



PAN AMERICAN HEALTH ORGANIZATION
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THE PAN AMERICAN HEALTH ORGANIZATION REVOLVING FUND FOR VACCINE PROCUREMENT

Introduction

1. Since its creation 32 years ago as part of the Pan American Health Organization's Expanded Program on Immunization (EPI), the PAHO Revolving Fund for Vaccine Procurement (RF) has been a critical technical cooperation mechanism for achieving the EPI objectives of reducing morbidity and mortality from vaccine-preventable diseases. The Member States of PAHO recognize the RF as a public good that has facilitated polio eradication, measles elimination, and advances in the elimination of rubella and congenital rubella syndrome (CRS) and in the control of neonatal tetanus, *Haemophilus influenzae* type b, and hepatitis B; moreover, the RF has proven instrumental in the rapid introduction of new vaccines against major causes of infant mortality, such as rotavirus and pneumococcus infection.

2. Over the past three decades, RF operations have adapted to epidemiological and operational changes, as well as to changes in the vaccine market, while faithfully upholding its foundational principles, which allow Member States to have equitable access to high-quality vaccines in a timely manner and at the lowest prices.

3. This document presents the conceptual principles and benefits that the RF, through its operating mechanisms, offers the Member States and the regional and global vaccine market.

Background

4. In 1977, by resolution of the Directing Council of PAHO (CD25.R27), the EPI was created and the FR as part of it, with a view to reducing mortality and morbidity from vaccine-preventable diseases. (1)

5. As an important part of the EPI and to facilitate a timely supply of quality vaccines in appropriate quantities at the lowest prices, Resolution CSP25.R27 authorizes the Director to create the Revolving Fund for Vaccine Procurement¹, whose specific objectives are: (a) to enable Member States to plan their immunization activities without disruptions occurring due to a lack of supplies or funds for vaccine procurement; (b) to enable Member States to use local currency for reimbursement of the funding provided through the RF; (c) to consolidate vaccine orders so that Member States can benefit from economies of scale for the procurement of vaccines at the lowest prices; (d) to guarantee that Member States receive quality vaccines that meet PAHO/WHO standards; and (e) to establish contracts with suppliers for the procurement of vaccines and related supplies to guarantee the timely processing and delivery of both regular and emergency orders.(2,3)

6. In 1978, Resolution CSP20.R16 adopted by the 20th Pan American Sanitary Conference established the working capital for RF operations.(4) The initial capitalization of the RF was US\$ 1 million from the initial contributions of PAHO itself and several countries, among them Barbados and the Netherlands, and subsequently the United States and UNICEF.(2,3,4) This enabled the RF to formally commence operations in 1979.

Conceptual Vision of the Revolving Fund

7. As a mechanism of cooperation, the RF is grounded in the principles of equitable access, the application of regional and international standards for product quality, the integration of national distribution systems, Pan-Americanism, and transparency in procurement and supply management.(5)

8. The RF employs a centralized procurement model in which the Member States participate and delegate the necessary authority to the Pan American Sanitary Bureau (PASB) to sign contracts, purchase vaccines and supplies, and make payments to suppliers.(6) The RF operates as a common fund; through which the PASB pays suppliers, giving Member States the option to defer payments for 60 days following satisfactory receipt of the vaccines and supplies and to use their national currency as necessary.(6) The PASB assumes all the operating costs; the entire recapitalization fee, which is equivalent to 3% of the net value of the vaccines and supplies, contributes to the 60-day line of credit to which the countries have access and represents resources that the countries provide in the spirit of Pan-Americanism.

9. The RF is not only a mechanism for the procurement of vaccines, syringes, and other supplies for immunization activities, but a mechanism for mutual cooperation among the Member States that, through centralized procurement and the negotiation of a single price for all Member States, generates economies of scale to secure the lowest prices, promoting the financial sustainability of the Region's immunization programs.

Moreover, the RF has been critical to the success of the EPI in the Americas. The close relationship between RF operations and the technical cooperation that the PASB provides to the Member States has led to the growth and strengthening of national immunization programs (NIPs), together with significant advances in regional public health.

Situation of the Revolving Fund

10. The EPI has enabled the Region of the Americas to be the first region to be declared polio-free, the first to eliminate indigenous measles, and the region that has made the greatest strides in the elimination of rubella and congenital rubella syndrome (CRS) and in the epidemiological control of whooping cough, diphtheria, and neonatal tetanus; it has allowed the Region to achieve the most significant reductions in morbidity and mortality from vaccine-preventable diseases. The RF has been vital to maintaining high coverage by vaccination services and, consequently, to achieving equity with respect to immunological protection for the population of Latin America and the Caribbean (LAC).

11. The EPI is making a significant contribution to the attainment of the Millennium Development Goals (MDGs), especially Goal 4 for the reduction of mortality in children under 5, and Goal 5 for the improvement of maternal health.⁽⁷⁾ Globally, it is estimated that immunizations have contributed with 50% of the reduction in mortality in children under 5. ⁽⁸⁾ In LAC, 174,000 deaths from vaccine-preventable diseases are prevented annually in children under 5, and it is estimated that universal use of the new vaccines — specifically, the rotavirus and pneumococcal conjugate vaccines— could prevent several thousand additional cases and deaths. ⁽⁸⁾

12. These achievements are due to the commitment of the Member States which, after identifying vaccination as a public good, have boosted their operational capacity to provide these services, established budget lines that guarantee the financial sustainability of these activities, and created the RF—a public health intervention widely recognized at the regional and international level as the ideal mechanism for procuring vaccines and other related supplies. ⁽⁹⁾

13. For three decades, the PASB has administered the RF on behalf of the participating countries of the Americas. Requests for vaccines through the RF are aligned with the plans of action prepared by the countries for the activities of their NIPs. After consolidating the demand, the PASB selects suppliers through a public tender, basing its choice on PAHO/WHO specifications relative to quality, price, and the supplier's history of timely vaccine delivery. By ensuring a continuous supply of vaccines at the lowest possible prices, the RF has played a key role in the immunization efforts of PAHO's Member States.

14. With the creation of the RF, the accuracy of demand forecasts and budgets for vaccine procurement in the Region of the Americas has improved. This is due to the application of strict planning requirements supported by technical assistance from the PASB, and it has led to a consequent decrease in vaccine price fluctuations.

15. Thanks to better forecasting and its strict payment schedules, the RF has boosted the pharmaceutical industry's confidence in the vaccine market of the developing world, facilitating economies of scale and better prices, not only for countries of Latin America and the Caribbean, but for all developing countries. There is no doubt that the higher demand has been critical to expanding regional production capacity, which in turn has been a key factor in the success of the RF.

16. To a large extent, the RF has served as a major catalyst for the rapid, equitable, and sustainable introduction of new and underutilized vaccines, among them the measles, mumps, and rubella (MMR); yellow fever; hepatitis B (HepB); *Haemophilus influenzae* type b (Hib);ⁱ seasonal influenza; rotavirus; and pneumococcus vaccines. Some investigators have dubbed this phenomenon "the PAHO effect." (10) Figures 1 and 2 show that the introduction of the Hib vaccine in the Americas was much faster and much more equitable than in other regions of the world. All countries of the Americas have included the Hib vaccine in their vaccination schedules, with the exception of Haiti, which plans to introduce it in 2010. This was achieved based on lessons learned through the introduction of the hepB vaccine, a process that took over 20 years due to high prices and delays in its supply through the RF. Since 2006, 16 countries have introduced the rotavirus vaccine and nine the heptavalent pneumococcal conjugate vaccine.

ⁱ In the Region of the Americas, the HepB and Hib vaccines are administered in the pentavalent vaccine (Diphtheria-Tetanus-Pertussis-HepB-Hib).

**Introduction of the Hib vaccine in PAHO
(through the Revolving Fund)**

**Introduction of the Hib vaccine in the
rest of the world (excluding PAHO)**

Figure 1

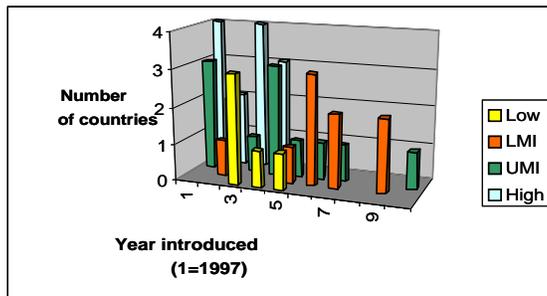
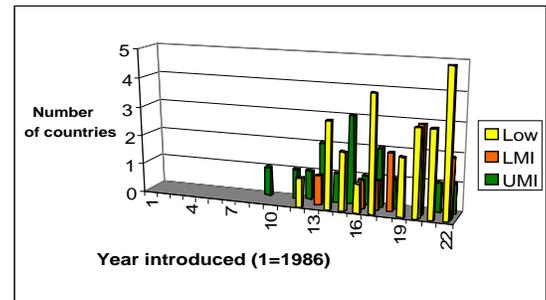


Figure 2



Low: low income LMI: low middle income UMI: upper middle income High: high income

17 The RF represents a healthy, growing market that benefits the global pharmaceutical industry. Since its creation, it has forged partnerships with vaccine manufacturers, improving demand predictability, establishing transparent operation rules, and furthering competitiveness. It has also promoted the development of producers in the developing countries.

18 RF operations commenced in 1979 with eight participating countries and six antigens. By 2008, most of the Member States were participating, and 27 antigens with 39 different PAHO/WHO-prequalified presentations were offered by 13 suppliers. In 2008, 270.3 million doses of vaccine were procured through the RF, at a total cost of \$271.7 million, four times the total cost in 2000. Projected vaccine procurement for 2009 is on the order of \$369.5 million.

19 By offering access to vaccines, the RF also fosters research and the operational development of immunization programs by promoting the strengthening of epidemiological surveillance systems, the laboratory network (e.g., identification of strains), and infrastructure, as well as the training of human resources.

20 The RF also contributes to the regulation of the quality and safety of vaccines. As part of the activities of the EPI and in coordination with producers, it monitors and investigates events supposedly attributable to vaccination and immunization (ESAVI), which, combined with the measures adopted by the national regulatory authority, is an important aspect of vaccine pharmacovigilance.

21 In 2004, the World Health Organization's Office of Internal Oversight Services (OIS/WHO) performed an audit of the PASB to examine the administration of the program for the procurement of public health supplies through the RF and the Strategic Fund (SF). The audit evaluated the efficiency of the process and the effectiveness of the activities for meeting its objectives, concluding that "the RF had been extremely successful and appreciated by the countries and external partners, achieving all of its objectives while contributing to AMROⁱⁱ/PAHO's [Pan American Sanitary Bureau (PASB)] leadership role in the immunization programme in the Americas. The close linkages between the RF procurement mechanism and technical support to the countries, leading to successful implementation of both aspects, was evident. While recognizing that there are many aspects of the RF unique to vaccines, lessons from the experiences with the RF will be useful for other procurement funds and mechanisms. Learning from the RF experience is very timely in view of the urgent need to assure continuous supplies of high quality drugs for the HIV/AIDS, TB, and Malaria control programs."⁽¹¹⁾

22 RF operating procedures have been updated periodically throughout its 30-year existence to achieve high levels of efficiency. These procedures spell out all relevant RF criteria and procedures, including: consolidation of the Member States' demand; product quality assurance; supply procurement procedures; characteristics of the public tender system; requirements for laboratories concerning the supply, sale, and delivery of products; procedures for receipt and claims by Member States; and product payment procedures. The most recent version of the Operating Procedures was issued in October 2008. ⁽¹²⁾ As part of the RF capitalization process and in preparation for the demand that the new vaccines will generate, an external evaluation was conducted in early 2009, whose recommendations are already being implemented. ⁽¹³⁾

23 Diverse resolutions of the Directing Council urge Member States to make use of the RF for vaccine procurement. The most recent is Resolution CD47.R10 of 2006 regarding the "Regional Strategy for Sustaining National Immunization Programs in the Americas", which places special emphasis on the introduction of new and underutilized vaccines. ⁽⁹⁾

Current Challenge

24. Today, the new, more expensive vaccines that fight diseases of Regional priority (including the rotavirus, pneumococcal, and human papillomavirus vaccines) pose significant challenges for the Member States and the RF. Based on past successes with the MMR, pentavalent (DPT-HepB-Hib)ⁱⁱⁱ and seasonal influenza vaccines, the RF has now turned its focus to accelerating sustainable and equitable access to these new-generation vaccines by all risk groups in the Region. Administered by the PASB, the RF

ⁱⁱ AMRO: WHO Regional Office of the Americas.

ⁱⁱⁱ DTP: diphtheria, tetanus and pertussis.

provides a platform for NIPs and the vaccine manufacturing industry to work together towards common objectives, including the achievement of several MDGs.

25. In 2006, an estimated 95% of the total cost of vaccines administered through NIPs in the Americas was financed with the countries' own resources. (14) Thus, one of the main hurdles for the introduction of these new vaccines is their high cost, which would imply substantial increases in the budget lines of the Member States. If a Member State adds the rotavirus vaccine to its regular vaccination schedule, procurement of the biologicals alone would double its current vaccine cost if the pneumococcal vaccine were added to the package, the cost would increase more than sevenfold.

26. The RF is an essential collective cooperation mechanism that seeks to provide access to these new vaccines for vulnerable populations and promote sustainability for public health care programs.

27. Given the worrisome trends in NIPs in other regions of the world during the 1990s, and in order to increase access to immunization, the Global Alliance for Vaccines and Immunization (GAVI) was created as a public-private initiative to help save lives and contribute to the sustainability of immunization services in the poorest countries. (15) The GAVI Alliance offers time-limited support to improve immunization services, health systems and the safety of vaccination activities; and to accelerate the introduction of new and underutilized vaccines. Support is currently provided only to countries whose gross national income (GNI) in 2003 was less than \$1,000 per capita.(16) Six countries in the Americas meet the criteria for receiving GAVI assistance: Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua.

28. Since the launch of the Alliance, PAHO's experience as a leader in the field of immunization provided the framework for GAVI's development, from concepts such as the EPI's multiyear planning to foster programmatic and financial sustainability to the critical role of coordinating the partners (at the national and regional levels) through the Interagency Coordinating Committees (ICC) on Immunization, to the methodology for periodically evaluating different components of the national immunization programs, etc. Since the approval of the first proposals presented by countries of the Americas eligible for GAVI support, PAHO collaboration with the Alliance has included coverage of the indirect costs of the technical and administrative support that PAHO provides for the implementation of GAVI support to the program. PAHO's added value in the field of immunization continues to be demonstrated by the fact that the Region of the Americas has the highest approval rates for submitted proposals and the highest levels of performance in the execution of GAVI support.

29. The first four countries to receive approval of their proposals for GAVI to support introduction of the rotavirus and/or pneumococcal conjugate (PCV) vaccines were Bolivia, Guyana, Honduras, and Nicaragua. The first round of applications to support

these new vaccines took place in 2007, and the proposals of these four countries were the first to be accepted. The Alliance has currently approved financing to support the introduction of the rotavirus vaccine in Bolivia, Guyana, Honduras, and Nicaragua, and of the pneumococcal conjugate vaccine in Guyana, Honduras, and Nicaragua. This support is a partial, time-limited subsidy (currently guaranteed until 2015); the countries must make progressive co-payments until they cover the entire cost of the vaccines in question. GAVI has recognized the RF as the vaccine procurement mechanism for the countries of the Americas that are eligible for its support.

30. November 2007 marked the opening of negotiations of a Memorandum of Understanding that would permit the transfer of resources for the procurement of rotavirus and pneumococcal vaccines for countries eligible for GAVI financial assistance. This debate lasted more than a year, owing to differences in the respective approaches of GAVI and PAHO. In October 2008, an agreement was reached on the transfer of resources for procurement of the rotavirus vaccine; however, differences persist between GAVI and PAHO over resources for the pneumococcal vaccine.

31. By mid 2008, the RF entered into the first procurement agreement with the sole supplier of the heptavalent pneumococcal conjugate vaccine, after its prequalification by WHO. Accordingly, the lowest price for that year was established: \$26.35 per dose. Under these conditions and per GAVI Secretariat's advise, Guyana, Honduras and Nicaragua asked the GAVI Board to adjust the financial support approved for the purchase of the vaccine. The GAVI Board discussed this request along with an offer by the vaccine's manufacturer to donate 3.1 million doses for two countries in another region (17) and made the following decisions: (a) It did not approve additional funds for introducing the vaccine in Guyana, Honduras, and Nicaragua at the price offered to the RF; (b) It unanimously reaffirmed its commitment to tiered pricing; and (c) It requested the GAVI Secretariat to facilitate discussions among partners to find a resolution in the area of tiered pricing, including addressing PAHO's single price clause. (18) This issue was taken up again during the following session, at which time GAVI's Executive Committee issued the following decisions: (a) It approved in principle GAVI's acceptance of the donation of 3.1 million doses of heptavalent pneumococcal vaccine for Rwanda and Gambia for a period extending through 2010; and (b) It requested the GAVI Fund to accept the donation. (19) The donation offered excluded the countries of the Americas.

32. The delay in making these vaccines available to the countries of the Hemisphere eligible for GAVI support —especially, the more than a year's delay following the announced approval in the case of the pneumococcal vaccine— has had serious consequences for immunization programs of the affected countries, given the high expectations created among the population.

33. In order to expedite procedures for eligible Member States to receive GAVI financial resources for the introduction of these vaccines, a PAHO-GAVI Working Group has been established with the collaboration of representatives from the World Health Organization (WHO), UNICEF, and the World Bank. The working group's main objective is to improve collaboration between GAVI and PAHO that will lead to the sustainable introduction of new vaccines in the poorest countries and populations of the Region of the Americas.

34. The Member States have stated their decision to continue procuring vaccines through the RF in official communications to the GAVI Secretariat and Board. With PAHO's support, the eligible countries of the Region have also had the opportunity to state their positions to the GAVI Board representative for the developing countries of the Americas and Europe and to the Chief Executive Officer of the GAVI Alliance, in May 2009 during the World Health Assembly.

Future of the Revolving Fund

35. Since in its 30 years of operation, the RF has proven an essential component of PASB technical cooperation to the Member States of the Region within the Expanded Program on Immunization, guaranteeing equitable access to quality vaccines at the lowest possible prices and helping to prevent thousands of cases and deaths due to vaccine-preventable diseases, the Member States have indicated the need to keep the RF faithful to its current criteria and principles, as declared in the Aide Memoire of the meeting of countries eligible for GAVI support, signed by the six respective ministers in October 2007 during the 27th Pan American Sanitary Conference (20) and the 2008 Nassau Declaration of the English-speaking Caribbean Countries. (21) The United Nations Regional Directors for Latin America and the Caribbean have determined that the EPI should be considered a "regional public good" and declared the use of the Revolving Fund a mechanism of regional solidarity. (22) The Regions of Africa and Eastern Mediterranean are interested in creating mechanisms similar to the RF to guarantee access to the vaccines and support the sustainability of their NIPs.

36. As it celebrates 30 years of operations, the RF continues to make progress toward a new approach that promotes family vaccination, preparations for the introduction of new vaccines (e.g., HPV, dengue, malaria, HIV, new influenza strains, among others) and the use of innovative technologies.

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