EVALUATION OF BUSINESS MODELS NEEDED FOR AN INNOVATIVE EBOLA VACCINE FINANCING SYSTEM

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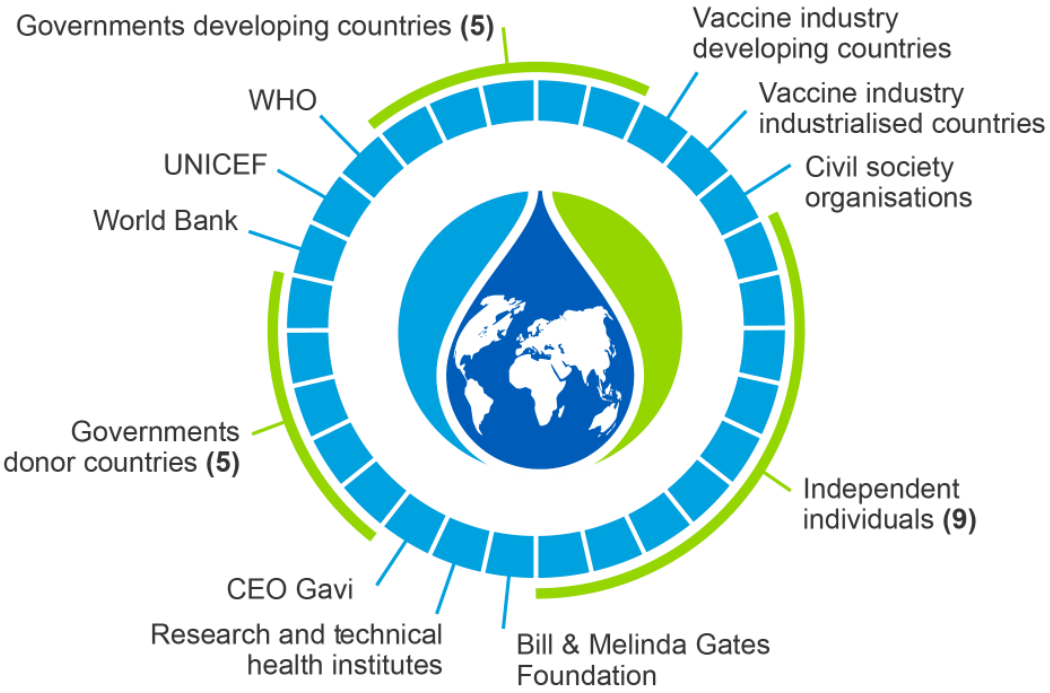
GAVI AS A MULTILATERAL APPROACH TO VACCINE AVAILABILITY

GAVI IS AN ALLIANCE OF PUBLIC AND PRIVATE PARTNERS, WITH FOUR STRATEGIC GOALS



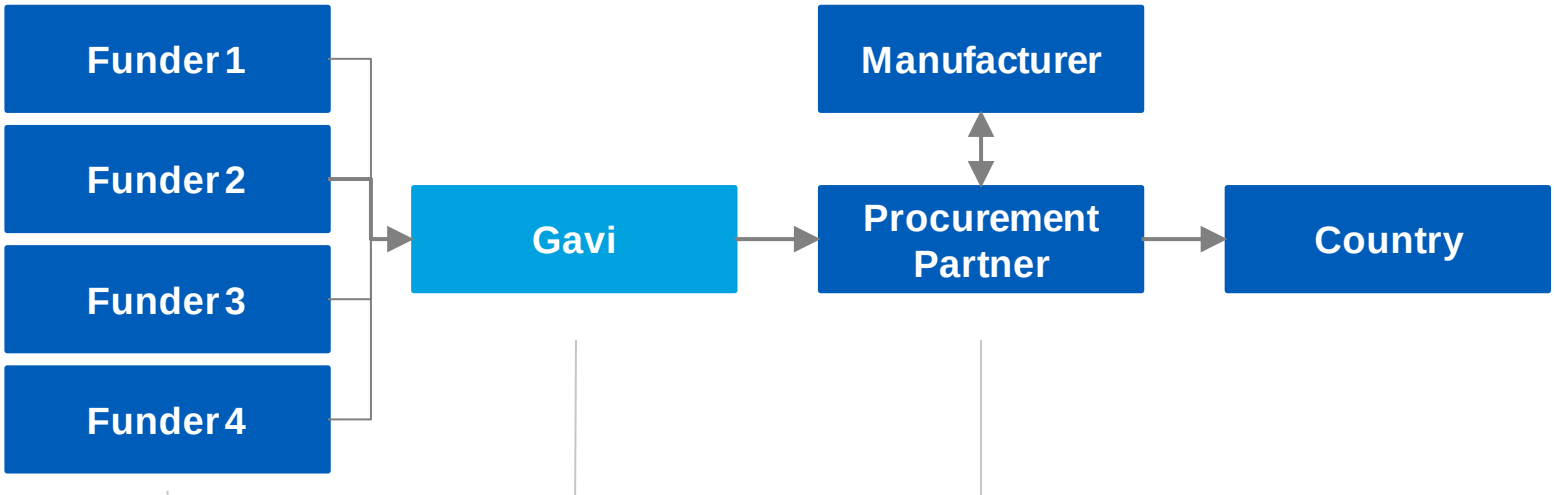
Accelerate uptake and use of underused and new vaccines

Ensure predictable and sustainable financing, both globally and nationally

Strengthen health systems that deliver vaccines

Shape vaccine markets to ensure supply and low, sustainable prices

GAVI ENABLES A MULTILATERAL APPROACH FOR INCREASING ACCESS TO NEW VACCINES



Provide funding

Aggregates donations, creating a multilateral approach

Aggregates demand across countries

Contracts with manufacturer, takes delivery, distributes to countries (partner most often UNICEF)

Leverages global resources to

- Accelerate availability
- Ensure sustainability
- Maintain affordability
- Enable equitable delivery

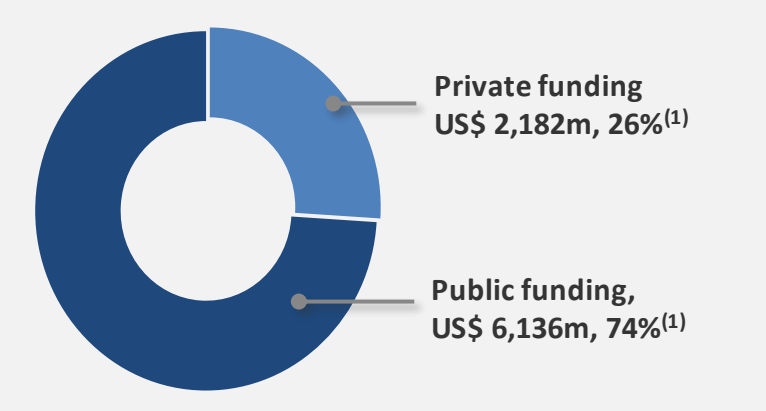
GAVI'S FUNDING MODEL

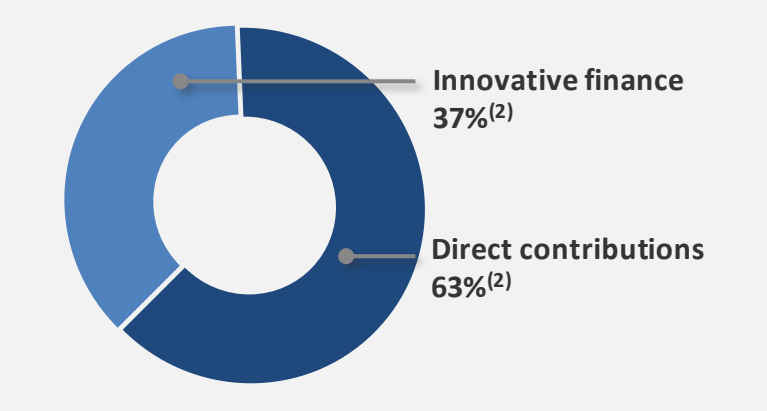
Mix of funders supports Gavi efforts...

1. **Government donors**
2. **Private sector donors, foundations** (e.g., Bill and Melinda Gates Foundation)

... via a range of financing mechanisms

1. **Direct contributions from donor governments and philanthropic organizations**
2. **Innovative funding mechanisms, including:**
   - International Finance Facility for Immunisation (IFFIm)
   - Pneumococcal Advance Market Commitment (AMC)
   - Gavi Matching Fund





1. Gavi's funding for 2000-2013; 2. Gavi's funding for 2000-2010

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INNOVATIVE FINANCE IS CORE TO GAVI

Goal of innovative finance

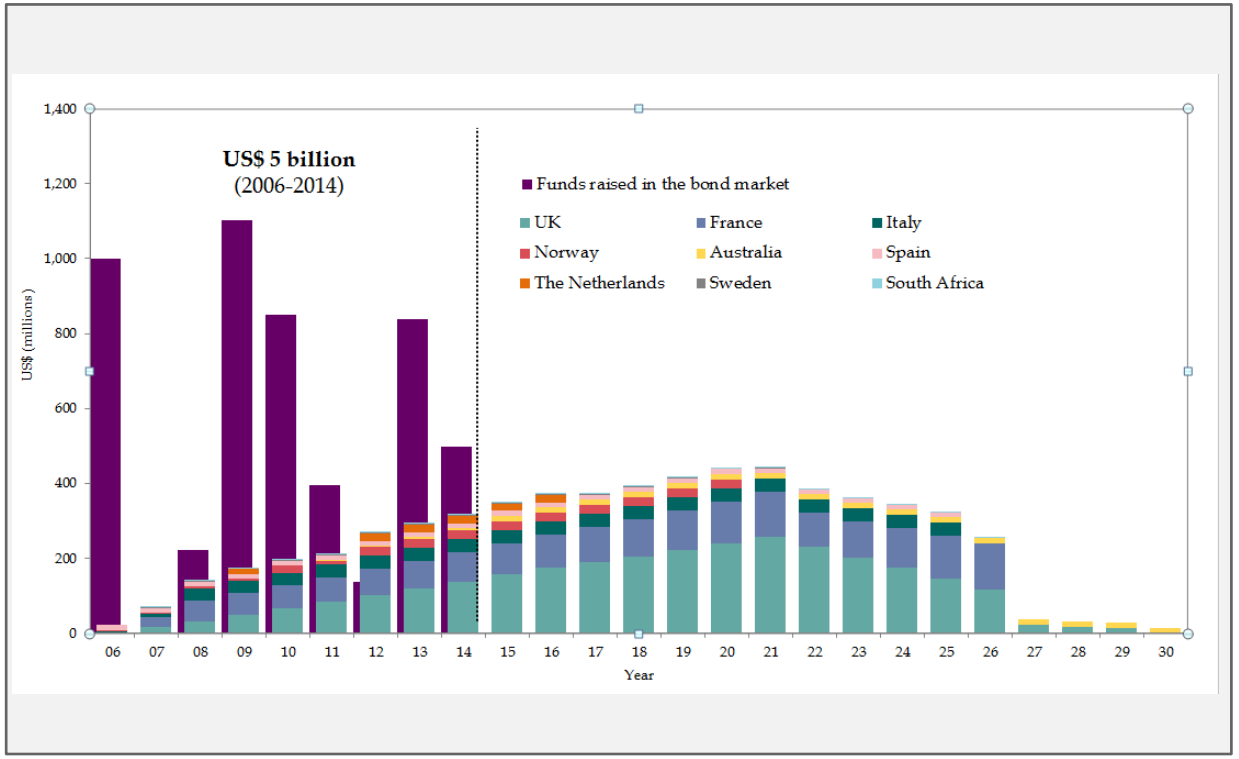
To secure "more money for health" and "more health for the money" by:

- Increasing **predictability** of funds
- Increasing **flexibility** of funds
- Increasing Gavi's **impact per dollar spent**
- Increasing the **diversification** of Gavi's funding sources

EXAMPLES OF INNOVATIVE FINANCE:
A) International Finance Facility For Immunisation (IFFIm)

Goals

- Assure **long term predictability** of financing
- **Leverage capital markets** to frontload funds (or shift them through time) to meet country demand as needed
- Since inception in 2006, **over US$ 5 billion has been raised** in the capital markets, backed by sovereign donor pledges



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EXAMPLES OF INNOVATIVE FINANCE:
B) Pneumococcal Advance Market Commitment (AMC)

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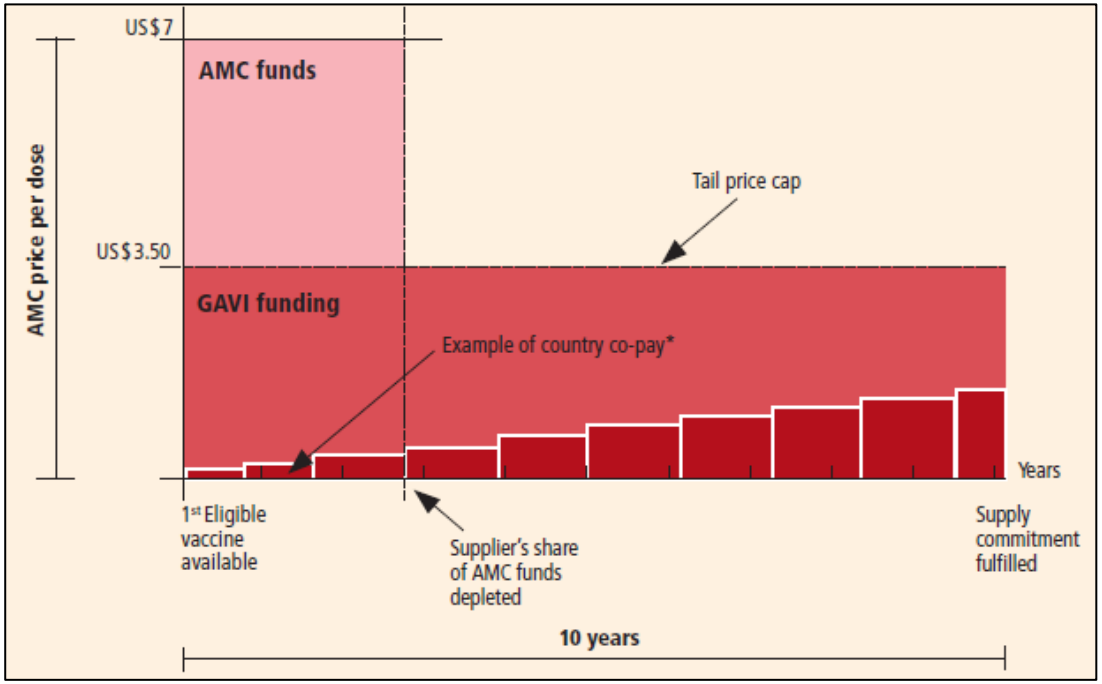
Objectives

Reduce burden of pneumococcal diseases by:

- Accelerating vaccine availability
- Stimulating vaccine uptake

<u>Goal</u>: Prevent > 1.5 M childhood deaths by 2020



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How it works

Donors commit funds to guarantee the price of vaccines

Manufacturers assured of **broad support for market**

Manufacturers agree to **provide the vaccines at a low price** to developing countries in the long term

Increased uptake in target countries

FUNDING CONSIDERATIONS FOR POTENTIAL EBOLA VACCINE EFFORTS

- **Gavi could quickly access funds through IFFIm, in advance of Ebola contributions**
  - Subject to donor action, schedule of funds available through IFFIm could be brought forward

- **Gavi's strong financial standing enables long-term funding or purchase commitments**
  - IFFIm can efficiently convert long-term capital (pledges) into liquid assets that can be used for investments

- **Note that Ebola vaccine funding is not within the current Gavi replenishment target**
  - Additional donor commitments needed, despite Gavi flexibility around timing of funds

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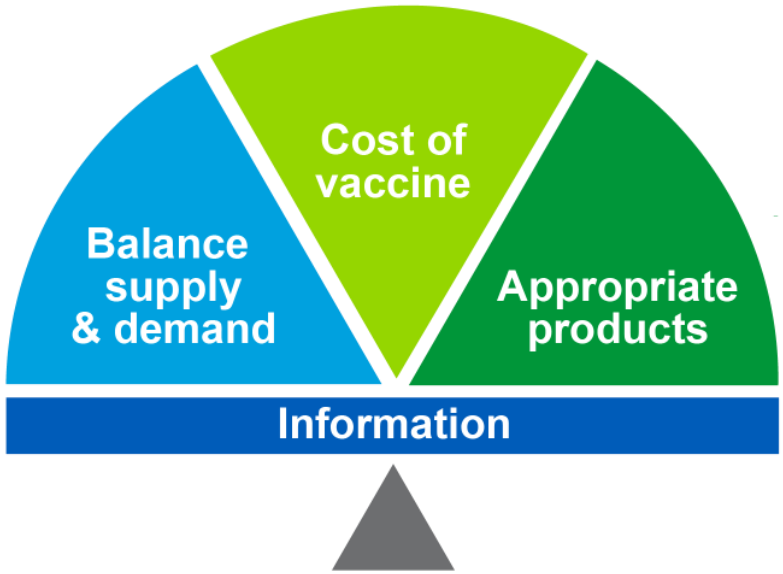
GAVI SHAPES VACCINE MARKETS VIA SUPPLY AND PROCUREMENT STRATEGIES

Goal of market shaping:
Ensure sufficient supply of appropriate, quality vaccines at low and sustainable prices



Gavi's Market Shaping includes:

- Forecasting country demand and vaccine prices
- Industry engagement and negotiations
- Procurement through UNICEF Supply Division and PAHO Revolving Fund
- Designing innovative vaccine procurement contracting
- Managing financial risks of innovative contracting
- Ensuring transparency of information

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EXAMPLES OF MARKET SHAPING MECHANISMS BEYOND AMC

	Objectives	Financial mechanism	Result
Pentavalent	• Prevent supply disruptions • Continued downward price trend	• Time-limited volume guarantee (30% of demand) • Fixed price per dose • Prepayment option	• Several prequalified vaccines, potential supply >400M doses / year • Prices range from USD 1.19-2.95
Rotavirus	• Develop supply base • Prices compatible with Gavi needs • Long-term, sustainable market	• Time-limited volume guarantee (70% of demand) • Fixed price per dose • Prepayment of 55% of volume	• $2.50/dose price achieved • High country demand for programmatically preferred product
Meningitis A	• Prevent supply disruptions • Cover other serotypes	• Firm contract for >90% of offered doses for a single season for a stockpile	• Several stockpile suppliers. • Several serotypes covered

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TYPES OF GAVI SUPPORT FOR CONTROL OF DISEASES WITH EPIDEMIC POTENTIAL

Global vaccine stockpiles	**Global stockpiles enable faster access to vaccines during outbreaks and emergencies** • Gavi currently funds MenA and Yellow Fever stockpiles[1] • Gavi covers cost of vaccines and shipment without co-financing • Operational costs (US$ 0.25) per individual in target group (via ICG)
Mass Preventive Campaigns	**Mass preventive campaigns rapidly increase population immunity in high-risk areas and protect susceptible populations** • Gavi covers **vaccine procurement and shipments** without co-financing • **Operational costs** (US$ 0.65) per individual in the target group - expected to cover approximately 80% of the total estimated cost, countries to cover the rest • Funding for case-based surveillance, risk assessment, vaccine impact study and other capacity-building activities (via business plan)

1. Gavi support approach for the global cholera vaccine stockpile is currently under development – it is not yet clear whether shipments and operational costs will be funded by Gavi. 2. International Coordinating Group

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WORKING TOGETHER TO CREATE EMERGENCY STOCKPILES

Gavi	• **Funds** emergency stockpile through International Coordinating Group (ICG)[1]
ICG members	
WHO (serves as ICG Secretariat)	• **Coordinates and manages** stockpile • Provides **technical support** to countries (e.g. surveillance, preparedness, and response to outbreaks)
UNICEF	• Performs vaccine **procurement and shipment**
IFRC[2]	• Strong **country presence** • E.g. Community health promotion, local social and resource mobilization, support to states during disasters and epidemics)
MSF[3]	• **Providing health care** to populations in emergency situations • Epidemiology, case management, vaccination, training, evaluation

ICG mechanism is tailored to ensure **rapid response** to outbreaks:
Takes **max 10 days** from submission of country request to vaccine arrival in country

1. ICG members include, among others, WHO and vaccine manufacturers. 2. International Federation of the Red Cross and Red Crescent Societies. 3. Médecins sans Frontières

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SUMMARY: GAVI'S CORE CAPABILITIES

Gavi works to increase access to vaccines by leveraging the expertise and financial resources of Alliance members

Core capabilities of the Alliance relevant to Ebola include:

- Flexible financing
- Vaccine procurement
- Market shaping to secure vaccine supply in the short and long term
- Funding support to emergency stockpiles
- Support to vaccine campaigns

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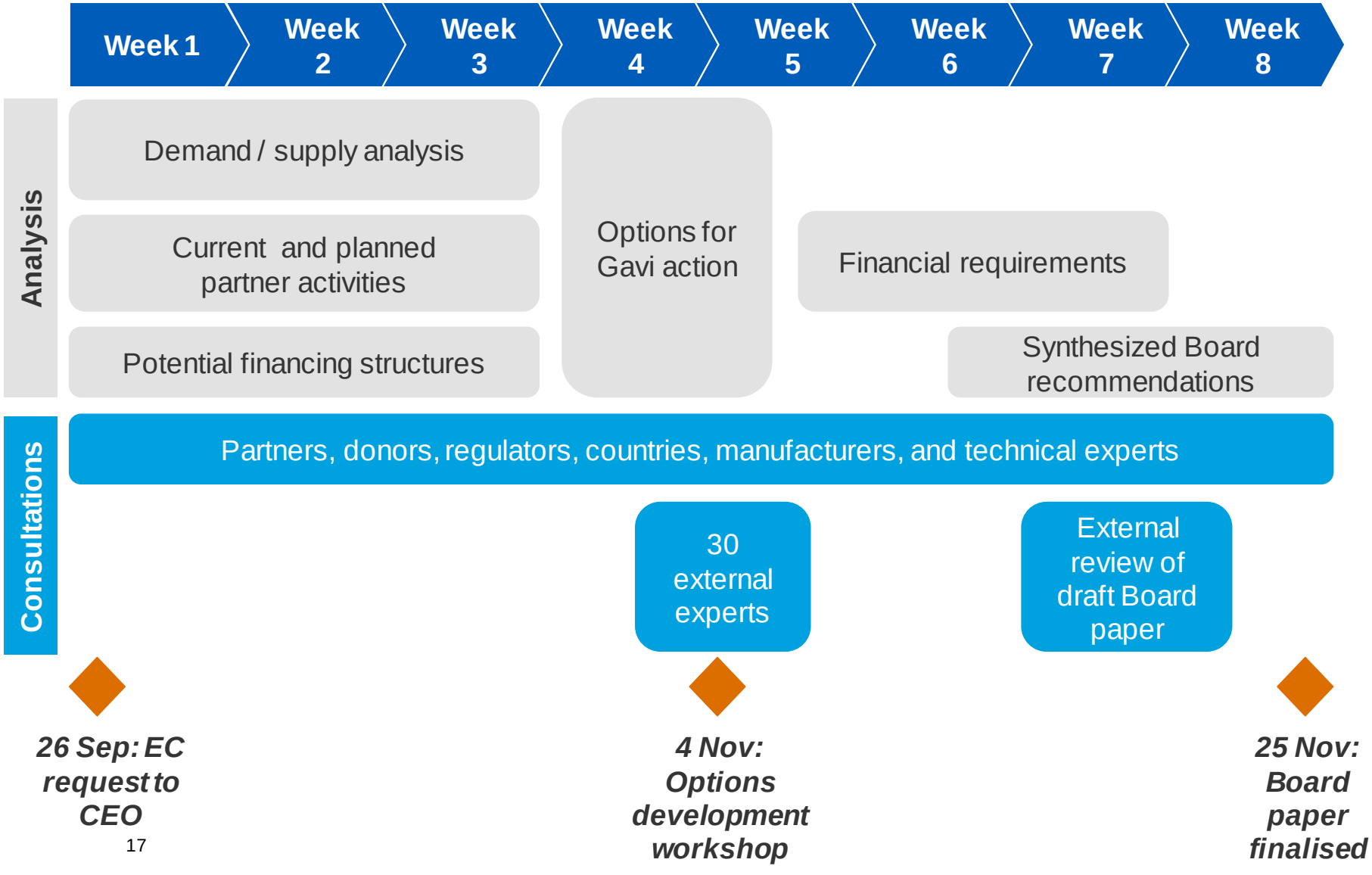
EBOLA VACCINE ACCELERATION

8-WEEK PROCESS TO GENERATE A BOARD RECOMMENDATION ON EBOLA RESPONSE



GATHERING INPUT TO INFORM OPTIONS

BILL & MELINDA GATES foundation

World Health Organization

NIAID

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

GLOBAL EBOLA RESPONSE

Outbreak projections & modeling
Vaccine R&D status
Manufacturing support
Deployment considerations
Policy and regulatory environment

unicef

Manufacturers

wellcome trust

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

THE WORLD BANK
IBRD • IDA | WORLD BANK GROUP

USAID
FROM THE AMERICAN PEOPLE

MEDECINS SANS FRONTIERES

European Commission

Affected & neighboring countries

Department for International Development

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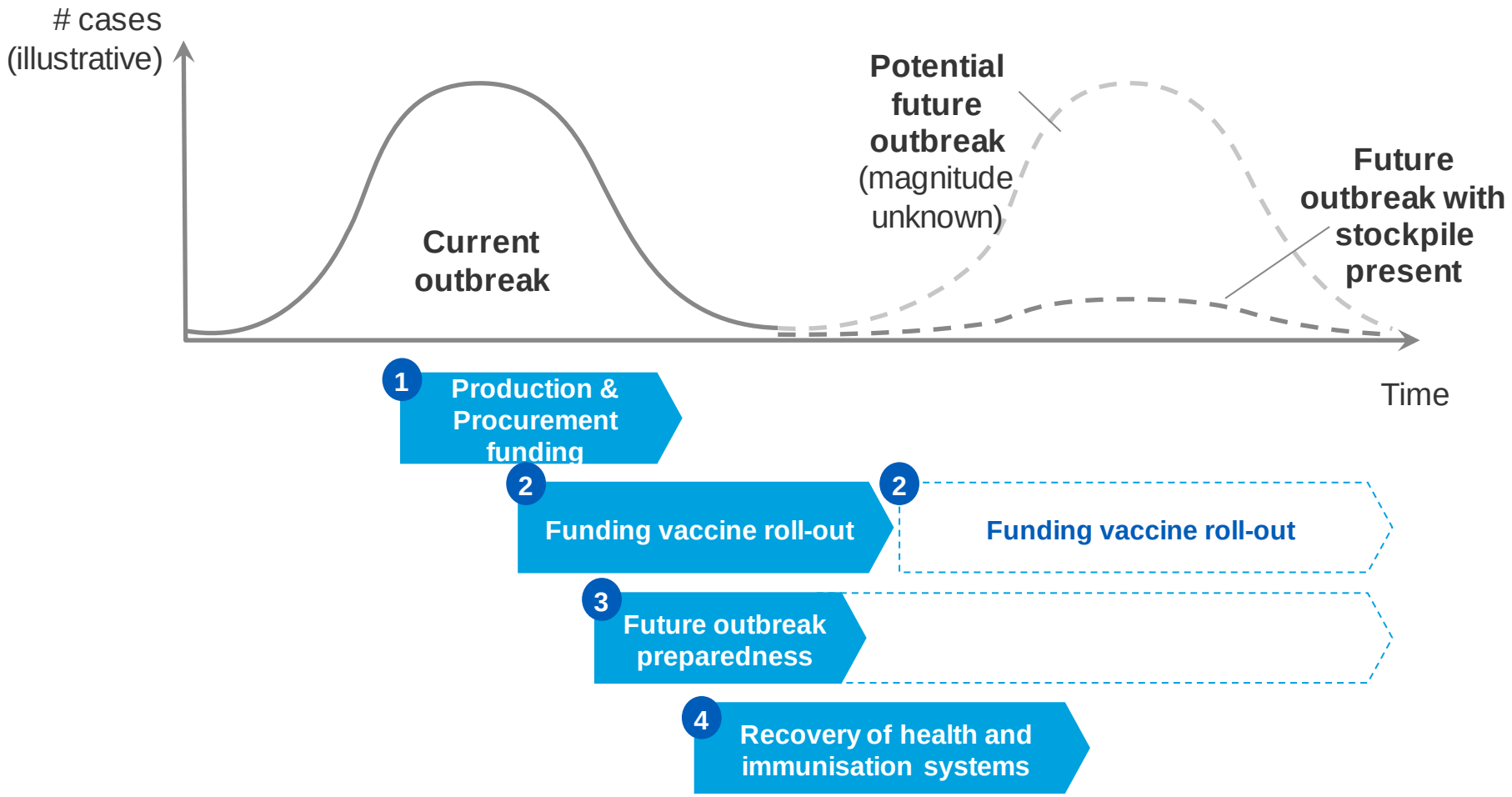
WHERE CAN GAVI CONTRIBUTE?

PARTNER LANDSCAPING AND GAVI CAPABILITY ASSESSMENT

Cost category		Critical funding area	Est. funding coverage	Fit with Gavi capabilities? (based on past experience, partner inp
Clinical trials		Phase I	High	✗
		Phase II	High	✗
		Phase III	High	✗
Production & procurement	Production scale up	Production at clinical trial scale	High	✗
		Scale up / scale optimisation	Medium	✓
		Commercial scale mfg	Low	✓
	Procurement	Vaccine procurement	Medium	✓
	Risk mitigation	Indemnification	Medium	✗
	Diverted manufacturer resources	Diverted manufacturer resources	Low	✓
Vaccine roll-out		Planning & coordination, socia mobilisation, IEC, training, HR, transport / logistics / cold chain, waste management, surveillance and monitoring of AEFI, etc.	Medium	✓
Future outbreak preparedness		Clinical trials	Low	✗
		Production scale up	Low	✓
		Procurement	Low	✓
		Vaccine roll-out	Low	✓

4 RECOMMENDED AREAS FOR GAVI ACTION



PLANNING ASSUMPTION: HIGH DEMAND SCENARIO IN 3 AFFECTED COUNTRIES

High end of target populations is ~12-20M[1]
– includes adults (~12M) or both adults and children (~20M)

Potential beneficiary populations		Estimated size of potential target population (in thousands)			
		Guinea	Liberia	Sierra Leone	Total
1	Heath workers in clinical settings (e.g. doctors, nurses, cleaners)	1.7	11.7	6.2	**19.8**
2	Community Ebola responders (e.g. burial teams, contact tracers etc)	25.3	40.3	32.2	**97.8**
3	Contacts providing home care of cases and ring vaccination of contacts	2.7	66.9	6.6	**16.0**
4a	Age-based strategy: Vaccinating children in affected areas	4717.4	1740.6	2351.0	**8809.0**
4b	Age-based strategy: Vaccinating adults in affected area	6458.6	2249.1	3261.7	**11969.4**
5	Geographical strategy: affected districts& counties vs unaffected				
6	Pregnant women	251.8	105.1	125.9	**482.8**
7	People with HIV	88.8	16.6	40.3	**145.7**

1. High demand based on trajectory of current outbreak limited to Liberia, Sierra Leone and Guinea. In the case of EVD spread to neighboring countries demand can be as high as 300M based on total population of those countries (which include Nigeria, Senegal, DRC, and Mali).
Source: WHO's background information for Gavi's workshop – Nov 2014

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1 VACCINE PRODUCTION AND PROCUREMENT

ENVELOPE DRIVEN BY LEVEL OF UNCERTAINTY AND EVOLVING LANDSCAPE

Procurement-related principles

1. **Plan for high vaccine demand**
2. **Focus on alleviating bottlenecks to vaccine availability**
3. **Prioritise solutions that are candidate-agnostic**
4. **Avoid prematurely locking into a market that is not fully understood**

Recommendation:
Envelope signaling Gavi potential spend

- ✓ **Utilises Gavi's multilateral mechanism to aggregate and coordinate funding**
- ✓ **Signals a market for Ebola vaccine and related supplies**
- ✓ **Allows addressing of different demand scenarios in an evolving environment**
- ✓ **Enables tailored agreements with individual manufacturers**
- ✓ **Enables support of multiple manufacturers**

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1 VACCINE PRODUCTION AND PROCUREMENT

DETERMINATION OF FUNDING ENVELOPE SIZE

Key drivers of size of US $300 million envelope	
Volume of vaccine required to combat current outbreak	Up to 12M courses
Number of manufacturers	2-3 manufacturers (with different economics)
Manufacturer costs	Marginal costs of production and unsubsidized scale up costs

Key drivers of uncertainty around spend within envelope	
Actual demand versus "high demand" scenario	Actual demand anywhere from <100K to >12M courses
Manufacturer from which vaccines are ultimately procured	Different cost structures, vaccine technologies
Level of subsidy for each manufacturer	Funding discussions still evolving

Funding structures within this envelope will be subject to EC approval

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2 FUNDING VACCINE ROLL-OUT

BASED ON CURRENT DATA – DETAILED COUNTRY-LEVEL COSTING UNDERWAY

A Standard campaign categories *with Ebola-specific cost multiplier assigned*

- Social mobilisation, IEC[1] , advocacy
- HR and training
- Vehicles and transportation
- Waste management
- Surveillance, including for AEFI[2]
- Evaluation

B Additional cost categories for Ebola vaccine roll-out

- Emergency Operations Centres
- Cold chain and logistics
- Security and crowd control
- Increased infection control measures

C Stockpile cost categories

- Management of stockpile
- Operational costs for use of stockpiled courses in future outbreaks

US$ 38 M [3]

US$ 7 M

US$ 45 M

1. IEC: Information, education, and communication 2. Adverse Events Following Immunisation 3. Assuming target population of 12M individuals

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3 FUTURE OUTBREAK PREPAREDNESS

Recommendation 1:
Stockpile of first-generation vaccines

- Relatively small stockpile required
- To be maintained until 2nd generation vaccine becomes available

Gaps remaining

Profile of first generation vaccine(s) expected to be suboptimal for longer-term application:

- Monovalent vaccine
- Thermostability concerns

Recommendation 2:
In-principle commitment to 2nd-generation stockpile

- Assure availability of effective vaccines for future outbreaks
- Vaccine availability dependent on timing of vaccine development and optimisation

Lack of longer-term availability of an effective Ebola vaccine could result in a repeat of the current situation

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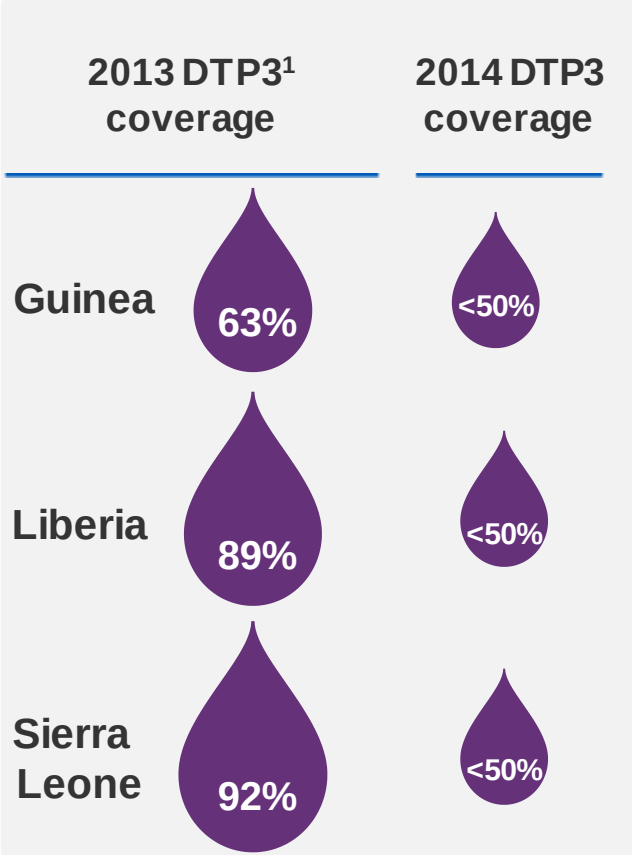
4 RECOVERY OF HEALTH AND IMMUNISATION SYSTEMS

Ebola has crippled health and immunisation systems



Recommendations to support recovery

(Upon country request)

Vaccines and related injection safety devices and programmatic support	up to **US$ 12.5 M**
Reprogramming of currently approved HSS grants	**No additional costs**
Increase of HSS funding	up to **US$ 30.5 M**
Waiving of 2014-15 co-financing requirements	up to **US$ 2 M**
Total	up to **US$ 45 M**

1. Coverage with 3rd dose of a DTP-containing vaccine

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GAVI BOARD - APROVED FINANCIAL IMPLICATIONS

Recommendation per Board Paper	US$ million
Ebola Programme Funding Envelope (2015-2020)	
Ebola vaccine production and procurement	300
Ebola vaccine roll-out	45
Recovery of health and immunisation systems	45
Sub-total: **Ebola Programme Funding Envelope**	**up to 390**
Addition to Business Plan budget (2015-2016)	
Secretariat costs	3.5
Support to WHO & UNICEF	7.0
Support to Civil Society Organisations	0.5
Sub-total: **Addition to Business Plan Budget**	**up to 11.0**
Total cost of funding the recommendations	up to 401
Less: **Already provided** in Gavi expenditure forecast for 2014-2015	(100)
Additional resources required	up to 301
Deduct: **Resources from other funding agencies / donors**	TBD
Balance to be funded through Gavi	TBD

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