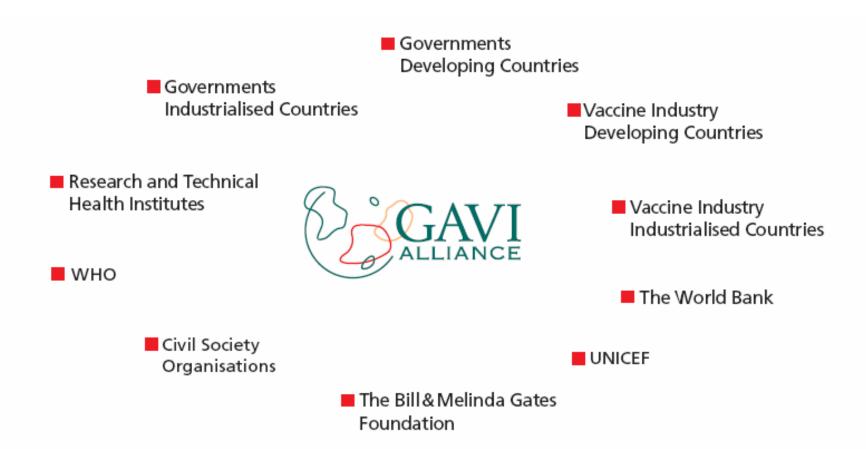
## Challenges in introducing new vaccines: GAVI experiences

**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

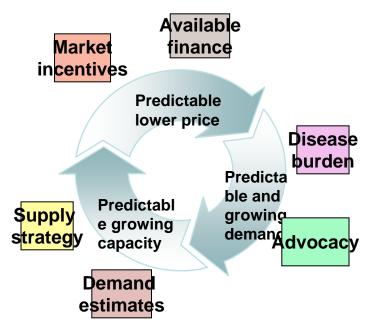
## Healthy systems, Healthy children?

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

Time

Lead

Industry Partners

Countries Partners

Countries Partners

#### **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

4			Funding over time		
Lead	Industry Partners	Countries Partners	Countries Partners		
	Pre- Introduction				
		Introduction phase			
			Routine		
	AMC √	Vaccine Intro Grant √			
	ADIPs √	Vaccines √			
GAVI catalytic action	ISS / INS / HSS / CSO √				
	Funds to partners $\sqrt{}$				
		Hib Initiative √	IFFIm √		
		Vaccine Intro Support ?	IOR ?		

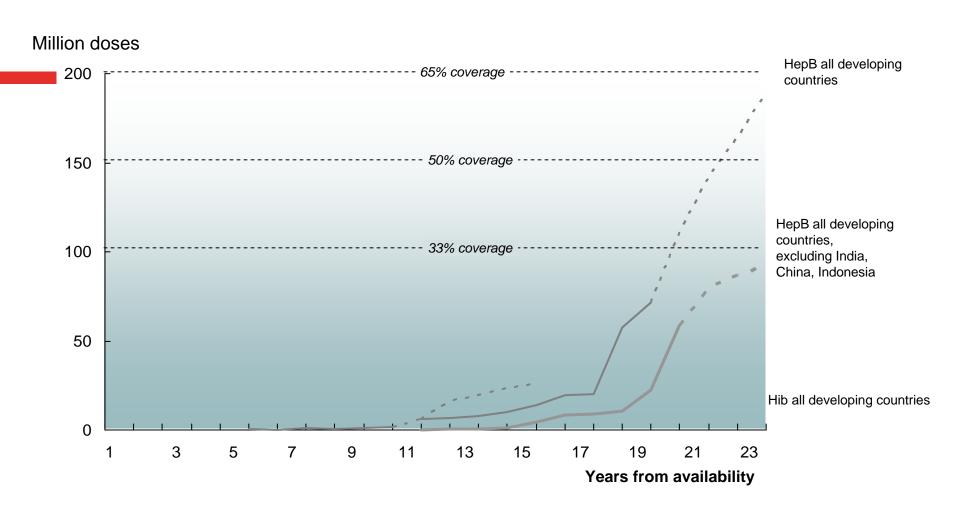
## History: The GAVI contribution to date What we have done

- 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

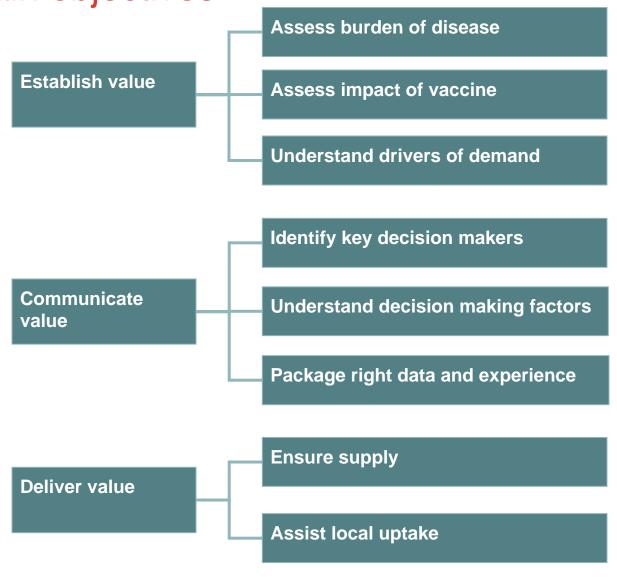
### **ADIPs and Hib Initiative**

- 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.

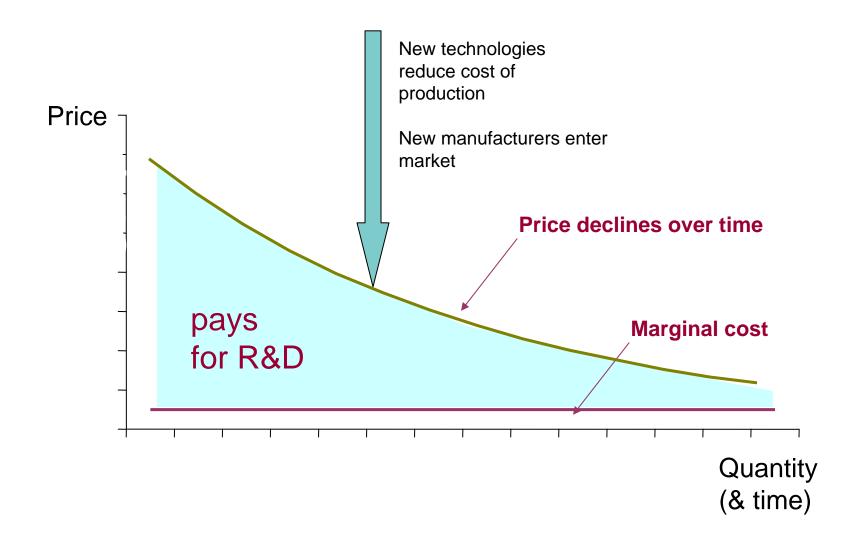
#### Solution:

- 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

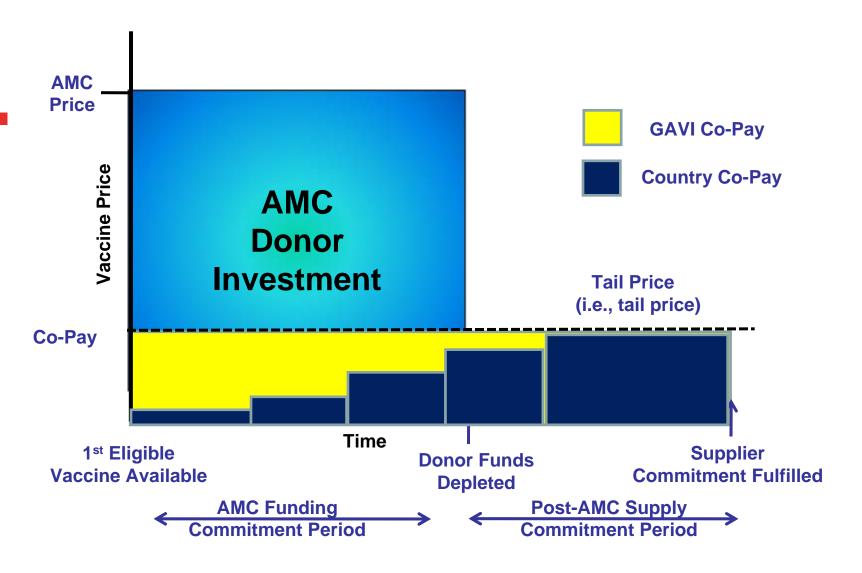


Source: GAVI

## Typical Vaccine Price Curve



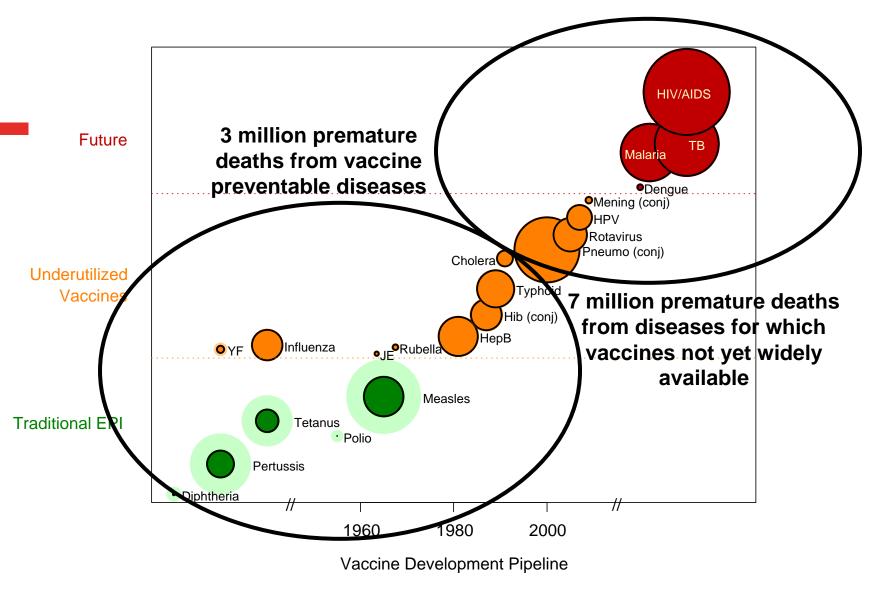
### **AMC Mechanism**



### 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
- B. Identify additional vaccines
  - outside WHO list (>5 years) . Plan country 8
- C. Plan country & global consultations
- D. Collect existing vaccine data & fill gaps as needed

- E. Conduct country consultations
- F. Conduct global J. Evaluate consultations vaccines
- G. Develop activity catalog by vaccine
- H. Analyze health impact and cost-effectiveness

- I. Synthesize diagnostic findings
- J. Evaluate vaccines against criteria
- K. Prioritize
  vaccines and
  required
  activities for
  Alliance support
- L. Communicate recommendatio ns 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?

Diagnostic

Is extra effort needed?

Is there a role for the Secretariat?

Synthesis and Evaluation

#### **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

ISS/ INS/

HSS

**Vaccines** 

Vaccine

Intro

grant

**Outsourced activities** Support to partners Support to countries ADIPS/HI, future? Role for regional and country peer support Coordination through Secretariat Vaccines Introduction programme Advocacy Communications Link to industry support Surveillance standards • Special studies Cold chain Ongoing research Training Surveillance and lab QA Record-keeping Vaccine quality & regulation • Surveillance & lab Vaccine procurement operations

**GAVI Work plan/** 

other mechanisms and

funding sources

**GAVI Secretariat** 

## 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

