Challenges in introducing new vaccines: GAVI experiences

Global Hepatitis A Meeting Susie Lee Technical and Policy December 1, 2007



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 longterm 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

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Industry Partners		Countries Partners	Countries Partners	
Pre- Introduc	tion			
Disease burden		Introduction phase		
analysis		 Decision-making in the 	Routine	
 Surveillance 		context of health systems	 Surveillance and 	
 Vaccine efficacy 		analysis	monitoring	
effectiveness an		 Financing 	 Documentation of vaccine efficacy, impact and safety 	
impact analysis clinical trials, pilo		 Surveillance, monitoring 		
studies)		 Introduction strategies 		
• Economic evaluation	ation	 Infrastructure, logistics 	 Maintenance of procurement, storage, delivery and waste management infra- structure 	
 Communication 	and	 Procurement 		
advocacy		 Health worker training 		
 Demand plannin 	g	 Supply negotiations 	Advocacy /	
 Supply planning 		 Manufacturer scale-up 	communication	
 Licensing 		 Advocacy, social 	 Emergency response (e.g., stockpiling, 	
 WHO pre-qualifi 		mobilisation		
		 Operational research 	outbreak response)	

* Selected and illustrative; global, regional and country components

Sustained financing

Time

GAVI Alliance support for vaccine introduction

Funding over time



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



The activity plans of the ADIPs were structured around three main objectives



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



AMC Mechanism



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.

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	Module 2: Diagnostic	Module 3: Synthesis and Vaccine Evaluation	Module 4: Strategy Development & Investment Requirements
A. Define evaluation criteria & metrics	 E. Conduct country consultations F. Conduct global 	I. Synthesize diagnostic findings J. Evaluate	K. Prioritize vaccines and required activities for Alliance support
B. Identify additional vaccines outside WHO list (>5 years)	consultations G. Develop activity catalog by vaccine	vaccines against criteria	L. Communicate recommendatio ns to key stakeholders
C. Plan country & global consultations	H. Analyze health impact and cost- effectiveness		
D. Collect existing vaccine data & fill gaps as needed			

Strategy: What does the Alliance do next?



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

Collaboration: Who does what? Partner mandates and leadership WHO has overall leadership in this area

Area of Work	Country role	Lead partner agency	Supporting partners	Role of GAVI Secretariat through support structures
Surveillance	major	WHO	technical institutes (CDC), others	Minor
Immunization programme	major	WHO / UNICEF	PATH/ civil society, bilateral donors, BMGF	moderate
Health systems	major	WHO	WB / donors	minor
Health financing	major	World Bank	WHO, BMGF	moderate
Regulation	moderate	WHO	UNICEF, industry,	minor
Industry relations	minor	GAVI support	UNICEF, industry	major
Advocacy	major	GAVI support	UNICEF, civil society, WHO	major
Special projects and studies	variable	GAVI support	WHO, UNICEF, BMGF, technical institutes, industry	major

Support to vaccine introduction



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

