Introduction of New Vaccines: Perspectives from PAHO’s Pro-Vac Experience

1 December 2007

Jon Kim Andrus, MD
Immunization Unit
Immunization currently prevents approx 174,000 child deaths per year*

Approx 36,000 preventable child deaths by 2015 if coverage reaches 95% in all municipalities*

Approx 149,000 preventable deaths by 2015 with rotavirus and pneumococcal vaccines*

Access to affordable vaccines

* WHO IVB VPD Disease Burden Modeling (2003 data)
Global Immunization Vision and Strategies (GIVS)

Family Immunization - reaching more...

Disease reduction targets for Rotavirus, Pneumococcus - introducing new...

Partnerships - linking with others...

Assured supply of safe vaccines - global interdependence...

Millennium Development Goals 2015
## Financial Requirements for Vaccines, Latin America and the Caribbean, 2007

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Cost</th>
<th>Vaccine Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic Vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCG</td>
<td>$0.10</td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td>$0.66</td>
<td></td>
</tr>
<tr>
<td>Penta+Booster</td>
<td>$12.37</td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>$2.80</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>$15.93</td>
<td></td>
</tr>
<tr>
<td><strong>Under-Utilized Vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric Yellow Fever</td>
<td>$0.65</td>
<td></td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>$0.65</td>
<td></td>
</tr>
<tr>
<td>Pediatric Seasonal Influenza</td>
<td>$1.20</td>
<td></td>
</tr>
<tr>
<td>Adult Seasonal Influenza</td>
<td>$3.50</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>$6.00</td>
<td></td>
</tr>
<tr>
<td><strong>Supplementary Immunization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rubella Elimination</td>
<td>$0.43</td>
<td></td>
</tr>
<tr>
<td><strong>New Vaccines Pre-qualified</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus (Oral Vaccine)</td>
<td>$7.20</td>
<td></td>
</tr>
<tr>
<td>Pneumococcus</td>
<td>$53.00</td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td>$120.00</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>$8.00</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>$588.00</td>
<td></td>
</tr>
<tr>
<td><strong>New Vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>$624.33</td>
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- **Current Estimated Prices; Rubella elimination listed but not included in sum total of costs**
- **Source:** PAHO's Immunization Unit & the PAHO Revolving Fund

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- **Total Vaccines Budget:** $624.33
Regional Challenge
Example of HPV

Cervical Cancer Disease Burden

- Taking advantage of new technologies while sustaining national immunization programs within national health priorities
- Reducing the developing country uptake lag time of two decades
- Recognizing new vaccines are orders of magnitude more expensive

77,291 new cases each year
30,570 deaths each year

Source: IARC
Urged Member States to:

Expand legal and fiscal space and identify new revenue sources to sustainably finance the introduction of new vaccines against rotavirus, pneumococcus, and human papillomavirus;

Support the mortality reduction targets, consistent with GIVS and the MDGs, for HPV, RV, influenza, and pneumo associated disease;

Utilize the PAHO Revolving Fund for Vaccine procurement to purchase new and underutilized vaccines
Improve coverage of underutilized vaccines

Yellow fever
Influenza
Pentavalent vaccine in Haiti

Introduce new vaccines

Rotavirus
Pneumococcal
Human papillomavirus
ProVac Framework: Technical Criteria

• Disease burden. Pneumococcal disease kills more people than tuberculosis and malaria combined.

• Characteristics of the vaccine. How effective is the vaccine? What are the adverse events? What kind of presentation?

• Adverse events and post-marketing surveillance. Monitoring and surveillance is essential for safety and public confidence.

• Cost-effectiveness and other economic evaluations. Economic analyses demonstrate the relative value of the vaccine.

ProVac Framework: Programmatic Criteria

- **Vaccine supply.** Can you guarantee the supply?

- **Logistical and operational issues.** How does the vaccine work in your program? Capacity in the cold chain? Difficulty with transport or freight?

- **Financing strategies.** Affordable vaccines, financed nationally, are easier to introduce sustainably.

- **Partnerships.** The support of partners can help countries with the initial challenges of introducing and financing the vaccine (example: GAVI)

**ProVac Framework: Social Criteria**

- *Perception of risk.* Public perceptions of the disease or the vaccine will affect demand.

- *Political will.* High-level political commitment has driven the introduction of some vaccines regardless of the evidence available.

- *Equity.* Vaccines can be an effective way to prevent significant burdens of disease in poor populations often unreached by other services or interventions.

Pro-Vac
Tools, Workshops, Long-term Support
Tools for Economic Analysis

Costs

Health Gains

Vaccine Intro Costs Tool

Burden of Disease Tools

Cost Effectiveness Studies HPV

Cost Effectiveness Studies Influenza

Cost Effectiveness Studies Rotavirus

Cost Effectiveness Studies Pneumococcus

Economic Analysis
## Twelve Month Vision

- Mobilize resources and provide technical cooperation for comprehensive evaluations of new vaccines in priority countries (5 GAVI, 1 non-GAVI)

<table>
<thead>
<tr>
<th>Country</th>
<th>Subregion(s)</th>
<th>Vaccine(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Honduras</td>
<td>Central America</td>
<td>Pneumococcus, RV</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>Central America</td>
<td>Pneumococcus</td>
</tr>
<tr>
<td>Cuba</td>
<td>Caribbean</td>
<td>Pneumococcus</td>
</tr>
<tr>
<td>Guyana</td>
<td>Caribbean</td>
<td>Pneumococcus, RV, HPV</td>
</tr>
<tr>
<td>Jamaica</td>
<td>Caribbean</td>
<td>HPV</td>
</tr>
<tr>
<td>Bolivia</td>
<td>Andean / Southern Cone</td>
<td>Pneumococcus</td>
</tr>
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</table>
Vaccine Laws in the Americas

Programmatic Sustainability:
- Public good
- National health priority
- National vaccination schedule
- Facilitates introduction of new and underutilized vaccines

Financial Sustainability:
- Independent budget line for purchase of vaccines, syringes and cold chain equipment
- Cost-control through exemption from value-added taxes and import duties
- Participation in the Revolving Fund
- Reduced risk of supply interruption

Source: Country reports as of June 2007
Creating Fiscal Space for Immunization

1. **Efficiency**
   - Prioritize expenses: importation taxes, eliminate wasteful expenditures, increase spending for goods and meritorious services (vaccines)
   - Combat corruption and the trafficking of vaccines and supplies

2. **Fiscal Revenues**
   - Improve tax collection and administration
   - Identify additional revenue sources

3. **Donations: think strategically**
   - Ensure financial sustainability following the completion of the donation or subsidy
   - Consider the limitations and international criteria for debt service and relief

4. **Partnering with the Private Sector**
   - When encountering opportunities… always strategizing to ensure equity and access
Hepatitis A Vaccine Use: Results of Survey of 22 Countries of Latin America & Caribbean, 2007 (1)

- Countries including HA vaccine in their universal childhood immunization programs: Argentina and Panama

- Countries using HA vaccine in public sector only: Bermuda

- Countries using HA vaccine in private sector only: 8 (Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Nicaragua, Paraguay, St. Maarten)

- Countries using HA vaccine for outbreak control: Colombia and Uruguay

- Strategies being utilized: Children aged 12-23 months, international travelers, individuals with occupational risk, upon request, outbreak control
Hepatitis A Vaccine Use: 
Results of Survey of 22 Countries of 
Latin America & Caribbean, 2007 (2)

• Countries with plans to introduce HA vaccine into the public sector:

  – Cuba 2012
  – El Salvador 2012
  – Mexico 2008 or 2009
Estimated Effect of PAHO’s Revolving Fund on Rotavirus Vaccine Price, 2007

- Pre-RF: $45 per dose
- RF: $7.20 per dose
Financing Vaccines, Latin America and the Caribbean, 1987-2006

<table>
<thead>
<tr>
<th>Year</th>
<th>National</th>
<th>External</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987-91</td>
<td>431</td>
<td>114</td>
</tr>
<tr>
<td>1992-96</td>
<td>654</td>
<td>57</td>
</tr>
<tr>
<td>1997-01</td>
<td>667</td>
<td>74</td>
</tr>
<tr>
<td>2002-06</td>
<td>886</td>
<td>55</td>
</tr>
</tbody>
</table>

$ in millions

$ in millions

- National
- External

- MMR
- Penta
PAHO Overview on Vaccine Financing

Mission and Vision

- Identify new revenue sources
- Support disease reduction targets of GIVS and MDGs
- Optimize utilization of the Revolving Fund

Directing Council and TAG

PAHO

Shared

National

Pan American Health Organization
Partnerships

Canadian International Development Agency
American Red Cross
pneumoADIP
USAID
JAPAN
UNIVERSITY OF OXFORD
UNITED NATIONS FOUNDATION
PATH

CDC
GAVI FUND
unicef
PolioPlus
Rotary International

March of Dimes
Sabin Vaccine Institute

Bill & Melinda Gates Foundation
International Federation of Red Cross and Red Crescent Societies

Ministerio de Asuntos Exteriores y de Cooperación

United States, Department of Health & Human Services

European Union
**Summary**

A key role of PAHO and its partners is to continue to build strong national immunization programs from which to bridge to new vaccines to achieve the MDGs with capacity development as a key guiding principle.

[www.paho.org/immunization](http://www.paho.org/immunization)
Acknowledgements

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Michael Davila
Cuauhtemoc Ruiz Matus

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