Inaugural Keynote Lecture: Contributions of Gavi and DCVMN to the global vaccine markets

DCVMN 18th AGM
Seth Berkley M.D, CEO
26 September 2017, Seoul
Gavi’s mission, model and achievements to date
Gavi’s mission

Saving children’s lives and protecting people’s health by increasing equitable use of vaccines in lower-income countries.

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Gavi’s partnership model

IMPLEMENTING COUNTRY GOVERNMENTS

DONOR COUNTRY GOVERNMENTS

CIVIL SOCIETY ORGANISATIONS

RESEARCH & TECHNICAL AGENCIES

VACCINE MANUFACTURERS

PRIVATE SECTOR PARTNERS

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Increasing immunisation coverage

- **High-income countries**
- **Global**
- **Gavi-supported countries**

**Post-Gavi increase 2000-2016**: 20% points

*Based on data officially reported to WHO and UNICEF by current member states. Note: Includes DTP-containing vaccines, such as pentavalent vaccine.

Accelerating access to new vaccines in poorest countries

Prior to Gavi support

<table>
<thead>
<tr>
<th></th>
<th>High-income countries</th>
<th>Low-income countries</th>
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</thead>
<tbody>
<tr>
<td>2000</td>
<td>86%</td>
<td>6%</td>
</tr>
<tr>
<td>2009</td>
<td>72%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Note: Only countries with universal national introduction are included. World Bank 2016 country classification has been applied to the whole time series.

Source: The International Vaccine Access Center (IVAC) VIMS database. Data as of 31 December 2016.

Now

<table>
<thead>
<tr>
<th></th>
<th>High-income countries</th>
<th>Low-income countries</th>
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<tbody>
<tr>
<td>2016</td>
<td>91%</td>
<td>86%</td>
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</table>

% of countries introduced vaccines nationally

Hepatitis B
Hib
Pneumococcal

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Gavi vaccine introductions and campaigns

Introductions by September 2017

- **Pentavalent***: 73 countries
- Pneumococcal: 58 countries
- Rotavirus: 41 countries
- Inactivated polio: 54 countries
- Meningitis A: 25 countries
- Yellow fever: 14 countries
- HPV: 25 countries
- Measles: 10 countries
- Measles-rubella: 24 countries
- Japanese encephalitis: 3 countries

* 5 of the 73 countries introduced pentavalent vaccine independently of Gavi support.
** Measles routine = measles 2nd dose
As of 20 September 2017

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Gavi partnerships with countries: the India example

**Pentavalent vaccine**
- India’s introduction with Gavi support and transition to full scale self-financing increased the Penta market by ~80m doses per year
- Increased and steady demand helped secure lower prices

**Measles-rubella vaccine**
- Campaign completed in five states and started in 6 additional states

**Pneumococcal vaccine**
- Launch started in three states

**Rotavirus vaccine**
- Launched in nine states, self-financed

**Aug-2017: Intensified Mission Indradhanush: Aim to reach 90% immunisation coverage by 2018**
GAVI’S RESOURCE MOBILISATION MODEL

Co-financing

Donor base

Market-shaping

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As economies grow, countries transition out of Gavi support

Country enters Gavi support, co-financing its vaccines

Note: the eligibility threshold is adjusted annually for inflation.
Source: Gavi, the Vaccine Alliance, 2016

As the country’s national income grows, payments increase by 15% a year

Low-income country threshold
< US$ 1,025 per capita gross national income (GNI)

Initial self-financing
100%

% of vaccine cost

Preparatory transition

Increasing GNI per capita

Variable duration

Variable duration

5 years

5 years

Fully self-financing

Access to vaccine price commitments for 5 or more years

Co-financing accelerates to reach 100%

End of Gavi financing

$0.20 per dose

Co-financing

Preparatory transition

Variable duration

Low-income country threshold

Eligibility threshold

> US$ 1,580 per capita GNI

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Growing country co-financing contribution

* In 2016, 67 countries were co-financing and 4 countries fully self-financing
One third of initial 73 Gavi countries in or completed transition

Initially 73 Gavi-supported
17 in accelerated transition
9 fully self-financing all vaccines

Note: Gavi’s support to the Ukraine ended before the co-financing and transition policies were implemented.

Source: Gavi, the Vaccine Alliance, 2017

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Innovative finance key to Gavi’s funding model

International Finance Facility for Immunisation (IFFIm)

Advance Market Commitment (AMC) for pneumococcal vaccine

Advance Purchase Commitment (APC) for Ebola vaccine

The Gavi Matching Fund

> US$ 5 billion

US$ 1.5 billion

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Affordable and sustainable vaccine prices

Cost to immunise a child with full course of:

- BCG
- HEPATITIS B
- DTP
- HIB
- ROTAVIRUS
- PNEUMOCOCCAL
- INACTIVATED POLIO
- MEASLES
- RUBELLA
- HPV (CERVICAL CANCER)

Gavi price: US$ 35

Approx. USA price: US$ 950

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Market shaping and the role of industry in the Vaccine Alliance
Vaccine markets, how partners achieve impact

<table>
<thead>
<tr>
<th>TACTICS</th>
<th>BMGF</th>
<th>GAVI</th>
<th>UNICEF</th>
<th>PROCUREMENT</th>
<th>OPERATIONS</th>
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<tbody>
<tr>
<td>Product innovation</td>
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<td>Providing financial resources</td>
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<td>Technical support</td>
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<td>Programmatically driven demand forecasts</td>
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<td>Market analytics</td>
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<td>Strategic vaccine roadmaps</td>
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<td>Information transparency</td>
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<td>Negotiating affordable pricing</td>
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<tr>
<td>Innovative financing mechanisms or market incentives</td>
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<td>Tender process execution</td>
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<td>Manufacturer award</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Supply chain operations</td>
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</tr>
<tr>
<td>Technical support for country-led programs, introductions, packaging and cold chain capacity</td>
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</tbody>
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Gavi started at a time of limited supply

2001: 5 suppliers from 5 countries of production

Belgium 1
France 1
Switzerland 1
Senegal 1
Republic of Korea 1

Source: UNICEF Supply Division
Gavi has helped create a viable market with more secure supply

2016: 17 manufacturers from 11 countries of production

- Netherlands 1
- Belgium 1
- France 1
- Russia Federation 1
- United States 2
- Senegal 1
- Brazil 1
- India 4
- Indonesia 1
- China 1
- Republic of Korea 3

* One US manufacturer also produces in the Netherlands.

Note: Country of production represents country of national regulatory agency responsible for vaccine lot release.

Source: UNICEF Supply Division and WHO list of pre-qualified vaccines, 2016

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DCVMN contribution to Gavi market

% of Gavi supplied doses 2012-2016

DCVMN supplied Gavi with 1.5bn doses over 2012-2016

* Non-member suppliers: FSUE of Chumakov IPV and Institut Pasteur de Dakar
Critical role of DCVMN in ensuring greater vaccine supply availability

Vaccines for endemic diseases

Vaccines for epidemics

Other vaccines

DCVMN Manufacturers
- PQ
- Locally licenced
- In development

Non-DCVMN Manufacturers
- PQ
- Locally licenced
- In development

Gavi
The Vaccine Alliance

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Gavi collaboration with industry: the example of SII

- Over 2012-2016, SII supplied 1,193 million doses of vaccines and contributed to immunizing 923 million children

Source: UNICEF shipment data, 2017
SII contribution to improving vaccine supply security: MenAfriVac success story

Meningitis A vaccine

The Challenge:
- No affordable vaccine against meningitis A
- Vaccine manufacturers reluctant to invest

Severe consequences:
- 10% of people infected die
- 25% of survivors suffer permanent disabilities

450 million people
Live in Africa’s “meningitis belt” across 26 countries

The Solution:
- Partnership between WHO, PATH, Bill & Melinda Gates Foundation
- SII vaccine development commitment
- Initial investment to develop affordable vaccine

Gavi funds campaigns and routine introductions

450 million people threatened
More than 235 million people vaccinated since 2010

Prevention vs Treatment
Cost per person

US$ 0.64
US$ 90

450 million
people vaccinated
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Yellow Fever vaccine: example of an increasingly healthy market

- Between 2013 and 2017, Gavi and partners identified opportunities to **improve supply security** for YFV:
  - **Encouraging manufacturers to invest** in securing and increasing supply
  - **Providing technical and financial support** to manufacturers
  - **Strengthening National Regulatory Agencies** responsible for ensuring vaccine quality and safety

![Graph showing supply and demand trends for Yellow Fever vaccine](image-url)
Gavi is committed to supporting product innovation

Accelerating product innovation to better meet country programmatic needs and improve coverage and equity

Align product innovation priorities and definitions across market-shaping partners

Weigh benefits of long-term product innovations to support investment decisions

Shape cold chain equipment markets

Delivery options
- Transdermal micro-array patch
- Needle free jet injectors
- Blow-filled seal technology
- Solar Direct Drive refrigerators

Product Presentations
Comparison of production processes: traditional, mRNA and DNA vaccines

Traditional vaccine:
- Target selection
- Produce target antigen
- Select/produce vaccine antigens
- Phase 1: Live growth/fermentation
- Phase 2/3: Investment decisions in production facility (3-5yr lead time)
- Commercial scale production
- Delivery: Bespoke facility ($100mm-$1bn) (kg scale)

mRNA vaccine:
- Identify antigen
- Standardized plasmid & mRNA
- Standardized (mg scale)

DNA vaccine:
- Identify antigen
- Standardized plasmid
- Standardized (kg scale)
- Standardized multiproduct facility (tonne scale)
- Specialized delivery system
Numerous mRNA vaccines in clinical/ pre-clinical development

In clinical development
- Influenza H10
- Influenza H7
- Rabies
- Chikungunya
- Zika

In late clinical development
- CMV
- HMPV/ PIV3
Increased access to vaccines also means lower prices for middle income countries: Penta example


Further 50% price reduction expected over 2017-2019
Emerging challenges and opportunities
The immunisation gap

~140 million children born every year

19.5 million are not fully protected with the most basic vaccines

80% in Gavi-supported countries

1 in 5 in Gavi countries do not get a full course of the most basic vaccines

Only 1 in 14 are fully immunised with all recommended vaccines


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...and to accelerate coverage of new vaccines

Vaccine coverage in Gavi-supported countries by 2020

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>1st dose</th>
<th>2nd dose</th>
<th>2000</th>
<th>by 2015</th>
<th>by 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles-containing vaccine</td>
<td></td>
<td></td>
<td>59</td>
<td>78</td>
<td>83</td>
</tr>
<tr>
<td>Pentavalent vaccine</td>
<td></td>
<td></td>
<td>68</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>Measles-containing vaccine</td>
<td>1</td>
<td>2</td>
<td>47</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Yellow fever vaccine</td>
<td>a</td>
<td></td>
<td>8</td>
<td>41</td>
<td>64</td>
</tr>
<tr>
<td>Pneumococcal vaccine</td>
<td></td>
<td></td>
<td>35</td>
<td>51</td>
<td></td>
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<tr>
<td>Rotavirus vaccine</td>
<td></td>
<td></td>
<td>20</td>
<td></td>
<td>70</td>
</tr>
<tr>
<td>Rubella vaccine</td>
<td>1</td>
<td></td>
<td>15</td>
<td></td>
<td>75</td>
</tr>
<tr>
<td>HPV vaccine</td>
<td>b</td>
<td>2</td>
<td></td>
<td>45</td>
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</tbody>
</table>

Coverage refers to the final dose of each vaccine, unless otherwise stated.

a Target population and coverage estimates are based on 32 yellow fever-endemic Gavi-supported countries in Africa.
b Target population for HPV is 10 year old girls.

Immunisation: a platform for universal health coverage

Children reached through routine immunisation worldwide 86% 14%

Tertiary
Secondary
Primary Health Care

Routine Immunisation

Build out system to reach the remainder

Towards universal health coverage

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Growing risk of infectious disease outbreaks

Climate change
Population growth
Urbanisation
Migration

increasing health threats
Routine immunisation key to global health security

- Countries are more connected than ever
- Diseases spread faster and further
- 70% of countries are not prepared*
- Threat to health security
- Threat to economic stability

Strong **routine immunisation** systems help build the capacity for communities and countries to **detect, prevent** and **respond to** outbreaks

*Source: CDC, Decoding GHSA: Global Health Security Agenda*

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Gavi’s growing role in outbreak preparedness and response

Yellow fever vaccine stockpile

Measles outbreak response

Meningitis vaccine stockpiles

Oral cholera vaccine stockpile

Ebola vaccine stockpile
Gavi’s investment in global OCV stockpile

Vaccine Investment Strategy (VIS)
- Identified evidence gaps: lack of vaccine effectiveness data for targeted vaccination strategy, unsure of demand, impact and programmatic feasibility
- Decision: global cholera vaccine stockpile contribution for epidemic response + research investment to understand role of OCV in endemic settings

Gavi Board
- Approved the use of the VIS funding to also support operational costs

2018 VIS
- Review of Gavi’s future investment in cholera

2013  2016  2018
Oral cholera vaccine: impact of investment

Number of doses used globally (millions)

- Dukoral
- Euvichol prequalified
- Shanchol prequalified
- Creation of stockpile/Gavi investment
- Gavi support for operational costs


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Cholera: affected countries

Countries reporting cholera, 2010-2015

- Somalia: ~60,000 cases
- Haiti: ~9,500 cases
- Yemen: ~650,000 cases
- South Sudan: ~14,000 cases
- Sudan: ~26,000 cases
- DR Congo: ~24,000 cases
- Sierra Leone

Countries reporting cholera, 2017

- Cameroon
- Malawi
- Mozambique
- Nigeria
- Sierra Leone
- Somalia

Approved for Gavi vaccine support in 2017

Source: WHO Cholera Update 20 Sep 2017

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Alliance Partners supported the introduction of a new oral cholera vaccine from EuBiologics.
Euvichol Innovative Packaging

Euvichol Carton for 10 vials

Appearance of Euvichol

Pull tab mechanism to facilitate removal of vaccine’s foil cover
Next version of Euvichol: further improving the convenience of administering the vaccine

Euvichol in glass vial presentation

Euvichol in plastic tube presentation

- Less expensive
- Ease of storage and transportation
- Ease of administration and waste management

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Looking ahead: Future vaccine investments to be decided in 2018 Vaccine Investment Strategy

Candidate Vaccines

**Incremental investments**
- Diphtheria
- Tetanus
- Pertussis
- PCV
- Hepatitis B
- Oral cholera vaccine
- Meningitis C, Y, W, X
- IPV post-eradication

**New or pipeline vaccines**
- Dengue
- Hepatitis E
- Hepatitis A
- RSV
- Rabies
- Rabies Ig/mAb
- RSV mAb
- Group B streptococcus
- Influenza – Routine Maternal Immunisation
- Malaria (RTS,S)
- Zika virus
- Chikungunya
- Influenza – Pandemic Response

Planned Preventative Immunisation for Endemic Diseases

Public Health Risk Reduction

IPV

Flu

* Further analyses and information might shift this list over the course of the next few months

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TED: The troubling reason why vaccines are made too late, if they are made at all......

Source: TED, Vancouver (March 2015)
Epidemic preparedness: launch of CEPI

Here broad group of partners celebrating #cepi launch @Davos #wef17 #globalhealth @wellcometrust @gatesfoundation

Mission

We want to stop future epidemics by developing new vaccines for a safer world.

Vaccines are one of the world’s most important health achievements. Yet their life-saving potential hasn’t yet been realised for many known and unknown epidemic threats, particularly in low-income countries, where the risks and needs are often greatest.
Immunisation and antimicrobial resistance

Declaration recognised that:

“the keys to tackling antimicrobial resistance are: the prevention and control of infections in humans and animals, including immunization, monitoring and surveillance of antimicrobial resistance…”

Days of antibiotic use prevented by Gavi support for Hib, pneumococcal and meningitis A vaccines:

- 30 million days (2011-2015)
- 35 million days (2016-2020)
2016-20: Saving millions of lives and growing economies in the world’s poorest countries in Gavi-supported countries, 2016–2020

- 5–6 million lives saved
- >100 million illness cases averted
- 80–100 US$ billion costs averted related to illness:
  - productivity loss due to death/disability
  - treatment costs
  - caretaker productivity loss
  - transport costs


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Thank you