Keynote Address: The Challenge of Achieving Universal Access to Vaccines

WIPO & AMF
Seth Berkley M.D, CEO
8 November 2017
Vaccine landscape
The world before vaccines

Examples of major disease outbreaks

- **Flu pandemic**
  - 1918-1920
  - > 50-100 million deaths worldwide

- **Polio**
  - New York
  - 1916
  - 6,000 deaths

- **Cholera pandemic**
  - Europe
  - 1829-1851
  - >200,000 deaths

- **Smallpox epidemic**
  - India
  - 1974
  - 15,000 deaths

- **Yellow fever**
  - Philadelphia
  - 1793
  - >5,000 deaths

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History of vaccine development

Source: Delaney et.al. 2014
Cumulative number of vaccines developed


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Growing market

Vaccine market value in $bn

Source: PATH (March 2016), Markets & Markets (2017)
Vaccine industry dynamics

Highly consolidated

Four companies: ~80% global vaccine revenues

Diverse business models
- Pipelines
- Portfolios
- Revenues and number of doses sold globally
Vaccine suppliers to Gavi (volume)

* Non-member suppliers: FSUE of Chumakov IPV and Institut Pasteur de Dakar

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Innovation needed to address challenges across the value chain

- R&D
  - Basic research
  - Translational research
  - Clinical development

- Supply
  - Manufacturing
  - Pricing
  - Product quality

- Delivery
  - Supply chain
  - Data
  - Health systems

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Product development partnership (PDP) model critical to drive innovation and fill gaps

Example: IAVI is an integrated organization that links its …

- Industry-style labs and diverse research portfolio
- Academic, government and private-sector partnerships
- Network of clinical trial centers in Africa and India
- Advocacy and outreach from community to international level
Acceleration in number of PDPs

Selected other public-private partnerships Working on health issues

BY YEAR STARTED


1977

Gates MRI

Concept Foundation

The Children’s Vaccine Initiative

SAAVI

INTERNATIONAL PARTNERSHIP for MICRHOIDES

KAVI

SABIN VACCINE INSTITUTE

Gates MRI

TB ALLIANCE

GAVI ALIANCE FOR VACCINE DEVELOPMENT

Finding

DNDi

Medicines for Malaria Venture

PATH

International Vaccine Institute

mVAC

European Malaria Vaccine Initiative

iCHW

AERAS Global TB Vaccine Foundation

Global Rights

Gavi

The Vaccine Alliance

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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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Vaccine Alliance partners
The Gavi business model: reinventing aid

Pooling demand of poorest countries

Long-term funding

Market shaping

Donor base

Co-financing

Accelerating access to vaccines

Shaping markets

Strengthening vaccine delivery platforms

Sustaining immunisation

Transition out of support

Continued support

Continued support
As economies grow, countries transition out of Gavi support

Country enters Gavi support, co-financing its vaccines

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

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

100% % of vaccine cost

Initial self-financing
Preparatory transition
Accelerated transition
Fully self-financing

100% Variable duration Variable duration 5 years 5 years years

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

Eligibility threshold
> US$ 1,580 per capita GNI

End of Gavi financing

Access to vaccine price commitments for 5 or more years

Co-financing accelerates to reach 100%

Increasing GNI per capita

$0.20 per dose

Prepared by
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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.

Map reflects 2017 eligibility
Source: Gavi, the Vaccine Alliance, 2017

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Immunisation coverage: closing the gap

- High-income countries
- Global average
- Lowest-income countries
- Gavi-supported countries

- Expanded Programme on Immunization takes off
- Stall in immunisation coverage
- Gavi support to world’s poorest countries

Note: Includes DTP-containing vaccines, such as pentavalent vaccine.

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Achieving impact: India

Under-immunised children (million)

- 9.3 (2007)
- 7.7 (2008)
- 6.6 (2009)
- 5.3 (2010)
- 4.5 (2011)
- 4.4 (2012)
- 4.2 (2013)
- 3.7 (2014)

Launch of Intensified Mission Indradhanush

Gavi HSS 1

Gavi HSS 2

Source: WUENIC 2016 (July 2017 Release)

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Currently 7 of 10 countries with most under-immunised children receive Gavi support

Top 10 countries, under-immunised, DTP3

<table>
<thead>
<tr>
<th>Country</th>
<th>Gavi</th>
<th>Transitioned</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nigeria</td>
<td>3.44M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>2.91M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pakistan</td>
<td>1.43M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td>1.02M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td>0.72M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRC</td>
<td>0.65M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iraq</td>
<td>0.44M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angola</td>
<td>0.41M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brazil</td>
<td>0.41M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Africa</td>
<td>0.39M</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Equitable access to life-saving vaccines

Prior to Gavi support
High-income countries
Low-income countries

<table>
<thead>
<tr>
<th>Year</th>
<th>Hepatitis B %</th>
<th>Hib %</th>
<th>Pneumococcal %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>86</td>
<td>72</td>
<td>67</td>
</tr>
<tr>
<td>2009</td>
<td>72</td>
<td>67</td>
<td>67</td>
</tr>
</tbody>
</table>

Now
High-income countries
Low-income countries

<table>
<thead>
<tr>
<th>Year</th>
<th>Hepatitis B %</th>
<th>Hib %</th>
<th>Pneumococcal %</th>
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<tbody>
<tr>
<td>2000</td>
<td>91</td>
<td>100</td>
<td>86</td>
</tr>
<tr>
<td>2009</td>
<td>100</td>
<td>100</td>
<td>77</td>
</tr>
</tbody>
</table>

% of countries introduced vaccines nationally

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.

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Gavi vaccine introductions and campaigns

Year of first introduction/use of stockpile

- 2001: Pentavalent, Hepatitis B, Yellow fever
- 2002: Hib
- 2007: Measles 2nd dose
- 2008: Rotavirus
- 2009: Pneumococcal
- 2010: Meningitis A
- 2013: Measles-rubella, HPV (cervical cancer)
- 2014: Oral cholera, Inactivated polio
- 2015: Japanese encephalitis
- 2017: Ebola

Introductions by September 2017

- Pentavalent*: 73
- Pneumococcal: 58
- Rotavirus: 41
- Inactivated polio: 54
- Meningitis A: 25
- Yellow fever: 14
- HPV: 25
- Measles: 10
- Measles-rubella: 24
- Japanese encephalitis: 8

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* 5 of the 73 countries introduced pentavalent vaccine independently of Gavi support.
** Measles routine = measles 2nd dose
As of 30 September 2017
Increased breadth of protection* delivered through routine immunisation

*Average coverage across all Gavi-supported vaccines in Gavi-supported countries
Coverage rates for new vaccines

Innovative finance key to Gavi’s funding model

**International Finance Facility for Immunisation (IFFIm)**

- > US$ 5 billion

**Advance Market Commitment (AMC) for pneumococcal vaccine**

- US$ 1.5 billion

**Advance Purchase Commitment (APC) for Ebola vaccine**

**The Gavi Matching Fund**

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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

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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
- United States 2*
- Senegal 1
- Brazil 1
- Russian Federation 1
- China 1
- Indonesia 1
- Republic of Korea 3
- India 4

* 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 (March 2017) and WHO list of pre-qualified vaccines (2016)
Affordable and sustainable vaccine prices

Cost to immunise a child with full course of:

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

USA price:
- US$ 950
- US$ 35

Approx. US$ 950

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Immunisation: a platform for universal health coverage

IMMUNISATION PLATFORM

~98% of children touched by immunisation

86% of children reached through routine immunisation worldwide

Towards universal health coverage

Build out system to reach the remaining 14%
Improving health and immunisation systems

- Integrated service delivery
- Health service workforce
- Health information systems
- Demand promotion & community engagement
- Management & coordination
- Vaccine supply chain – Cold Chain Equipment Platform

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Emerging challenges and opportunities
Emerging disease priorities – addressing the gaps

DISEASES TO BE URGENTLY ADDRESSED UNDER THE R&D BLUEPRINT, AS OF MAY 2016

- Crimean-congo Hemorrhagic fever virus
- Filovirus diseases (i.e. EVD & Marburg)
- Highly pathogenic emerging coronaviruses relevant to humans (MERS Co-V & SARS)
- Lassa fever virus
- Nipah virus
- Rift Valley fever virus
- Novel Agent: a new severe infectious disease

SERIOUS DISEASES NECESSITATING FURTHER ACTION AS SOON AS POSSIBLE, AS OF MAY 2016

- Chikunguya virus
- Severe fever with thrombocytopenia syndrome
- Congenital abnormalities and other neurological complications associated with Zika virus
Epidemic preparedness: launch of CEPI

Richard Hatchett
CEO, Coalition for Epidemic Preparedness Innovations (CEPI)

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.
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

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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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Vaccine candidates will be evaluated and prioritised to enable potential investment decisions in 2018.

### Ranking criteria
- Health impact
- Economic impact
- Equity and social protection impact
- Global health security impact
- Value for money

### Secondary criteria
- Gavi comparative advantage
- Broader health systems benefits
- Implementation feasibility
- Availability of alternate interventions

### Cost
- Vaccine procurement cost
- In-country operational cost
- Additional implementation costs

#### Vaccine analyses during Oct 2017 – Feb 2018

- Likely vaccination strategy
- Uptake in countries
- Target population
- Coverage
- Efficacy
- Impact
- Price
- Etc.

### Funding decisions
- E.g.
  - Financing vaccines for routine immunisation
  - Catalytic (operational) support for introduction
  - Stockpile
  - Learning agenda

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Looking ahead: Gavi’s future vaccine investments to be decided in 2018

Candidate Vaccines

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

**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

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

Planned Preventative Immunisation for Endemic Diseases
- Public Health Risk Reduction
- IPV
- Flu
- AMR

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Increasing volumes, growing number of suppliers, reducing prices: Penta example


Further 50% price reduction expected over 2017-2019

| # Gavi Suppliers | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 4 | 4 | 5 | 4 | 4 | 5 | 6 | 6 | 6 |

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

**Start of YF Gavi support**
Oral cholera vaccine: impact of investment

- Euvichol
- Shanchol

Number of doses used globally (millions)

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

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Aligning vaccine supply with demand: unmet needs

Current supply status (against demand) for WHO recommended antigens and gaps

<table>
<thead>
<tr>
<th>Manufacturers with pre-qualified vaccines at end of 2016</th>
<th>Total</th>
<th>Supply vs. Demand (2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentavalent</td>
<td>8</td>
<td>Supply exceeds demand</td>
</tr>
<tr>
<td>Yellow fever</td>
<td>4</td>
<td>Needs planning</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>2</td>
<td>Limited supply</td>
</tr>
<tr>
<td>PCV</td>
<td>2</td>
<td>Needs planning</td>
</tr>
<tr>
<td>Men. A conj.</td>
<td>1</td>
<td>Supply exceeds demand</td>
</tr>
<tr>
<td>Measles</td>
<td>3</td>
<td>Needs planning</td>
</tr>
<tr>
<td>MR</td>
<td>1</td>
<td>Needs planning</td>
</tr>
<tr>
<td>HPV</td>
<td>2</td>
<td>Limited supply</td>
</tr>
<tr>
<td>IPV</td>
<td>4</td>
<td>Limited supply</td>
</tr>
<tr>
<td>JE</td>
<td>3</td>
<td>Needs planning</td>
</tr>
<tr>
<td>Cholera</td>
<td>3</td>
<td>Limited supply</td>
</tr>
</tbody>
</table>

Source: WHO 2016, UNICEF 2017

Note: The antigens listed are those funded by Gavi. The manufacturers listed represent all prequalified vaccines for each antigen but not necessarily suppliers to Gavi.
Intellectual property regime – impact on innovation

Example: Prevnar

- **Australia**
  - patent granted in 2013

- **Europe**
  - patent granted in 2015
  - grant of patent opposed
  - final decision pending

- **India**
  - patent granted in 2017

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Stagnating global immunisation coverage rates

Children immunised with DTP3 containing vaccine (Gavi68)

- 2010: 59.5M
- 2011: 60.3M
- 2012: 60.6M
- 2013: 62.4M
- 2014: 63.1M
- 2015: 63.9M

DTP3 containing vaccine (Gavi68)

- 2001: 60%
- 2005: 68%
- 2010: 78%
- 2014: 80%
- 2015: 80%
- 2016: 80%

MCV1 (Gavi68)

- 2001: 60%
- 2005: 68%
- 2010: 78%
- 2014: 78%
- 2015: 78%
- 2016: 78%

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Low polio3 coverage a risk to achieving and sustaining eradication

Onset of paralysis: 6 March 2017 – 5 September 2017

Data source: DTP3 WUENIC 2016

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Low polio3 coverage a risk to achieving & sustaining eradication

Onset of paralysis 6 March 2017 – 5 September 2017
Data source: DTP3 WUENIC 2016
Persisting challenge of measles outbreaks

Number of reported measles cases (over a 6 month period)
Based on data received 2017-10 Surveillance data 2017-3 to 2017-8 * Countries with highest cases for the period
(Source: WHO 2017)

<table>
<thead>
<tr>
<th>Country</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>29115</td>
</tr>
<tr>
<td>Pakistan</td>
<td>5849</td>
</tr>
<tr>
<td>Nigeria</td>
<td>5188</td>
</tr>
<tr>
<td>China</td>
<td>4095</td>
</tr>
<tr>
<td>Italy</td>
<td>5704</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>2551</td>
</tr>
<tr>
<td>Romania</td>
<td>1888</td>
</tr>
<tr>
<td>Ukraine</td>
<td>1574</td>
</tr>
<tr>
<td>Malaysia</td>
<td>1347</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1191</td>
</tr>
</tbody>
</table>
Supporting product innovation and new partnerships

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

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Zipline – reaching the last mile in Rwanda
Reaching the fifth child

~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

Number of children globally not receiving the third dose of DTP-containing vaccine, 2016.
Thank you