Challenges in introducing new vaccines: GAVI experiences

Global Hepatitis A Meeting
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Technical and Policy
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An innovative public-private partnership
GAVI Alliance Strategic Goals

- Contribute to strengthening the capacity of the health system to deliver immunisation and other health services in a sustainable manner
- **Accelerate the uptake and use of underused and new vaccines and associated technologies and improve vaccine supply security**
- Increase the predictability and sustainability of long-term financing for national immunisation programs
- Increase and assess the added value of GAVI as a public-private global health partnership through improved efficiency, increased advocacy and continued innovation.
Framing the question

Healthy systems, Healthy children?
Immunise the right people with the right vaccine at the right time in the right place in the right way for the right price

A healthy market?
Generate demand, ensure supply, avert child deaths: a virtuous cycle
Activities* required for vaccine introduction

Pre-Introduction
- Disease burden analysis
- Surveillance
- Vaccine efficacy, effectiveness and impact analysis (e.g., clinical trials, pilot studies)
- Economic evaluation
- Communication and advocacy
- Demand planning
- Supply planning
- Licensing
- WHO pre-qualification

Introduction phase
- Decision-making in the context of health systems analysis
- Financing
- Surveillance, monitoring
- Introduction strategies
- Infrastructure, logistics
- Procurement
- Health worker training
- Supply negotiations
- Manufacturer scale-up
- Advocacy, social mobilisation
- Operational research

Routine
- Surveillance and monitoring
- Documentation of vaccine efficacy, impact and safety
- Maintenance of procurement, storage, delivery and waste management infrastructure
- Advocacy / communication
- Emergency response (e.g., stockpiling, outbreak response)
- Sustained financing

* Selected and illustrative; global, regional and country components
GAVI Alliance support for vaccine introduction

Funding over time

Lead
Industry Partners
Countries Partners
Countries Partners

Pre-Introduction

Introduction phase

Routine

AMC √
Vaccine Intro Grant √
Vaccines √

ADIPs √

ISS / INS / HSS / CSO √

Funds to partners √

Hib Initiative √
IFFIm √

Vaccine Intro Support ?
IOR ?

GAVI catalytic action
Countries Partners
History: The GAVI contribution to date
What we have done

- Create incentives and stabilise the market
- Turn sequential tasks into parallel work streams
- Establish and communicate value
- Vaccines and immunisation-specific funding
- Broad-based, country-driven funding
- Synergistic global funding
- Targeted support for partners (e.g. staff)

- Funded a wide array of complementary upstream and downstream interventions accelerating vaccine development and introduction
- Offered a menu of options for countries
ADIPs and Hib Initiative

- PneumoADIP
- Rotavirus Vaccine Program
- Hib Initiative
Avoiding time lag and slow uptake

Million doses

- HepB all developing countries
  - 65% coverage
  - 50% coverage
  - 33% coverage

- HepB all developing countries, excluding India, China, Indonesia
- Hib all developing countries

Years from availability
The activity plans of the ADIPs were structured around three main objectives:

- **Establish value**
  - Assess burden of disease
  - Assess impact of vaccine
  - Understand drivers of demand

- **Communicate value**
  - Identify key decision makers
  - Understand decision making factors
  - Package right data and experience

- **Deliver value**
  - Ensure supply
  - Assist local uptake
ADIPs

- Established surveillance systems in key GAVI-eligible countries to demonstrate the burden of infection;
- Improved the rigour and accuracy of demand forecasts, an area where the public sector has traditionally been weak;
- Worked with partners to better and more accurately estimate the global, regional and country level burden of disease and communicated the value of the vaccination to address this public health problem;
- Have sent signals to industry both multinational and emerging suppliers that rotavirus and pneumococcal vaccines would be purchased for use in developing countries thus encouraging the entry of a larger number of potential suppliers leading to a more healthy market and more affordable prices;
- Supported clinical trials in Africa and Asia to determine whether rotavirus vaccines would be efficacious in all GAVI countries;
Advanced Market Commitment (AMC)

Problem:
- Small, risky, and unpredictable markets lead to under-investment in products of importance to the developing world.
- Industry’s investments in development/capacity determine what products are available, when, and to whom.

Solution:
- Assurances of a future market as incentive for more timely investment by industry
- Provide credible commitments to guarantee future financing for priority vaccines – before funds are needed to purchase doses
- Only use funds – and buy vaccines – if there are results

Source: GAVI
Typical Vaccine Price Curve

- Price declines over time
- New technologies reduce cost of production
- New manufacturers enter market

Price

pays for R&D

Marginal cost
AMC Mechanism

AMC Price

Vaccine Price

Co-Pay

AMC Donor Investment

1st Eligible Vaccine Available

Time

Donor Funds Depleted

Supplier Commitment Fulfilled

AMC Funding Commitment Period

Post-AMC Supply Commitment Period

GAVI Co-Pay

Country Co-Pay

Tail Price (i.e., tail price)

Country Co-Pay

GAVI Co-Pay
Market Incentives

- **Market entry**: Open to all players – multinational and emerging, biotechs and vaccine manufacturers

- **Competition**: Designed to sustain 2-3 firms to encourage adequate capacity and price competition

- **Continued innovation**: Designed to last 7-10 years to allow multiple products. Countries “demand” product that best meets their needs
Vaccine investment strategy

Halos represent current deaths being averted, and solid circles represent deaths estimated to occur.

3 million premature deaths from vaccine preventable diseases

7 million premature deaths from diseases for which vaccines not yet widely available
A New Vaccine Investment Strategy for GAVI

- GAVI Alliance 2007 work plan calls for vaccine investment decision-making process
- As work began on process, Secretariat recognized:
  - Need for long-term vaccine investment strategy
  - Complexity of designing such an effort
- GAVI Board approved a proposal to design process & methods to develop strategy to be completed in May 2008
Overview of Vaccine Investment Strategy Development process

Alliance Process Design
- Agreement on policy objectives to guide investment decisions
- Design of processes and methods for development of vaccine investment strategy

WHO Vaccine Prioritization
- Definition of priority vaccines
- Separate process (serving broader purposes)
  - Alliance process of analysis, evaluation and prioritization will start with this list

Alliance Vaccine Investment Strategy Development
- Definition of Alliance’s vaccine investment strategy
  - Vaccines for investment
  - Activities for support
  - Timeframe for investment
  - Through a consultation process with countries and other stakeholders
Proposed Vaccine Investment Strategy Development process

Module 1: Pre-Consultation Work
A. Define evaluation criteria & metrics
B. Identify additional vaccines outside WHO list (>5 years)
C. Plan country & global consultations
D. Collect existing vaccine data & fill gaps as needed

Module 2: Diagnostic
E. Conduct country consultations
F. Conduct global consultations
G. Develop activity catalog by vaccine
H. Analyze health impact and cost-effectiveness

Module 3: Synthesis and Vaccine Evaluation
I. Synthesize diagnostic findings
J. Evaluate vaccines against criteria

Module 4: Strategy Development & Investment Requirements
K. Prioritize vaccines and required activities for Alliance support
L. Communicate recommendations to key stakeholders
Strategy: What does the Alliance do next?

For each vaccine and each potential activity, consider:

- Is this activity critical to the introduction of this vaccine?
- Is anyone pursuing (or planning to pursue) this activity?
- Is extra effort needed?

Useful information:

- ADIP / HI evaluation and supporting board decisions
- Partners’ mandates, plans, capacity and willingness to take the lead
- Monitoring and evaluation of contributions of other GAVI programmes
- Design options for additional support for pneumococcal and rotavirus vaccines
- Results of the vaccine investment strategy
- Secretariat capacity for additional work

-is there a role for the Secretariat?
Collaboration: Who does what?
Partner mandates and leadership
WHO has overall leadership in this area

<table>
<thead>
<tr>
<th>Area of Work</th>
<th>Country role</th>
<th>Lead partner agency</th>
<th>Supporting partners</th>
<th>Role of GAVI Secretariat through support structures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance</td>
<td>major</td>
<td>WHO</td>
<td>technical institutes (CDC), others</td>
<td>Minor</td>
</tr>
<tr>
<td>Immunization programme</td>
<td>major</td>
<td>WHO / UNICEF</td>
<td>PATH/ civil society, bilateral donors, BMGF</td>
<td>moderate</td>
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<td>WHO</td>
<td>WB / donors</td>
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<td>Regulation</td>
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<td>WHO</td>
<td>UNICEF, industry</td>
<td>minor</td>
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<tr>
<td>Industry relations</td>
<td>minor</td>
<td>GAVI support</td>
<td>UNICEF, industry</td>
<td>major</td>
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<tr>
<td>Advocacy</td>
<td>major</td>
<td>GAVI support</td>
<td>UNICEF, civil society, WHO</td>
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<tr>
<td>Special projects and studies</td>
<td>variable</td>
<td>GAVI support</td>
<td>WHO, UNICEF, BMGF, technical institutes, industry</td>
<td>major</td>
</tr>
</tbody>
</table>
Support to vaccine introduction

Support to countries
- Vaccines
- Communications
- Cold chain
- Training
- Record-keeping
- Surveillance & lab operations

Support to partners
- Introduction programme support
- Surveillance standards
- Surveillance and lab QA
- Vaccine quality & regulation
- Vaccine procurement

Outsourced activities
- Advocacy
- Link to industry
- Special studies
- Ongoing research

Role for regional and country peer support

Coordination through Secretariat

GAVI Secretariat

GAVI Work plan / other mechanisms and funding sources

Vaccines
Vaccine Intro grant
ISS/INS/HSS

Funding flow

Activities
Issues and challenges

- Financial sustainability
- National health budget ceilings
- Displacement within the Health Sector
- High opportunity costs for introducing new vaccines in countries with large population
- Competing regional and global priorities (polio, measles campaign)
- Link at country level with other GAVI programmes and other health priorities
- Eligibility policy
Thank you