Report from Gavi

Seth Berkley, CEO
Meeting of the Strategic Advisory Group of Experts on Immunization
April 2016
Why SAGE matters to Gavi

• Gavi relies on SAGE technical guidance for decision-making
  • Gavi Board decisions follow SAGE guidance
  • SAGE Chair is a non-voting member of Gavi Policy & Programme Committee

• A number of upcoming Board decisions contingent on SAGE recommendations
Vaccines in the global context

- Midpoint of Decade of Vaccines
- More kids immunised than ever
- 86% coverage by DPT3 containing vaccine (81% Gavi countries)
- 70 introductions 2015
- New Gavi Strategic Period 2016-2020
- One year on from replenishment
- Vaccines and Global Health Security
Immunisation: a platform for universal health coverage

- Tertiary care
- Secondary care
- Primary care
- Immunisation (fixed site and outreach)
AGENDA 2030: monitoring framework – a missed opportunity

3.8.1 Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population)

The Board was shocked to learn that perhaps the single most relevant indicator in the health sector, immunisation coverage, is not currently being considered as an individual item in the SDG monitoring framework.

Based on the Global Vaccine Action Plan:

“Reach and sustain 90% national coverage and 80% in every district with all vaccines in national programmes”
RETURN ON INVESTMENT

Income growth + Value of life years gained in that period = Change in country’s full income over time period

44x (full income)

16x (cost of illness)

Public infrastructure
The Economic Benefits of Public Infrastructure Spending in Canada. The Centre for Spatial Economics, September 2015

Pre-school education
The rate of return to the HighScope Perry Preschool Program. Department of Economics, University of Chicago, April 2009

Community health workers

Immunisation
Board Chair: Ngozi Okonjo-Iweala
TAKING ACTION

1. Prioritise investment in immunisation
2. Ensure vaccine line-item in health budgets
3. Focus on equity by investing in health to fully immunise every child
4. Act now to achieve the 2030 SDG’s and be on track for Agenda 2063
5. Become an immunisation champion
Recent studies underway on vaccine impact

- Over 20 studies
- Across Sub-Saharan Africa and Asia
- Supporting impact assessment of pneumococcal conjugate and rotavirus vaccines in a variety of settings
- Supporting cholera and rabies studies through VIS learning agenda
PCV, The Gambia: The impact of the vaccines on severe pneumococcal pneumonia, sepsis, and meningitis

Pneumococcal conjugate vaccine impact study

Pneumococcal disease surveillance with

14,650 patients

PCV in The Gambia reduced severe pneumococcal pneumonia, sepsis and meningitis in children by 55%

"If children in The Gambia develop serious pneumococcal pneumonia, sepsis or meningitis they have a 1 in 7 chance of dying"

PCV, The Gambia: Vaccine-type invasive pneumococcal disease incidence in children under 2, the Gambia

Before and after pneumococcal vaccine introduction (PCV13)


Note - other age groups available: 2-4 years, 5-14 years, >15 years; also: PCV7 type only, PCV 13 type only, NVT, and all-type. Data here (PCV13 type, under 2) show highest impact.
Rotavirus, Rwanda: Hospital admissions for diarrhoea before and after rotavirus vaccine introduction, Rwanda

Gavi programme update
Key Board decisions – December 2015

- Gavi’s Measles and Rubella strategy
- Alliance Partnership Strategy with India, 2016-2021
- Partners’ Engagement Framework
- Data strategic focus area
Measles immunisation coverage has stagnated

- MCV1 coverage also flat globally since 2010
- MCV2 38% in Gavi 73

Measles and rubella: Enhanced engagement (up to $800M for 2016-20)

<table>
<thead>
<tr>
<th>Current Gavi support</th>
<th>Proposed changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Measles 2nd dose for 5 years</td>
<td>Routine Measles 2nd dose and MR as normal co-financed vaccines</td>
</tr>
<tr>
<td>Measles SIAs in 6 high risk countries for under-5s</td>
<td>Extend support to all Gavi countries that need measles SIA before introducing MR</td>
</tr>
<tr>
<td>MR campaigns for under-15s before routine introduction</td>
<td>Support follow-up campaigns where required</td>
</tr>
<tr>
<td>Outbreak response fund to MRI until 2017</td>
<td>Consider supporting outbreak response beyond 2017</td>
</tr>
</tbody>
</table>

Key conditions of Gavi support:
- Countries develop 5-year M and R plan as part of national RI plan
- Countries finance routine first dose of measles vaccine or equivalent
- Better use of data and independent monitoring to target and strengthen SIAs

NOTE: Gavi already projected to invest ~US $600M in measles and rubella 2016-20
India strategy: Approved up to $500 million in investments

Indicative vaccine/cash allocation

<table>
<thead>
<tr>
<th>Vaccines support</th>
<th>Scope of support</th>
<th>Number of children immunised (million)</th>
<th>Cost estimates ($ million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rota</td>
<td>20% cohort for 3 years</td>
<td>15</td>
<td>~$80</td>
</tr>
<tr>
<td>Pneumo</td>
<td>20% cohort for 3 years</td>
<td>15</td>
<td>~$180</td>
</tr>
<tr>
<td>MR (campaign)</td>
<td>2 out of 4 phases</td>
<td>170</td>
<td>~$110</td>
</tr>
<tr>
<td>HPV*</td>
<td>~15% cohort for 1 year</td>
<td>2</td>
<td>~$30</td>
</tr>
<tr>
<td>Cash support</td>
<td></td>
<td></td>
<td>~$100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>$500</td>
</tr>
</tbody>
</table>

Health impact: Additional ~440,000-860,000 future deaths averted

* Subject to NTAGI recommendation and Government approval for new vaccine introduction
Country focus: A bottom-up approach

1. Understanding country needs
   - 72 in-country Joint Appraisals (JAs) in 2015
   - Articulation of key barriers and needs

2. Responding to country needs
   - Proposals from UNICEF/WHO seek to respond to JAs
   - Initial submissions include ~200 ‘boots on the ground’

3. Countries at the design table
   - Improved harmonisation
   - Greater transparency
   - Enhanced accountability
Data strategy: What the Alliance aims to achieve by 2020

Focus areas

- Immunisation Delivery, Coverage & Equity (DCE)
- VPD surveillance
- Vaccine safety

Goals for 2020

- Measurable improvements in availability, quality, use and transparency of data to improve immunisation coverage and equity
- Quality and timely data on VPD to strengthen programme management, inform decisions and provide evidence for measurement of impact and risk
- Ability to identify and investigate signals of severe AEFI, respond efficiently and effectively and address public concerns on safety
Punjab, Pakistan: Using data for accountability and results

A province-wide third-party survey has confirmed the progress

Antigen coverage (children aged 12 months)

<table>
<thead>
<tr>
<th>Antigen</th>
<th>December 2014</th>
<th>December 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPV 0</td>
<td>92</td>
<td>95</td>
</tr>
<tr>
<td>BCG</td>
<td>89</td>
<td>87</td>
</tr>
<tr>
<td>OPV 1</td>
<td>97</td>
<td>96</td>
</tr>
<tr>
<td>Penta 1</td>
<td>86</td>
<td>84</td>
</tr>
<tr>
<td>Pneumo 1</td>
<td>96</td>
<td>96</td>
</tr>
<tr>
<td>OPV 2</td>
<td>96</td>
<td>93</td>
</tr>
<tr>
<td>Penta 2</td>
<td>92</td>
<td>92</td>
</tr>
<tr>
<td>Pneumo 2</td>
<td>92</td>
<td>92</td>
</tr>
<tr>
<td>OPV 3</td>
<td>87</td>
<td>68</td>
</tr>
<tr>
<td>Penta 3</td>
<td>86</td>
<td>64</td>
</tr>
<tr>
<td>Pneumo 3</td>
<td>86</td>
<td>63</td>
</tr>
<tr>
<td>Measles 1</td>
<td>70</td>
<td>48</td>
</tr>
</tbody>
</table>

NOTE: Based on record and recall reporting of immunizations received in children aged 49-52 weeks within the larger Nielsen sample of children aged 0-12 months.


Penta3 and MCV1 increased >20 percentage points in one year
Key issues on Gavi agenda
Gavi’s engagement in Ebola

- Gavi and Merck announced advanced purchase commitent (APC) for Ebola vaccines
- Gavi prepayment of US$5M for future procurement of licensed Ebola vaccine
- In return, Merck committed to:
  - Have EUAL application accepted by WHO by December 2015
  - Make available 300,000 investigational doses by May 2016
  - Submit for licensure by December 2017
- Other manufacturers declined APC, but engagement continuing
Angola yellow fever outbreak a reminder of potential epidemic threat
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
Outbreak response and preparedness: Strategic questions cover 4 potential areas of engagement

<table>
<thead>
<tr>
<th></th>
<th>Stockpile Investments</th>
<th>To what extent should Gavi develop a more comprehensive and engaged strategy with regard to Gavi-supported vaccine stockpiles used in outbreak response?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Existing Vaccines/Flu</td>
<td>What role, if any, should Gavi have in preparedness and response for outbreak diseases where there exists vaccines which Gavi currently does not support such as pandemic influenza?</td>
</tr>
<tr>
<td>3</td>
<td>Vaccines in Development</td>
<td>For vaccines in development for emerging infectious diseases, what role, if any, should Gavi have?</td>
</tr>
<tr>
<td>4</td>
<td>Country Capacity</td>
<td>To what extent should Gavi take a more deliberate approach to support countries to strengthen core capacities to prevent, detect and respond to disease outbreaks?</td>
</tr>
</tbody>
</table>
Gavi HSS and other Direct Financial Support critical for improving immunization coverage and equity

Example: Alliance support to Burkina Faso in 2014

Vaccine Support ($30M)
- Penta
- Pneumo
- Rota
- Measles
- MR campaign

Direct Financial Support ($9M)
- Health system strengthening ($2 M)
- Vaccine introduction grant for measles ($0.6 M)
- Operational support for Measles-Rubella campaign ($5 M)

Technical Assistance
- WHO
- UNICEF
- Catholic Relief Services
Shaping vaccine markets is a key responsibility for the Alliance

Objectives:
- Supply security
- Sustainable price
- Innovation

Ambitious new market shaping goals for 2016-2020
- 13 vaccine markets in scope and suggestion that Gavi should seek to shape all markets where it funds procurement (including stockpiles)
- Achieve ‘healthy market dynamics’ in 5 markets

Review of Supply and Procurement Strategy: Gavi Board decisions in June
- Healthy markets: balance trade-offs between supply/price/innovation, tailored risk tolerance for stockpile procurement
- Longer term view: monitor externalities, support country transition
- Innovation for equity: vaccines an cold chain equipment
HPV new way forward: shift to single pathway

Mandatory Pre-application workshop:
• Reduce risk of delivery approach discrepancy btw Demo and National – Learn to scale-up
• EPI ownership, utilization of existing infrastructure
Issues on the SAGE agenda
71 IPV introductions: Jan.15 vs Mar.16 plans

Objective set by Board in Nov 2013

Status Mar 16: 45 introductions

Interruptions likely in countries which have introduced

Jan-15  Mar-16
Gavi’s support for IPV approved post-2018 contingent on additional funding

- Gavi committed to support IPV through 2018 when Board will review

- Board approval was dependent on resources provided by GPEI and their donors

- Extension of Endgame to 2019 raises questions of how IPV will be supported post-2018

- SAGE recommendation on IPV across different scenarios and timelines, and possible revised IPV dose schedule, will facilitate global planning
# Gavi’s engagement in polio legacy

**Approach approved by Gavi Board**

- Country-driven, country-specific approach
- Resources integrated in national programmes
- No resources/mandate to take over partners’ full human resources/assets
- Focus on equitable and sustainable immunisation coverage
- Health system strengthening and Partners’ Engagement Framework are key instruments for support
New vaccines for Gavi investment

Malaria, dengue, RSV...

The Vaccine Investment Strategy (VIS) defines evidence-based new vaccine priorities for Gavi support

- Evidence review, analyses, stakeholder consultations, independent expert advice
- Once every five years, aligned with strategic cycle
Malaria vaccine (RTS,S)

Shortlisted in 2013 VIS
- Board requested final review after trials and WHO recommendation

Dec 2015: Board update on WHO pilot recommendations
- concerns around potential Gavi role in implementation research (safety, fit with mandate, timing)

May 2016: PPC review of WHO request for pilot funding
- exploring Gavi – UNITAID – Global Fund cost-sharing though not in budget
- WHO leading (sovereign) donor initial outreach
- outstanding questions on budget and technical validation of pilot approach
Dengue assessment 2013

Considered in 2013 VIS alongside 14 other vaccines

Reasons for low ranking

• At the time, significant uncertainty about efficacy of lead candidate, timing and availability of an effective vaccine
• Lack of burden data from Gavi countries and uncertain demand
• Relatively high expected cost and relatively low health impact compared with other vaccines
VIS 2018

Criteria to be developed with stakeholders

- Normally direct health impact. Other potential criteria: equity impact, implementation feasibility, cost, outbreak preparedness, maternal immunisation, 2nd year of life platform

Vaccines likely in scope for consideration

- **For re-assessment**: dengue, Oral Cholera Vaccine, (maternal) influenza, rabies PEP, meningococcal multivalent, Hepatitis E, DTP booster, Hepatitis B birth dose, Typhoid conjugate
- **New**: RSV, Group B Streptococcus, norovirus, …?

Process starts mid 2017
Many vaccines supported by Gavi given in "second year of life" immunisation platform

1. Potential to raise coverage of vaccines given at the same time
2. Important to keep this in mind in preparation for introduction and for sustainably increasing coverage

- **Birth**
  - 1 visit (BCG, OPV, hepB)

- **Infants** 6/10/14 weeks
  - 3+ visits
  - Penta, PCV, RV, IPV-OPV

- **Adolescents** 9–13 years
  - 2+ visits (HPV)

- **Not supported by Gavi**

- **Pregnant women**
  - 1 visit (TT, flu)

- **Toddlers** 9 months–2 years
  - 2+ visits
  - MCV1, MCV2, Men A, YF, JE
  - PCV 2+1 (booster 9 months)
  - PCV catchup (2 doses 12-24 months)
  - RTS,S
Immunisation ever higher on the political agenda
# vaccineswork

THANK YOU

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