Report from Gavi, the Vaccine Alliance

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

Dr. Seth Berkley, CEO
2 April 2019, Geneva
Strategic updates
### New and expanded vaccine programmes conditionally approved + learning agenda for flu

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<tr>
<th>Endemic</th>
<th>D, T &amp; P-containing boosters</th>
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<tr>
<td></td>
<td>Hepatitis B birth dose</td>
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<td>Oral cholera vaccine (planned immunisation)</td>
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<td>Rabies vaccine post-exposure prophylaxis</td>
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<td>Multivalent meningococcal vaccine (<em>in principle</em>)</td>
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<td>Respiratory syncytial virus vaccine and monoclonal antibodies (<em>in principle</em>)</td>
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<td>Polio</td>
<td>Inactivated poliovirus vaccine</td>
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<td>wP-containing hexavalent (<em>in principle</em>)</td>
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<td>Epidemic</td>
<td>Learning agenda for influenza vaccination in health care workers for pandemic preparedness</td>
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- How to ensure implementability of global strategies for non-infant vaccination?
- How to support national prioritisation of vaccine introductions?
Support to reduce bottlenecks in yellow fever diagnostics approved

Reliable YF diagnostic capacity can increase early and specific detection to target vaccination

**Problem**

- Validated, standardised YF tests not available
- Frequent stockouts of critical reagents
- Limited QA/QC and proficiency testing
- Insufficient training and communication

**Gavi approach**

- Diagnostics market shaping and procurement mechanism
- Laboratory capacity strengthening
Board retreat on Gavi 5.0: Alliance to contribute to the SDG vision of leaving no one behind

Vaccine introductions
- All 18 vaccines available for all countries (incl. VIS vaccines)
- Ambitious yet flexible introduction agenda with countries prioritising vaccines (depending on local context and disease burden)

Reach the underimmunised
- Equity as organising principle
- High ambition in reducing number of under-immunised
- Differentiation of support model across country contexts

Financial and programmatic sustainability
- Transition model to include aspects of programmatic readiness
- Continued engagement in former Gavi MICs

Healthy markets & innovation
- Market shaping remains core comparative advantage
- More balanced view of healthy markets
- More deliberate approach to take innovation to scale
Transitioning from 4.0 to 5.0: Continue the agenda of reducing the number of underimmunised

- Number of under-immunised nearly halved despite growing birth cohort
- Progress slowing in recent years, especially in fragile countries where coverage has been stagnant since 2012
Key challenges for Gavi
Coverage and equity:
What do we need to accelerate progress?

- Definitions
- Data
- Demand
How do we define the underimmunised?

Of the underimmunised, some receive only DTP1, some receive vaccines other than DTP, and some receive **zero doses**

**Definition:** DTP or other vaccines? No routine or no vaccination at all?

**Drivers:** no services available? Services available but not utilised?

**Source:** WUENIC July 2018 release for DTP1 & DTP3; Gavi preliminary projections of zero-dose in Gavi68 countries based on modeling WUENIC coverage indicators and DHS measurements of zero-dose.
Who and where are the underimmunised?
How do we find and reach the underimmunised?

Broader systems strengthening: EPI data into DHIS2

Linking with innovations
Innovative data solutions to track mobile populations using satellite imagery and GIS providing information at granular levels
Growing recognition of the risk of insufficient demand to achieve high coverage

Individual choice also plays a role in increasing uptake of vaccines

Vaccine HESITANCY
Accept some, delay some, refuse some

Vaccine REFUSAL
Refuse all vaccines

Active DEMAND
Pro-actively seek immunisation

Passive ACCEPTANCE
Agree to have children immunised

Source: WHO Strategic Advisory Group of Experts on Immunisation Working Group on Vaccine Hesitancy
Designing for impact: How do we ensure timely and implementable policies for effective programming?

✓ Typhoid
✓ Gavi-supported stockpiles
✓ Ebola
✓ Influenza

Pictures: Labmedica.com; The Native Antigen Company; Randwater.co.za; Medical News Today
Typhoid conjugate vaccine: Translating global policy to country context

Initial learnings

- **Use for outbreak response**
  - Preliminary data: ~85% coverage; higher in school-age children
- **Applications for Gavi support**
  - Blood-culture-confirmed burden data limited
  - Countries need support to assess burden and develop applications

Key programmatic questions

- How to monitor impact where surveillance using blood culture is limited?
- Appropriate vaccination strategy for countries (i.e. sub-national vs. national) where no robust surveillance data?
Increasing use of vaccines for outbreaks and emergencies

Use of Gavi-supported stockpiles over time

Need for stronger systematic approaches to predict and prevent outbreaks and long-range forecasting for optimal use of stockpiles
Ebola vaccines: considerations for a long-term strategy

Investment case for a long-term Ebola strategy to Gavi Board:
- What size of global stockpile should Gavi fund, for what vaccination strategy?
- How might recommendations for preventive vaccination evolve?
- Will other vaccines be licensed and what could be their role in preparedness and response?

Gavi is working with WHO, including engagement with the SAGE Ebola WG
How could the influenza learning agenda inform future programmes to protect HCWs in epidemics e.g. Ebola?

Areas indicated for further scoping as part of the influenza learning agenda

- Defining and quantifying HCWs, including informal health care workers
- Approaches to reaching and increasing coverage in HCWs
- Given majority of HCWs are female, ensure programmes include pregnant women
- Integrate with broader epidemic and pandemic preparedness efforts
- Additional considerations e.g. co-administration
Disease elimination: how do we manage challenges emerging in pursuit of these goals?

- Measles
- Cervical cancer (HPV)
- Others?

*Pictures: The Native Antigen Company; Shutterstock*
Losing ground globally in measles elimination

Notable reported measles cases in 2018 in countries with no reported cases in 2017

- Brazil: 10,262
- Colombia: 188
- Montenegro: 203
- Moldova: 312
- Timor-Leste: 59
- Uzbekistan: 17
- Peru: 38
- Chile: 23
Losing ground globally in measles elimination

Top 10 countries with highest increase in cases between 2017 and 2018

- Brazil: 10,262
- Venezuela: 4,916
- Madagascar: 4,307
- Sudan: 3,496
- Yemen: 6,641
- France: 2,269
- Serbia: 4,355
- Ukraine: 30,338
- Thailand: 2,758
- Philippines: 13,192
Stagnating measles RI coverage leading to outbreaks and repeated cycle of campaigns at high cost

- Frequent / unplanned national and large campaigns
  - Divert HR and other resources away from RI
  - Perverse incentives
- Cannot deliver routine services including immunisation
- Focus on campaigns
- Fiduciary risk

Monitoring / modelling and subnational / differentiated approaches could improve quality and better target campaigns

Continued low coverage, outbreaks and lack of RI strengthening
Aiming at the elimination of cervical cancer may pose increased risk of supply constraint in LMICs

Despite current SAGE recommendations, non-Gavi countries may follow OECD country guidelines:

- Adopt gender neutral
- Expand age-range
- Shift demand towards a specific vaccine product e.g. higher valency

How can the risk this poses to Gavi countries be managed?

WHO Director-General calls for all countries to take action to help end the suffering caused by cervical cancer

Woman being screened for cervical cancer in a rural clinic, Kenya

Jonathan Torgovnik
HPV vaccine introduction inequitably distributed across geography, income and disease burden

Gavi-eligible countries:
- with national HPV vaccine programme
- without national HPV vaccine programme

As of January 2019, over 86 countries have introduced the HPV vaccine (13% among Gavi countries)
This has resulted in Gavi prioritising a single cohort

Gavi’s current HPV vaccines allocation strategy

- Allocation scenarios reviewed by Alliance partners (target girls 9-14yrs)
- Routine and MAC during 1st year introduction
- Prioritize single age cohort and delay MAC
- Extended interval dose schedule e.g. 0-36 mths

- Lower age range (e.g. 9 years)?
- Last age of primary school (e.g. 12 years)?
- Upper age range (e.g. 14 years)?

Is this the best approach in the face of supply constraints, how can we encourage vaccine supply for high incidence countries?
Increasing number of elimination agendas: opportunity and obligation for global synergies?
Evolving approaches
Strengthened Gavi – GPEI collaboration and increasing programmatic engagement

• Development of joint accountability framework at global and country levels
  • to strengthen RI and mitigate the long-term risk of VDPV emergence and other VPD outbreaks
• Papua New Guinea: cVDPV1 outbreak
  • use of surge staff to support MR campaign and jump-start weak RI
  • a model for multi-antigen campaigns and future outbreak response?
Innovating on VIS 2018: decision-making for vaccine investments for epidemic preparedness and response

Gavi to develop living assessments for epidemic preparedness and response vaccines for potential stockpiles

**Information gaps**
- Monitoring the research pipeline and other interventions
- Epidemiological uncertainty
- Implementation feasibility

**Analytical challenges**
- Quantifying impact
- Partner roles in a complex landscape
- Defining Gavi’s comparative advantage

Will require strong collaboration to leverage partner expertise and analyses, e.g. CEPI and WHO
Looking beyond VIS 2018: anticipating and resolving future evidence and policy gaps

Vaccines conditionally approved in VIS 2018

- Rabies
- Mening.
- Cholera
- RSV
- DTP boosters
- Hep B birth dose
- RTS,S
- e.g. HIV
- e.g. GBS

Blockbusters in the pipeline

- 2nd gen TB

- How to identify and address critical evidence gaps (disease burden, delivery challenges) for future blockbusters?
- How to ensure implementable strategies to guide decision-making?
Updating Gavi’s policy model for the next strategic period (and beyond)

In 2019-2020, Gavi will update core policies, including:

- Eligibility and Transition
- Co-financing
- HSIS support framework
- Gender

- Gavi portfolio of countries increasingly complex and multifaceted
- Challenges in targeting funding to reaching zero-dose children

- A more differentiated policy approach to accelerate equitable coverage
- Evolving support model to further unlock domestic resources