STRENGTHENING IMMUNIZATION PROGRAMS

Concept Paper

Introduction

1. In 1977, the Directing Council of the Pan American Health Organization (PAHO), through Resolution CD25.R27 created the Expanded Program on Immunization (EPI), to reduce morbidity and mortality from vaccine-preventable diseases to levels that no longer constitute a public health problem.

2. Thirty-two years after its creation, the Expanded Program on Immunization continues to make a fundamental contribution to reducing infant morbidity and mortality in the Americas, and is an example of organization, commitment, solidarity, equity, and quality.

Background

3. The issue of immunization has been taken up at various meetings of the Governing Bodies of the Organization, always for the purpose of drawing attention to new challenges and addressing them. In recent years a number of documents have been discussed and approved, among them the “Regional Strategy for Sustaining National Immunization Programs in the Americas” (Resolution CD47.R10 (2006)); “PAHO Procurement Mechanisms for Strategic Supplies, including Vaccines” (Information Document CD48/INF/8 (2008)) of the 48th Directing Council, and “The Pan American Health Organization Revolving Fund for Vaccine Procurement” (Document CD49/21 (2009)) of the 49th Directing Council.
4. Although there have been major advances in the field of immunization in the Americas, there is a need for the adoption of strategies to sustain those achievements, tackle the unfinished agenda, and take on new challenges such as the introduction of new vaccines.

5. When the EPI was created, the majority of the Member States did not have regular immunization programs, which meant there were no national immunization authorities, skilled human resources, necessary infrastructure, or budgets for these activities.

6. With the full commitment of their ministers of health, and in collaboration with PAHO and its partners, the Member States proceeded to develop all the components of the EPI at the national level and put a basic immunization program in place that included vaccines against polio (OPV), diphtheria, tetanus, and whooping cough (DPT), measles, and serious forms of tuberculosis (BCG).

7. As the EPI evolved and was consolidated at the national level, new vaccines were also developed. The hepatitis B vaccine was introduced in 1990 and the pentavalent vaccine (DPT-Hib-HepB) was added to the Haemophilus influenza type b (Hib) vaccination series in 1995. The Region of the Americas was the first region that introduced with greater speed the use of this vaccine in regular immunization programs.

8. Moreover, at the recommendation of PAHO's Technical Advisory Group on Immunization, the yellow fever vaccine was added to the regular vaccination program in countries with enzootic areas. Introduction of the seasonal influenza vaccine began to be accelerated in 2004.

9. As part of its mandate, PAHO provides technical assistance to countries. Among other things, this has facilitated the development of strong national teams, specific budget lines for the programs, national vaccination laws, information systems, national immunization committees, interagency cooperation committees, and strong participation by civil society.

10. The firm commitment of the Member States promoted the EPI as a public good and established vaccination programs as the responsibility of the public services. Thanks to this strong political commitment, it is estimated that over 95% of the current budget for procuring vaccines and operating National Programs in Latin America and the Caribbean comes from national funds.

11. At the same time, PAHO brought together a group of experts on the topic at the regional level, and teams of epidemiologists were formed to serve as immunization focal points in most countries of the Region, creating a laboratory network and an
epidemiological surveillance system for vaccine-preventable diseases. Moreover, an extensive network of partners was created, in which international research institutions, civil society organizations, the media, well-known celebrities, and the governments of donor countries participated.

**Situation Analysis**

12. The EPI is fundamental both to strengthening health and primary care services, as well as to an integrated approach to family and community health.

13. The EPI is the most socially accepted health program, which reflects the commitment and shared responsibility of countries, health workers, international and regional organizations, and various social actors.

14. Coverage in the Region is among the highest in the world. In 2008, coverage was reported at 97% for BCG, 95% for OPV3, 93% for DPT-Hib3 in children under 1 year of age, and 94% for mumps/measles/rubella (MMR) in children 1 year of age.

15. Among other things, the coverage levels attained have kept the Region free of poliomyelitis cases caused by the wild poliovirus since 1991, free of indigenous measles cases since 2002, and with no reports of endemic rubella cases for more than a year. In March 2010, the Region of the Americas concluded Phase I of laboratory containment of the wild poliovirus, which is a prerequisite for declaring the global eradication of poliomyelitis. Phase I consists of identifying the laboratories in the Hemisphere that still store the wild virus.

16. The EPI is also on alert to the risk of the reintroduction of diseases already eradicated or eliminated from our Region. An example of this effort is the strengthening of epidemiological surveillance related to major international events that involve large movements of people (the Olympics, the Cricket World Cup, Soccer World Cup) and the preparation of a rapid response to cases or outbreaks.

17. However, when coverage is analyzed at the national, subnational, and, especially, municipal levels, it is clear that major challenges persist. According to information provided by the Member States for WHO-UNICEF (*Joint Reporting Form on Immunization*) for 2008, 44% of municipios in Latin America and the Caribbean had coverage below 95% (with DPT3 vaccine as the tracer). An estimated 55% of children under 1 year of age live in these municipios.

18. The impact of the EPI on the health of the Region's population has been significant. It is estimated that from 1990 to 2002, one-third of the deaths prevented in children were attributable to immunization. Through the regular immunization program,
it is estimated that 174,000 deaths in children are prevented annually in Latin America and the Caribbean, and that the use of the “new vaccines” (rotavirus, pneumococcus, and human papillomavirus) will also prevent thousands of cases and deaths in various age groups. These results represent EPI’s progress toward the achievement of the Millennium Development Goals (MDG).

19. An essential element for the development and success of the EPI has been PAHO’s Revolving Fund for Vaccine Procurement, which was also created in 1977 by resolution of the 25th Directing Council (CD25.R27). The Revolving Fund is the cooperation mechanism that gives Member States timely and sufficient access to quality vaccines at the lowest prices. Based on the principles of equity, solidarity, Pan-Americanism, and transparency, the Revolving Fund has permitted the timely availability of vaccines and is fundamental to introducing the new vaccines.

20. The majority of the Member States currently participate in the Revolving Fund. Through the Fund, 27 antigens with 39 different WHO-prequalified presentations are offered by 13 producers. In 2009, without taking into account the A (H1N1) flu vaccine, a total of 156 million doses were procured through the Revolving Fund for a total cost of US$302 million. This represents a little more than four times the total cost procured in 2000 ($69 million).

21. As part of the Revolving Fund’s activities, PAHO has provided technical support for countries to ensure the quality of the vaccines and syringes used in national programs. To this end, work is aimed at boosting the capacity of national regulatory authorities, as well as training the laboratory network in the quality control of syringes and supplies for immunization programs.

22. The Regional Plan for Quality Control and Safety of Syringes was created in 2005 to support the process of procuring syringes through the Revolving Fund for national immunization programs. The purpose of the plan is to assure the quality, efficacy, and safety of syringes, strengthening procurement and quality control mechanisms through (a) the use of laboratory tests to confirm conformity and compliance with ISO standards for products procured through bidding and the monitoring of products received by countries; and (b) institutional capacity building in the National Regulatory Authority to conduct quality-control tests.

23. Rapid and timely response to any public concern about vaccinations, and development of the concept of safe vaccination have succeeded in preserving the integrity of immunization programs and maintaining public confidence in vaccines.

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1 Unless otherwise indicated, all monetary figures in this document are expressed in U.S. dollars.
Therefore, all immunization programs should guarantee the safety of vaccination and be prepared to address any concern raised by the general public.

24. PAHO’s Expanded Program on Immunization has been working with the countries on the three components of the “Cold Chain”: proper storage, distribution, and transport of vaccines. This is to ensure that vaccines retain their immunologic properties and to prevent interruption of immunization services due to lack of vaccines. With the introduction of new vaccines, the cold chain has been strengthened at all levels, as has the training of health personnel in this area.

25. Information, a fundamental aspect of decision-making, has been one of the building blocks for the success of the program, as it has permitted documentation of vaccination coverage, epidemiological surveillance data, and the monitoring of indicators. However, even more work is needed on data quality.

26. The laboratory network for the diagnosis of vaccine-preventable diseases helps make timely information available for decision-making as well as for verification of processes for the control and elimination of these diseases. There are over 148 laboratories in the Region that perform measles/rubella diagnosis and 11 laboratories that diagnose poliomyelitis. With the integration of new vaccines into the regular immunization programs of the Member States, the capacity of laboratories to diagnosis rotavirus, pneumococcus, and human papillomavirus (HPV) has been strengthened.

27. Vaccination Week in the Americas has managed to ensure that the EPI receives high political priority, social commitment, high public visibility, and considerable public attention in the media, with activities that foster the participation of governments, civil society organizations, volunteers, academic institutions, international organizations, etc. Since its inception in 2003, this initiative has helped position vaccination as a regional public good. Through the initiative, the countries have succeeded in vaccinating nearly 300 million people across all age groups, especially vulnerable and hard-to-reach populations. In this way it has become a tool for generating equity and equality by reducing gaps in access to health and especially, by maintaining the commitment of all stakeholders to these preventive activities. This year marked the eighth Vaccination Week in the Americas, whose theme was “Reaching Everyone.” Following the example of this successful experience in the Americas, Europe launched a similar program five years ago, and the Eastern Mediterranean Region did so this year. This means that, in the last week of April 2010, 122 countries in three WHO regions simultaneously held International Vaccination Week. This initiative is expected to keep expanding to include other regions in the world until it becomes World Vaccination Week.

28. The Americas has seen the rapid introduction of the seasonal influenza vaccine in the past five years (2004–2008). In 2003, 13 countries and territories used the vaccine in
the public sector, while in 2008 the number increased to 35 countries and territories, 26 of which use the Northern Hemisphere vaccine formulation and nine the Southern Hemisphere formulation. The experience with the seasonal vaccine enabled the countries to be better prepared for vaccination against pandemic influenza.

29. One example of the response capacity developed with the EPI, from a technical and organizational standpoint, has been the response to the pandemic influenza A(H1N1) virus and the planning to introduce the corresponding preventive vaccine. National immunization plans have been buttressed with the development of national response plans, training for human resources, the production of manuals and guidelines, preparation of the study on events supposedly attributable to vaccination or immunization (ESAVI), and the administration of this vaccine.

30. Access to the influenza A(H1N1) vaccine in the Member States of the Region came through the direct procurement by the countries of approximately 315 million doses from producers (Argentina, Brazil [partial], Canada, Mexico, Suriname [partial], and the United States of America); the donation of approximately 11 million doses through WHO (Bolivia, Chile, Cuba, El Salvador, Guatemala, Guyana, Haiti, Honduras, Nicaragua, Paraguay, [partial], and Suriname); and procurement through the Revolving Fund, which enabled 24 countries to procure 20 million doses of the vaccine, thus fully meeting the demand in the Member States. As of 6 August, over 400 million doses had been administered worldwide and approximately 197 million had been administered in the Region of the Americas.

31. The availability of new vaccines that help reduce mortality and morbidity from rotavirus, pneumococcus, and HPV offers a great opportunity to achieve the MDGs, but these vaccines should only be introduced when the countries can do so sustainably.

32. The introduction of new vaccines into the regular immunization programs should be the decision of each country, based on existing scientific evidence as well as technical and programmatic criteria. Social aspects and a political commitment to guarantee the financial sustainability of these vaccines should also be considered. To this end, PAHO provides technical support for strengthening infrastructure, logistics and management, skilled human resources, the cold chain, information systems, epidemiological surveillance, the laboratory network, oversight, and impact assessment.

33. One important element in the introduction of new vaccines is to ensure the financial sustainability of national immunization programs. Based on the current cost of vaccines procured through the Revolving Fund, it can be estimated that adding the rotavirus vaccine to the vaccination series would require the doubling of a country's budget for vaccine procurement; adding the pneumococcus vaccine would require a sevenfold increase in the budget.
34. Given the significant financial impact that the introduction of new vaccines represents for the Member States, PAHO has developed the ProVac Initiative, whose mission is to boost national capacity for evidence-based decision-making through, among other things, cost-effectiveness studies and guidelines on how to conduct impact monitoring studies.

35. One element that is essential for the long-term financial sustainability of the immunization program and the introduction of new vaccines is the existence of laws or regulations that include a budget line for EPI operations and vaccine procurement. To date, 17 countries in the Region have vaccine legislation or regulations (Argentina, Bolivia, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, French Guiana, Guatemala, Guyana, Honduras, Nicaragua, Paraguay, Peru, Suriname, Uruguay, and Venezuela).

36. Currently, 13 countries and one territory in the Region have added the pneumococcus vaccine to their regular immunization programs (Aruba, Barbados, Bermuda, Canada, Cayman Islands, Costa Rica, Ecuador, El Salvador, French Guiana, Mexico, Panama, Peru, the United States of America, and Uruguay); and 15 countries and one territory that have added the rotavirus vaccine (Bolivia, Brazil, Cayman Islands, Colombia, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Mexico, Nicaragua, Paraguay, Panama, Peru, the United States of America, and Venezuela). It is hoped that by the end of 2010, the number of countries that universally employ the pneumococcus vaccine will increase to 17 (adding Brazil, Chile, and Trinidad and Tobago) and the number employing the rotavirus vaccine will also increase to 17 (adding Costa Rica).

37. As part of these actions to introduce new vaccines, PAHO provides technical cooperation in epidemiological surveillance of these diseases and identification of the circulating serotypes and strains. To date, 15 countries in the Region have implemented sentinel surveillance systems for the rotavirus (Bolivia, Brazil, Chile, Colombia, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Nicaragua, Panama, Paraguay, Saint Vincent and the Grenadines, Suriname, and Venezuela) and nine have implemented sentinel surveillance systems for pneumococcus (Bolivia, Brazil, Ecuador, El Salvador, Honduras, Guatemala, Panama, Paraguay, and Venezuela). Two countries (Argentina and Peru) are in the process of implementing sentinel surveillance systems for the rotavirus this year, and one country (Nicaragua) is in the process of implementing a sentinel surveillance system for pneumococcus.

38. Although new vaccines represent an opportunity to expand the benefits of the EPI, it is important to consider the challenges that they pose, such as their high cost, the limited number of producers, the new actors in the field of immunization, and the various public-private cooperation mechanisms in the international area.
39. Vaccine production in the Latin American and Caribbean countries is limited. Given the high cost of the new vaccines and the emergency created by influenza A(H1N1), the Member States have noted the need to bolster regional productive capacity to help cover regional vaccine requirements and guarantee the quality of these biologics.

Proposals

40. The existence of diseases in other regions of the world that have already been eliminated in the Region of the Americas, the ease with which people move across all countries, and the persistence of vaccination coverage of less than 95% in many municipalities of the Region are cause for concern about continuing to give the EPI the highest political, social, and public health priority.

41. It is advisable for the Member States to support the EPI as a public good, which will make it possible to sustain the achievements to date and face the new challenges ahead.

42. Based on previous resolutions of the Directing Council and on the provisions in the Health Agenda for the Americas, the Member States are requested to support the Regional Immunization Strategy, maintaining the goal set in 1977 when the EPI was established, of reducing morbidity and mortality from vaccine-preventable diseases to levels that no longer constitute a public health problem. To this end, achievement of the following objectives is necessary:

(a) Sustain the achievements: a Region free of polio, measles, rubella, and congenital rubella syndrome, with control of diphtheria, whooping cough, and Hib.

(b) Complete the unfinished agenda: elimination of neonatal tetanus; epidemiological control of hepatitis B, seasonal influenza, and yellow fever; ensure that all municipalities have coverage above 95% (using DPT3 as the tracer), and complete the transition from an immunization approach geared to children to one focused on comprehensive family immunization.

(c) Tackle new challenges: introduce new vaccines that contribute to the achievement of the MDGs; improve national decision-making capacity; promote the financial sustainability of the EPI, and strengthen vaccination and immunization services within the framework of systems and services based on primary health care.

(d) Maintain the PAHO Revolving Fund for Vaccine Procurement as a basic element to guarantee timely access to quality vaccines while at the same time preserving
the principles of equity, solidarity, Pan-Americanism, and the lowest possible prices, and strengthening its operations to make it more efficient.

(e) Strengthen the operational capacity of national immunization programs within the framework of primary health care through strategies that promote activities in municipios with low coverage, as well as action to help disadvantaged and hard-to-reach populations.

43. PAHO will continue providing technical assistance to member countries for evidence-based decision-making with the support of the ProVac Network of Centers of Excellence, comprised of academic centers with recognized experience in economic evaluation and decision analysis.

Action by the Directing Council

44. The Directing Council is requested to review the progress and challenges of the Expanded Program on Immunization in the Americas and reiterate its commitment to the Regional Immunization Vision and Strategy in order to maintain the achievements to date and successfully tackle the new challenges that lie ahead. Moreover, please consider approval of the resolution recommended by the 146th Session of the Executive Committee (Annex B).

Annexes