource use.
3. NIPs are data-driven programs. Therefore, gathering all the evidence needed to evaluate the introduction of vaccines is a practical and effective first step toward a health

technology assessment (HTA) approach.¹ As other health intervention programs become stronger and able to generate and gather more evidence, countries will be able to move toward a health sector-wide HTA approach that will allow for comparisons among health interventions. The initial experience gained from NIPs in gathering a broad national evidence base should be helpful. This policy document proposes that countries strengthen their national infrastructure and processes for evidence-based immunization policy-making, leading to a greater impact on vaccine-preventable diseases along with a more efficient use of resources to achieve this impact.

Background

4. In the past decade, national immunization programs have faced increasingly complex decisions with the arrival of new vaccines and other technological advances in the field of immunization (9–10). The regional Technical Advisory Group (TAG) on Vaccine-Preventable Diseases was established in 1985 to provide policy guidance on regional goals for the elimination of poliomyelitis. Today, the TAG continues to advise on regional immunization policies and strategies. While this evidence-based regional guidance is very valuable, it is important to ensure that local evidence complements regional recommendations on new vaccine introduction so that country-specific characteristics such as disease burden profiles, program capacity, national priorities, and budgetary constraints will be taken into account (9).

5. Recognizing a need to bolster national capacities to incorporate evidence-based approaches to policy-making, the Pan American Health Organization's regional immunization program, the EPI, established the ProVac Initiative in 2004 as an integral part of the technical support it provides to Member States. The PAHO Directing Council endorsed the Initiative's main focus in 2006 through Resolution CD47.R10, requesting that the PAHO Director "support country activities to integrate in-depth economic studies into the decision-making process for the introduction of new and underutilized vaccines" (11). The overarching goal of the Initiative is to strengthen national capacities for evidence-based decision-making around new vaccine introduction, with a particular focus on the use of economic evaluations in the decision-making process (9).² In 2009, the ProVac Initiative was awarded a five-year grant by the Bill & Melinda Gates Foundation to support country decision-making around new vaccine introduction. Over 25 economic evaluations and costing studies have been conducted by multidisciplinary national teams

¹ "Health technology assessment (HTA) [is] defined as the systematic evaluation of properties, effects, and/or impacts of those technologies, including medical, social, ethical, and economic dimensions" (7).

² To achieve this goal, the Initiative has focused its efforts on five key objectives: (a) strengthen evidence-based decision-making processes and infrastructure; (b) develop tools and methods for countries to use in economic evaluations; (c) conduct analyses to generate evidence on the economic and health benefits of vaccines; (d) develop policy briefs to inform decision-makers of the available evidence; and (e) support the development of national plans for new vaccine introduction, when the evidence supports this decision.

in 15 countries (10, 12). The cornerstone of all technical assistance provided to Member States by the Initiative has been the bolstering of national capacities, South-South cooperation, and country ownership of the process of generating evidence (9–10, 12).

6. Following the 2006 Directing Council Resolution, the 50th Directing Council in 2010 requested the PAHO Secretariat to “provide technical assistance to the Member States for evidence-based decision-making through the ProVac Network of Centers of Excellence” (13). The ProVac Centers of Excellence are academic institutions with expertise on economic evaluations that develop tools and guides to be used by countries conducting economic studies with local and regional data. These studies have served to inform technical recommendations and resource allocation decisions on a series of policy issues including introduction of vaccines to prevent rotavirus, pneumococcal disease, seasonal influenza, and human papilloma virus. More recently, these studies have incorporated the evaluation of health interventions that are complementary to vaccination strategies, such as cervical cancer screening as a complement to HPV vaccination (5).

7. These efforts to strengthen national capacity for evidence-based decision-making in the Americas have gained global recognition and have led to repeated requests for support by other Regions of the World Health Organization (WHO). Accordingly, PAHO was awarded a small additional grant to provide time-limited support for the use of economic evaluations in immunization decision-making in select countries of Africa, Europe, and the Eastern Mediterranean. This work is being carried out in collaboration with international partners and the WHO Regional Offices (12).

8. This policy proposal seeks to further bolster the capacity of national immunization programs to ground their immunization policy decision-making in evidence, especially with respect to the arrival of new vaccines currently in the pipeline. Specifically, this proposal identifies the need to institutionalize existing capacity for evidence-based decision-making around immunization; to promote the development and use of a broad, national evidence base for immunization decision-making; and to tackle the new challenges related to effectively planning and budgeting for the adoption of new vaccines and the evaluation of health interventions that complement vaccination strategies.

Situation Analysis

9. Progress toward building capacity for evidence-based decision-making in the Americas can be seen in the increasing number of scientific publications and other technical documents with epidemiological and economic studies that are at least partially based on local data. The evidence derived from these studies is a crucial input to the decision-making process on new vaccine introduction. However, national institutional support for generating, collecting, and analyzing locally derived evidence for NIPs remains sparse.

10. In recent decades, a small number of countries (e.g., Brazil, Chile, Colombia, and Mexico) have contributed to building the evidence base on the economic costs and health benefits of new vaccine introduction. To develop and strengthen these capacities in other countries in the Region, PAHO established the ProVac Initiative. Since its inception, ProVac has trained over 30 countries in the use of economic models for cost-effectiveness analyses, and 15 countries have opted to develop locally derived cost-effectiveness analyses to support national decision-making using ProVac models and tools (10, 12). With technical support from ProVac, countries as different as Argentina, Nicaragua, and Paraguay have fed local data into these models to produce country-specific results, which are more valuable and better received by national decision-makers than desk-based evaluations using internationally available data that may not be representative of the country (12, 14).

11. Despite the important steps that Member States have taken to adopt the recommendations of the 2006 Directing Council, much remains to be done to incorporate evidence, particularly economic evaluations, into the immunization decision-making process. Countries must strive to create a broad, nationally based evidence framework for their decision-making, one that will consider not only technical criteria but also programmatic, financial, and social criteria. Countries have successfully used cost-effectiveness analysis as an initial framework for generating information about new vaccine introduction related to the anticipated incremental program costs and projected cost savings from health service visits, cases, and deaths averted. However, these data do not provide much guidance on programmatic, financial, or social concerns, such as equity. While most Member States would recognize the importance of incorporating these other criteria into national immunization decision-making, there is a need for additional tools and guidance on how to evaluate all criteria—technical, programmatic, financial, and social.

12. Additionally, there is a need to continue strengthening an important player in immunization decision-making, namely the National Immunization Technical Advisory Groups (NITAGs). These advisory bodies provide technical recommendations on immunization to the ministries of health based on available evidence. In 2012, of 20 Latin American countries, 18 reported having a NITAG. In the Caribbean, the immunization programs of the English-speaking states instead rely on the annual EPI Managers' Meeting as their advisory body.³ Throughout the Region, the public health sector often suffers substantial turnover in personnel and political leadership without adequate institutional frameworks to protect their role, NITAGs can be affected by similar instability, putting at risk previous policy recommendations. Measures to legally establish the NITAGs and define their role are therefore essential to equip these bodies with the institutional support and authority they need to provide informed recommendations. In

³ In other words, the annual EPI Managers' Meeting plays a role equivalent to that of a NITAG.

2011, two countries ratified laws either to formally establish the NITAG or to require the use of evidence to inform immunization policy-making⁴ (15–17).

13. Finally, decision-making for new vaccine adoption happens on a continuum, extending into the program planning phase. If a decision is misinformed by poor evidence or lack of evidence, the planning process will not adequately prepare the NIP for a successful and sustainable introduction (18). Therefore, it is essential that countries assess the operational implications, financial feasibility, and long-term sustainability and impact of incorporating a new vaccine into the routine immunization program. The pneumococcal conjugate vaccine alone can double or triple the national NIP budget. It is important to ensure that new vaccine introduction costs do not displace financial support for the routine program, especially in countries that require simultaneous strengthening of the routine program and new vaccine introduction capacities. While disease burden, vaccine profile (immunogenicity, efficacy, and safety), and cost-effectiveness data all may support the introduction of a new vaccine, information about the financial cost is necessary to inform budget increases and programmatic plans for introduction. However, there is limited capacity and guidance in the Region to help countries incorporate routine budgeting exercises into their planning for new vaccine introduction in a standardized and robust way.

14. The Region of the Americas has always been a pioneer and a global leader in immunization. In the last decade alone, the Region has achieved not only early but also equitable introduction of new vaccines, with low-, middle-, and high-income countries adopting new vaccines at a similar rate. All these achievements are at risk due to the increased complexity of the decision-making and planning that must be undertaken by the NIPs. New vaccine adoption without an adequate evidence base and careful planning could lead to an overall decrease in performance of the NIPs. The programs will face problems of underfunding and inefficiencies, resulting in decreased public health benefits. This would also affect other health programs that benefit from the structure and reach of the national immunization programs to provide additional health services and interventions.

Proposal

15. To ensure that national immunization programs are equipped with the necessary capacities to meet decision-making challenges, a threefold approach is proposed.

⁴ Chapter 3 of El Salvador's Vaccine Law 1013 lays out the composition and requirements of the NITAG. In July 2012, El Salvador's Ministry of Health developed a standard operating procedures manual for the NITAG. Article 10 of Paraguay's Vaccine Law 4621 lists the kinds of evidence to consider when modifying the national immunization schedule. In articles 11–13 it establishes the existence of a NITAG and requests that an operations manual be developed by the Ministry of Health.

Expand the evidence base beyond cost-effectiveness

16. The technical aspects of immunization policy-making should always be balanced with the programmatic and social aspects and should be considered in the context of the health system overall. In particular, the Region of the Americas is affected by the crippling effects of inequities within countries, in health and other areas of life, and immunization policy should aim to redress some of these inequities. Other dimensions that countries should include in their policy evaluations include assessing how new vaccines could prevent high out-of-pocket health care expenditures and assessing subnational variations in the likely impact of new vaccines.

Institutionalize an evidence-based decision-making process for new vaccine introduction

17. Institutionalization of NITAGs or similar technical policy bodies, through ministerial decree or national law, is advisable to ensure continuity of policy recommendations and to establish explicit relationships between the advisory bodies and government agencies. These legal frameworks should also provide financial support to carry out relevant research and operational studies to inform national immunization policies. Technical working groups will expand the national evidence base, further cementing the infrastructure necessary to have a comprehensive, national, evidence-based decision-making process.

Integrate policy-making and planning for NIPs

18. Policy decisions followed by successful planning for adoption of new vaccines into national routine immunization schedules requires collaboration between several actors and harmonization of processes that have generally been treated separately. Integration of costing, budgeting, and planning processes and their accompanying tools will ensure that the incorporation of new vaccines in the routine program generates sustainable and positive results. The integration of these processes can be supported by existing ProVac tools and methodologies and by technical cooperation from PAHO's regional immunization program.

Action by the Executive Committee

19. The Committee is requested to review the information provided in this document and consider adopting the proposed resolution presented in Annex A.

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152nd SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 17-21 June 2013

CE152/14 (Eng.)
Annex A
ORIGINAL: ENGLISH

PROPOSED RESOLUTION

EVIDENCE-BASED POLICY-MAKING FOR NATIONAL IMMUNIZATION PROGRAMS

THE 152nd SESSION OF THE EXECUTIVE COMMITTEE,

Having reviewed the document *Evidence-based Policy-making for National Immunization Programs* (Document CE152/14);

RESOLVES:

To recommend that the 52nd Directing Council adopt a resolution along the following lines:

EVIDENCE-BASED POLICY-MAKING FOR NATIONAL IMMUNIZATION PROGRAMS

THE 52nd DIRECTING COUNCIL,

Having considered document CE152/14 on evidence-based policy-making for national immunization programs;

Recognizing the increasing need for governments to have strong evidence bases for their resource allocation decisions in order to ensure positive, equitable, and sustainable health results;

Recalling the commitment of all Member States and stakeholders to bolster national capacities for evidence-based immunization decision-making documented in the Global Vaccine Action Plan endorsed by the 65th World Health Assembly;

Aware of ongoing efforts to institutionalize evidence-based decision-making in public health and acknowledging existing capacity in several countries to foster a broader scale-up of these efforts;

Noting the need for Member States to prepare and plan for evaluating the adoption of vaccines in the pipeline that may come at a substantially higher cost than traditional vaccines, while maintaining other achievements on immunization;

RESOLVES:

1. To urge Member States to:
 - (a) Implement the policy approaches described in *Evidence-based Policy-making for National Immunization Programs*, in collaboration with the Pan American Health Organization Secretariat and other relevant stakeholders, with particular emphasis on:
 - i. formally establishing and strengthening existing National Immunization Technical Advisory Groups (NITAGs) or regional policy bodies that serve the same purpose, as is the case of the Caribbean Advisory Committee, which provides recommendations for the whole subregion;
 - ii. grounding immunization policy-making in a broad national evidence base comprising the technical, programmatic, financial, and social criteria necessary to make informed decisions;
 - iii. developing technical working groups, where a need is identified, to synthesize and/or generate locally derived evidence to inform NITAG recommendations;
 - iv. institutionalizing activities to harmonize planning and costing processes of the national immunization programs, forging strong links between the uses of cost information in budgeting, planning, and decision-making;
 - v. sharing these experiences to evaluate other health interventions within the health technology assessment (HTA) framework.
 - (b) Seek measures to formalize these policy approaches by:
 - i. enacting comprehensive legal frameworks to promote and protect evidence-based decision-making around immunization;

- ii. ensuring a small budget to support data collection and synthesis and use of evidence in the decision-making process for immunization.
2. To urge the Director to:
- (a) continue providing institutional support to Member States to strengthen capacities for the generation and use of evidence in their national immunization decision-making processes through the regional immunization program's ProVac Initiative;
 - (b) foster the participation of Member States in the ProVac Network of Centers of Excellence;
 - (c) promote the harmonization of national immunization program planning and costing processes among Member States;
 - (d) support resource mobilization efforts to allow the regional immunization program to continue the efforts of the ProVac Initiative.



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
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CE152/14 (Eng.)
Annex B
ORIGINAL: ENGLISH

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.5 Evidence-based Policy-making for National Immunization Programs

2. Responsible unit: Comprehensive Family Immunization, Family and Community Health (FCH-IM)

3. Preparing officer: Barbara Jauregui, Cara Janusz and Gabriela Felix

4. List of collaborating centers and national institutions linked to this Agenda item:

Collaborating ProVac Centers:

Harvard University, Center for Health Decision Science
London School of Hygiene and Tropical Medicine
New Jersey School of Medicine

ProVac Centers of Excellence:

Institute for Clinical Effectiveness and Health Policy, Buenos Aires Argentina
Universidad de Cartagena, Colombia
Universidade do Rio do Janeiro, Brazil
Universidade de Sao Paulo, Brazil
Universidad Nacional de Colombia, Bogota, Colombia

5. Link between Agenda item and Health Agenda for the Americas 2008-2017:

- Reducing the risk and burden of disease
- Harnessing knowledge, science and technology
- Diminishing health inequalities among countries and inequities within them

6. Link between Agenda item and Strategic Plan 2008-2013*:⁵

SO1: To reduce the health, social and economic burden of communicable diseases.

7. Best practices in this area and examples from countries within the Region of the Americas:

Argentina: conducted 3 full economic evaluations with support from the ProVac Initiative and the PAHO Secretariat and created a post within the Ministry of Health to manage evidence generation for immunization decisionmaking.

* A new Strategic Plan is in preparation and will be presented to the 52nd Directing Council for adoption.

Honduras: developed a program costing study to estimate the economic and financial impact of the routine immunization program to better inform programmatic planning and monitoring.

Jamaica: conducted the first country-led cost-effectiveness analysis on the introduction of HPV vaccine to inform the national decision making process.

ProVac Centers of Excellence: *participating academic centers from Argentina, Brazil and Colombia* collaborate with PAHO to share their national capacity in the area of health economics and decision science for immunization by way of this network with other countries of the Region.

8. Financial implications of this Agenda item:

US\$ 3.2 million for 5 years



PAN AMERICAN HEALTH ORGANIZATION
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CE152/14 (Eng.)
Annex C
ORIGINAL: ENGLISH

**Report on the Financial and Administrative Implications
for the Secretariat of the Proposed Resolution**

<p>1. Agenda item: 4.5 Evidence-based Policy-making for National Immunization Programs</p>
<p>2. Linkage to Program and Budget:</p> <p>(a) Strategic Objective: SO1: To reduce the health, social and economic burden of communicable diseases.</p> <p>(b) Expected result: Strengthened national capacities to make evidence based immunization policies and plans that lead to positive, equitable and sustainable results for reducing vaccine-preventable diseases.</p>
<p>3. Financial implications:</p> <p>(a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities): US\$ 3.2 million for 5 years</p> <p>(b) Estimated cost for the biennium 2014-2015 (estimated to the nearest US\$ 10,000, including staff and activities): US\$ 1.28 million</p> <p>(c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities? US\$ 200,000</p>