Report from Gavi, the Vaccine Alliance

Meeting of the Strategic Advisory Group of Experts on immunisation (SAGE)

Dr. Seth Berkley, CEO
17 April 2018, Geneva
Overview

1. Context
2. Looking forward to Gavi’s next strategic period
3. Gavi updates: vaccination programmes
4. Gavi updates: cross-cutting challenges and opportunities
5. Conclusions
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Context
Immunisation is a key component of the 2030 agenda

• One of the most effective global health intervention contributing to other SDGs.

• Best buys in global health and critical for achieving 14 of the 17 SDGs
Improved SDG indicators adopted, but work remaining to ensure it drives performance

**Improved SDG immunisation indicator adopted:**

3.b.1 Proportion of the target population covered by all vaccines included in their national programme

- Includes DTP3, PCV3, MCV2, HPV2 coverage

**UHC indicator adopted:**

3.8.1 Coverage of essential health services

- Immunisation included as a tracer intervention
Immunisation a platform for Universal Health Coverage

Towards universal health coverage

14% Build out system to reach the remainder

86% Children reached through routine immunisation worldwide

Routine Immunisation

Primary Health Care

Secondary

Tertiary
Gavi has started process to define 2021-2025 strategy

**How does Gavi finish the job?**
18 of 1,000 children will be dying of vaccine-preventable diseases in 2020; at current pace U5 mortality SDG target will be missed

**How can Gavi’s tools contribute to global health security?**
Controlling for confounding variables, number of outbreaks has grown steadily from 1980 to 2010, over 3-fold increase

**To what extent should Gavi engage in reaching the unreached in MICs?**
More than two-thirds of world’s poor live in MICs today; more than half of underimmunised in MICs in 2025

**How can the Gavi / immunisation platform be used to accelerate the scale-up of other health interventions?**
Immunisation: 8 touchpoints per child in first 9 years of life, 500m touchpoints each year worldwide
More than half of under-immunised children (DTP3) will be in MICs in 2025

- **2016:**
  - HIC: 74%
  - Never eligible MICs: 16%
  - Former Gavi-eligible MICs: 7%

- **2025 forecasts:**
  - HIC: 45%
  - Never eligible MICs: 40%
  - Former Gavi-eligible MICs: 3%
  - Gavi-eligible: 12%

More than doubles in 10 years
Looking forward to Gavi’s next strategic period
Gavi has supported >380 vaccine introductions and campaigns

Year of first introduction/use of stockpile
Significant gains made in increasing access to immunisation

Based on Gavi 68 countries.
Source: WUENIC and UNWPP estimates
However, opportunity for substantial improvement in many countries
Plateaued coverage in fragile countries, which contain half of under-immunised

<table>
<thead>
<tr>
<th>Year</th>
<th>50 NON-FRAGILE countries</th>
<th>18 FRAGILE countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>83%</td>
<td>63%</td>
</tr>
<tr>
<td>2014</td>
<td>84%</td>
<td>66%</td>
</tr>
<tr>
<td>2015</td>
<td>85%</td>
<td>65%</td>
</tr>
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<td>2016</td>
<td>86%</td>
<td>65%</td>
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</tbody>
</table>

The list of 18 fragile countries includes Afghanistan, Burundi, CAR, Chad, Congo, DRC, Eritrea, Ethiopia, Haiti, Mali, Nigeria, Papua New Guinea, Solomon Islands, Somalia, South Sudan, Sudan, Yemen & Zimbabwe.

Data Source: WUNIC estimates
Sub-national data allows Alliance to engage with countries on targeted plans to improve coverage

**Ethiopia** – 2016 penta3 coverage

- In-country, multi-stakeholder Joint Appraisal discussions
- Sub-national data allows for identification of targeted strategies
- Critical that this level of granular data becomes standard for planning and implementation

Data Source: JRF 2017
The number of displaced has risen significantly, reaching 64 million people in 2015.

- Lack of data
- Lack of medical supplies & medical staff
- Increased risk of outbreaks in poor living conditions
- Lack of infrastructure (living in camps)
- Stigma / fear within displaced
- Constant inflow and outflow of people

CHALLENGES TO REACH THE DISPLACED:

NUMBER OF DISPLACED PEOPLE (millions)

<table>
<thead>
<tr>
<th>Year</th>
<th>Other</th>
<th>Internally displaced persons (IDPs)</th>
<th>Refugees and asylum seekers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>22</td>
<td>20</td>
<td>17</td>
</tr>
<tr>
<td>2005</td>
<td>21</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>2010</td>
<td>34</td>
<td>36</td>
<td>36</td>
</tr>
<tr>
<td>2015</td>
<td>55</td>
<td>43</td>
<td>64</td>
</tr>
</tbody>
</table>

+192% increase from 2000 to 2015.
Increasing focus on ensuring refugees receive life-saving vaccines

**REFUGEES IN BANGLADESH**

Over **600,000** refugees from **Myanmar**

**Flexibilities offered to refugees include:**
- Additional vaccine support (Cholera, Penta, PCV, MR, fIPV injections)
- Additional operational support

**REFUGEES IN UGANDA**

Over **1 million** refugees from **South Sudan**

**Flexibilities offered to refugees include:**
- Additional vaccine support (Penta, PCV, Rota, IPV, HPV, MSD, injections)
Country transition from Gavi support of growing importance: 8 additional countries in past year

2016
- Bhutan
- Honduras
- Mongolia
- Sri Lanka

2017
- Guyana
- Indonesia
- Kiribati
- Moldova

2018
- Angola
- Armenia
- Azerbaijan
- Bolivia
- Congo Rep.
- Cuba
- Georgia
- Timor-Leste

Countries currently transitioning from Gavi support (9):
- India
- Lao PDR
- Nicaragua
- Nigeria
- Papua New Guinea (PNG)
- São Tomé
- Solomon Islands
- Uzbekistan
- Vietnam

November 2017: Gavi Board approves continued Alliance engagement with transitioned countries and targeted support under PEF

Note: excludes Ukraine
Countries can now apply for new vaccine introduction during transition from Gavi support

- In November 2017 Gavi Board approved the extension of the grace period for new vaccine introduction during the accelerated transition phase from one year to the full five years

- These transitioning countries have an opportunity to apply for the following new vaccine support (NVS):

<table>
<thead>
<tr>
<th>Country</th>
<th>Current portfolio</th>
<th>Applied (not introduced)</th>
<th>Potential new vaccines introductions</th>
<th>Opportunity to apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lao PDR</td>
<td>Penta, PCV, MR, JE</td>
<td>Rota, HPV</td>
<td>Typhoid</td>
<td>2018 -2021</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>Penta, PCV, Rota, YF</td>
<td>HPV, Typhoid</td>
<td></td>
<td>2018-2020</td>
</tr>
<tr>
<td>São Tomé</td>
<td>MR, Rota, YF, Penta, PCV</td>
<td>HPV, Typhoid</td>
<td></td>
<td>2018-2022</td>
</tr>
<tr>
<td>Solomon Isl</td>
<td>PCV, Penta, MR,</td>
<td>Rota, HPV</td>
<td>JE, Typhoid</td>
<td>2018 -2021</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>PCV, Penta, Rota</td>
<td>HPV</td>
<td>Typhoid</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Penta, MR</td>
<td>HPV, PCV, Rota, Typhoid</td>
<td></td>
<td>2018-2019</td>
</tr>
</tbody>
</table>
Gavi Board to take decisions at upcoming meeting on transition / post-transition support

Transitioning Nigeria from Gavi support

- Potential Gavi support for achievement of coverage & equity targets and new vaccine introductions

Engagement with countries post-transition

- Angola
- Congo Republic
- Timor-Leste
Vaccine Investment Strategy (VIS) ongoing – one approach to continue delivering health impact

1. WHO landscape analysis
2. VIS candidate list
3. Evaluation framework
4. Vaccine analyses
5. Prioritisation methodology
6. Shortlist options

VIS decision-making timelines:
- Nov 2017 – Methodology
- Jun 2018 – Prioritised shortlist
- Nov 2018 – Investment decisions
VIS: candidate vaccines span delivery timepoints and present integration opportunities

- **Pregnancy**
  - RSV
  - Maternal influenza

- **Birth**
  - Hepatitis B birth dose
  - RSV mAb

- **1st year of life**
  - Multivalent Meningitis
  - IPV

- **2nd year of life**
  - Multivalent Meningitis
  - Hepatitis A
  - DTP booster

- **School-age**
  - Dengue
  - DTP booster

- **Adolescent**
  - Dengue
  - DTP booster

**Other**

- Rabies – PEP, RIG
- Cholera (preventive)
- Pandemic flu

**Based on analysis 6, candidates for potential shortlisting:**
- HepB birth dose
- Cholera (preventive)
- Multivalent meningitis
- DTP boosters
- RSV
- Rabies PEP

VIS also considering pandemic flu and IPV
VIS: Antimicrobial resistance (AMR) amongst new lenses by which vaccines are being assessed

VIS evaluation results – expert input (0= low vaccine impact on AMR; 10=high vaccine impact on AMR)

- PCV: 6.8
- Typhoid: 6.7
- Malaria (RTS,S): 6.2
- Pentavalent: 4.8
- Men ACWY/ACWXY: 4.3
- Cholera: 4.1
- Men A: 3.9
- Influenza: 3.9
- DTP: 2.9
- RSV mAb: 2.8
- RSV Vaccine: 2.6
- Measles & Rubella: 2.4
- Measles: 2.4
- Rotavirus: 2.1
- Dengue: 1.7
- Hep B birth dose: 1.6
- Japanese Encephalitis: 1.5
- Yellow Fever: 1.3
- Rabies vaccine: 1.1
- HPV: 1.1
- Hepatitis A: 1.1
- Rabies IG: 1.1

Impact on AMR assessed across multiple dimensions:
- Mortality and morbidity impact
- Societal impact
- Addressing inequity
- Antibiotic use prevented
- Urgency related to AMR threat (e.g. reduction in available treatment options)

Source: Expert consultations
1. Is the epidemic potential sufficient to prioritise a stockpile or similar investment?

2. Would the vaccine be feasible to use and impactful?

3. What is Gavi’s comparative advantage and potential contribution to the funding and delivery of this vaccine?

4. What is the appropriate scale of the stockpile (or related intervention) and the financial implications?

VIS: Gavi also assessing vaccine investments for epidemic preparedness and response

While routine immunisation investments evaluated every 5 years, epidemic investments will be considered on continual basis.
VIS: Gavi specifically exploring options to support pandemic flu preparedness

Focus area for potential Gavi investments in 2018 based on feedback

(Beyond vaccine investments, potential role for Gavi to work with countries to ensure preparedness plans in place)
VIS: Gavi considering its support for IPV post-2020

Gavi’s involvement in polio centred on IPV introduction but also,

- Increased engagement and discussion at joint assessments on polio legacy issues

In VIS, considering continued IPV support after 2020, potentially not fully financing vaccine for all countries

And considering,

- POB request to support IPV for the period 2019-20
- Expanded role in broader polio activities including the Post-Certification Strategy, for example stockpiles of polio vaccines
Gavi updates: vaccination programmes
Measles and Rubella: control or elimination

Among Gavi 73, only 14 countries have been certified “measles eliminated”

MCV1 in Gavi 73 was still 78% in 2016, no change from 2015

- MCV1 coverage in Gavi countries ranged from 22%-99%
- 60% of surviving infants in Gavi73 living in countries with MCV1 <80% (excl. India and Indonesia)

Cycle of low routine coverage, repeated campaigns & below-target campaign coverages remain

- Eg. Chad and Nigeria in every 2 year cycle, with campaign coverages <90% and MCV1 coverages <60%

MTR of Global MR strategic plan 2012-2020 recommended improving ongoing immunisation systems, to ensure gains in measles control are sustained
Improving the quality of SIAs remains a critical challenge

- 12 campaigns conducted in 2017, with Gavi support
- 0/5 with coverage survey reached 95%
Multiple and frequent campaigns have broader negative implications

**Negative effects:**

- Divert resources away from RI
- More frequent AEFIs with more kids vaccinated, eroding vaccine confidence
- Perverse incentives: vicious cycle of campaigns and **fiduciary risk**
- Overall impact: reputational risk and inability to achieve immunisation goals

**Nigeria case study:**

- 2015-2016: 37 rounds of subnational/national campaigns (2 measles, 35 polio*)
- DTP3 coverage <50% (WUENIC) and at 33% according to latest National Indicator Cluster Survey study
- In 2015-2016 OPV coverage remained at <50%, increased from 30% to 49% (WUENIC)
- MCV1 <55% (WUENIC) since 2011

* Nigeria is one of the last countries undergoing extensive polio eradication efforts
Progress on implementing Yellow Fever EYE Strategy, but significant ways to go

What have we achieved?

- African Regional Committee endorsement (Aug 2017) and EYE Strategy kick-off last week in Nigeria
- Continuation of Nigeria’s 2nd phase mass preventive campaign (January 2018), 3rd phase planning underway
- DRC approved Gavi application for national mass preventive campaign
- Coordinated outbreak responses (Brazil and Nigeria) underway

Continued challenges

- Surveillance and diagnostics to inform timely response measures
- 4 High Risk countries pending routine YF vaccination introduction (Ethiopia, Sudan, South Sudan, Uganda)
- Coordination and management of global vaccine supply and country planning
- Risk-based planning and prioritisation (particularly sub-national)
- Is EYE governance structure functioning optimally?
Between 2005-17, dominant meningitis serotype in Africa's 'meningitis belt' has changed

Note: Disease burden is strongly underestimated. Only 3-19% of suspected cases are confirmed and serotype identified.


With anticipated growing availability of multivalent conjugate meningitis vaccines, Gavi reconsidering investment

Current status of meningitis programme

- Of the 26 'meningitis belt' countries, 7 have introduced MenAfriVac in routine with Gavi support, 15 are forecasted to do so by 2019, and 4 have not yet defined plans for introduction
- Support for emergency vaccine stockpile – polysaccharide vaccines low cost, but increasingly unavailable; turning to higher priced multivalent conjugates
- WHO projects increased risk of meningitis epidemics due to hyper invasive NmC strains in the coming years

Considerations for VIS

- Multivalent conjugate vaccines in routine vaccination alongside a mass campaign in 'meningitis belt’ countries, or subset with highest risk of endemic or epidemic disease
Significant cholera outbreak affecting 11 Gavi-support countries

Active cholera outbreaks as of March 2018

*Note: DRC, Nigeria, Mozambique and Tanzania have used OCV to respond to outbreaks in the past*
OCV demand is matching supply increases, VIS is evaluating long term support for preventive use

- Ending Cholera Roadmap promotes a multi-sectoral approach and increasing use of vaccine
- Gavi’s investment in OCV for preventive settings is being evaluated in VIS 2018

**OCV shipped and approved, as of March 2018**

- Shanchol PQ
- Euvichol PQ
- GTFCC revitalised
- Creation of stockpile / Gavi’s investment

**Approved**

**Shipped**
Funding for typhoid conjugate vaccine approved Dec 2017, applications being accepted

**Single dose routine**
- Co-financed
- Vaccine introduction grant
- Gavi recommends to link to MCV1 or MCV2

**One time single dose catch-up**
- Fully financed by Gavi
- Operational cost support
- Up to 15 years
A number of key questions regarding typhoid vaccination still to be addressed

Current strategy for rolling out typhoid vaccine still unclear:

• What type of data will countries need to make informed decisions about introduction?

• How do countries choose the most appropriate vaccination strategy (e.g., subnational) in light of poor diagnostics, heterogeneity of disease, population movement?

• What is the impact of vaccination on the disease and anti-microbial resistance?
As licensure of Merck Ebola vaccine nears, Gavi is readying for funding an emergency stockpile

<table>
<thead>
<tr>
<th>Year</th>
<th>Licensure</th>
<th>Gavi’s engagement</th>
<th>Vaccination strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>Commitment to fund future stockpile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>300K doses of investigational vaccine available</td>
<td>300K doses of investigational vaccine available</td>
<td>Outbreak response / reactive use</td>
</tr>
<tr>
<td>2019</td>
<td>Funding of a global stockpile</td>
<td></td>
<td>Ring vaccination for contacts and contacts of contacts, and HC and FL workers</td>
</tr>
<tr>
<td>2020</td>
<td>Merck’s vaccine licensed for reactive use and at-risk &gt;18 y old populations</td>
<td>Merck’s vaccine PQ’d</td>
<td>?</td>
</tr>
<tr>
<td>2021+</td>
<td>“2nd generation” vaccine licensed?</td>
<td>Preparing to fund?</td>
<td>?</td>
</tr>
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Preventive use?
Malaria pilots a historic partnership between health financing institutions

Pilot introduction of the RTS,S/AS01 malaria vaccine recommended by SAGE/MPAC to answer key questions on:

- Operational feasibility of administering 4 vaccine doses
- Impact on severe malaria and mortality and gender-specific impact
- Safety profile

Historic partnership between Gavi, Global Fund, Unitaid – bringing together biggest health financing institutions to tackle one of the leading killers of children.

--Gavi following debate on triggers for SAGE/MPAC recommendation for broader roll out of vaccine

--Pilots help Gavi on programme design, need for introduction grants, technical support required to countries
Gavi updates: cross-cutting challenges and opportunities
Work has commenced to define an Alliance vaccine product innovation strategy

Vaccine Innovation Prioritisation Strategy (VIPS) – An Alliance wide effort to drive product innovation to better meet country needs and support Alliance goals on immunisation coverage and equity

Outcome: Alliance common voice through a clear and aligned perspective on prioritisation of vaccine innovations to provide greater clarity to manufacturers and partners to make investment decisions

<table>
<thead>
<tr>
<th>Preparatory phase</th>
<th>Phase 1</th>
<th>Phase 2</th>
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<tbody>
<tr>
<td>2018</td>
<td></td>
<td>2019</td>
</tr>
</tbody>
</table>

- Innovation landscape analysis and consultations with partners and countries
- Analyses of antigen-agnostic innovations
- Analyses of antigen/vaccine-specific innovations
- Short list of ‘antigen-agnostic’ innovations
- Final ‘antigen-specific’ prioritisation decisions

The Alliance will leverage the SAGE community and its expertise
Gavi considering new investment in strengthening yellow fever surveillance and laboratory capacity
Current overview of Gavi Support for Innovations in Digital Health

**Haiti:** Dalberg support for managerial use of data

**Cote d’Ivoire:** SMS reminders to reduce dropouts

**Bolivia:** Linking EVR to birth registries

**DRC:** ACASUS App for managerial use of data

**Ghana:** Smart paper technology using Shifo tool

**Nigeria:** SMS reporting linked to DHIS2

**Ethiopia:** Electronic Community Health Information System developed by JSI

**Kenya:** Linking EVR to birth registries

**Pakistan:** Electronic Child Tracking through Zindagi Mehtooz

**India:** Use of ANMOL app for data management

**Indonesia:** Phone-based campaign monitoring through Rapid-Pro

**Tanzania:** Nexleaf temperature monitoring

**Mozambique:** SELV initiative to link Nexleaf data to other information systems

**Madagascar:** AVADAR use of tablets for surveillance data

**Ethiopia:** Electronic Community Health Information System developed by JSI

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**Madagascar:** AVADAR use of tablets for surveillance data
Gavi supporting political will building towards driving improvements in coverage and equity

Strategic Focus Areas (SFAs)

- Supply chain
- Leadership, Management & Coordination
- Data
- Demand Generation
- Sustainability
- Political Will

- Recently rolled out
- Theory of change developed, focus countries identified
Conclusions
Questions for SAGE with significant implications on Gavi’s work

• **Coverage and equity:** How can improvements be accelerated in non-fragile countries & what approaches are needed for fragile countries?

• **Measles:** How to provide guidance to countries on what to focus on, based on their position on control-elimination continuum?

• **Yellow fever:** How to strengthen routine immunisation to coverage levels that would prevent epidemics?

• **Ebola:** What volume of vaccine is required for stockpiling and preventive use?

• **Pandemic flu:** VIS exploring potential support for seasonal immunisation in high risk groups & reserving supply capacity. What other opportunities should Gavi explore?
Looking ahead: mid-term review and 3rd replenishment

2016-2020 promise to donors

2nd REPLENISHMENT
BERLIN 2015
Secured funding for 2016-2020
Investment Opportunity

MID-TERM REVIEW
TBD 2018
Report back on progress made against 2016-2020 ‘promise’
Lay groundwork for next replenishment

3rd REPLENISHMENT
TBD 2020
Secure funding for 2021-2025
THANK YOU