Gavi, the Vaccine Alliance: strategic updates

UNICEF Vaccine Industry Consultation 2023
Ed Baker
13 September 2023
>1 billion children immunised; >68 million in 2022 alone
Gavi’s 2025 objectives are ambitious, seeking to leave no one behind.

- 25% reduction in zero-dose children
- 300m additional children to be reached through routine immunisation
- 7–8m future deaths averted
- 10% reduction in child mortality
- US$ 80–100bn in economic benefits unlocked
Gavi strategic goals

**Vision**
Leaving no one behind with immunisation

*To save lives and protect people’s health by increasing equitable and sustainable use of vaccines*

**Mission**
To save lives and protect people’s health by increasing equitable and sustainable use of vaccines

**Set of principles**

1. **Introduce and scale up vaccines**
   - Prioritisation of vaccines; introduce & scale up coverage; outbreak & pandemic response

2. **Strengthen health systems to increase equity in immunisation**
   - Reach under-immunised & zero-dose children; resilient, well-managed, sustainable, innovative immunisation services; build demand; address gender-related barriers

3. **Improve sustainability of immunisation programmes**
   - Strengthen political and social commitment to immunisation; promote domestic public resources; self-financing countries maintain or increase performance

4. **Ensure healthy markets for vaccines and related products**
   - Healthy markets with diversified supply; incentivise innovations; scale up innovative immunisation-related products

**Enablers**
Countries continue to prioritise routine introductions, exceeding targets for 2022

- Overall, **new routine vaccine introductions on track to achieve 5.0/5.1 cumulative target of 82**
- New introductions of **measles-containing vaccines (MCV2)** key driver of performance
- **A further 24 preventive vaccination campaigns** also supported in 2022
Outbreaks on the rise, representing top risk for Alliance

# of outbreaks (non-exhaustive):
75% increase vs. 2021

- Yellow fever: 3 (2021) vs. 6 (2022)
- Measles: 4 (2021) vs. 10 (2022)
- Cholera: 10 (2021) vs. 20 (2022)

- Disruptions to routine immunisation, delays in campaigns increased number of measles-susceptible children and thus outbreaks
- Improving quality, reach of campaigns remains top priority
- Process improvements needed to deliver timely campaigns
- Controlling outbreaks depends upon rapid detection – progress has been made in diagnostic testing capacity in Africa

Note: Other outbreaks in 2022 not shown in chart include 2 Ebola, 2 Marburg and 2 Meningitis outbreaks
Restore routine immunisation, reach zero-dose children: DTP3 coverage rebounded in 2022

- Early indications of recovery with DTP3 coverage rebounding by 3pp in 2022 (approaching 2019 levels)
- In 2022, health systems reached 68 million unique children with Gavi-supported routine vaccines, administering 9% more routine vaccine doses than in 2019
- Continued regional variability and variability between segments: majority of recovery driven by high-impact countries; many low-income countries not yet increasing coverage

Source: WUENIC July 2023 estimates; WHO Monthly admin estimates, April 2023; Reflecting 20 Gavi57 countries with reporting through December 2022, accounting for 67% of the surviving infant population

Alliance-wide “Big Catch-up” launched to accelerate progress on catching up children missed during the pandemic and reaching zero-dose children
Number of zero-dose children decreased by 17% in 2022 to 10.2m

Following a ~two-year pandemic-related increase, progress is now accelerating – 2022 saw a 17% reduction in zero-dose children from 2021

Number of zero-dose children across Gavi57 countries

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11.7</td>
<td>9.0</td>
<td>11.6</td>
<td>12.4</td>
<td>10.2</td>
<td></td>
<td></td>
<td>6.7</td>
</tr>
</tbody>
</table>

-23% -17%

Gavi 4.0 baseline
Gavi 5.0 baseline
IA2030 goal
(50% reduction)

Source: July 2022 WUENIC data – note, number of zero-dose children in 2020 revised down vs. previous WUENIC data
Making immunisation sustainable: Gavi support evolves with country income, co-financing capacity

Co-financing model, 2022

Initial self-financing

Preparatory transition

Accelerated transition

Vaccine price

Variable duration

Variable duration

8 years

Per Board-approved Middle-Income Countries (MICs) Approach

Former Gavi-eligible countries

Never Gavi-eligible countries

Gavi MICs Approach support threshold:
Lower middle-income countries
(< US$ 4,095 GNI per capita) and/or IDA eligible

Low-income country threshold:
US$ 1,045 GNI per capita

Eligibility threshold:
US$ 1,660 GNI per capita
Despite strong performance on co-financing, risks for countries in accelerated transition

2022 co-financing performance

$162 million co-financing contributions
down from 6 in 2021

DTP3 coverage (2021) of accelerated transition countries

Design of Gavi 6.0 strategy provides opportunity to reflect on eligibility and transition model
Sustainability: Middle-Income Countries (MICs) Approach addresses key threats to equity

Inter-country equity

63% of eligible-MICs lag in critical vaccine introductions

Drive sustainable introduction of key missing vaccines in former and select never Gavi-eligible countries

Intra-country equity

Lowest-income, most vulnerable left behind

Backsliding exacerbates inequities, threatens investments

Prevent backsliding in former Gavi-eligible countries

Budget for Gavi 5.0: US$ 301m for 45 MICs-eligible countries (19 former and 26 never Gavi-eligible)
Healthy markets goal (SG4) measured by three success indicators

Healthy market dynamics (on track in 2022)

Gavi’s ongoing market shaping efforts and collaborations with manufacturers helped ensure that 10 vaccine markets exhibited acceptable levels of healthy market dynamics, compared with a record 11 markets in 2021. Each market’s status for 2022 has been formally assessed with partners. This outcome is in line with Gavi’s target, despite a regression in the rotavirus vaccine market in 2022.

Scale up innovations (on track in 2022)

Two new products with improved characteristics are newly offered. A liquid rotavirus vaccine was procured, improving ease of delivery for health care workers. A new presentation for a yellow fever vaccine was also procured, changing from ampoule to vial containers, improving its cold chain footprint.

Incentivise innovations (on track in 2022)

The Vaccine Innovation Prioritisation Strategy (VIPS) sees continued progress. In 2022, five microarray patch (MAP) pipeline candidates have advanced through development; and two products have received approval for controlled temperature chain (CTC) labelling. The 2022 progress has brought the overall achievement to nine, meeting the Alliance target for 2025 well ahead of schedule.
SG4 target met; supply issues in several vaccine markets show need for continuous market shaping

2022 market health for vaccines and related products

Penta  Hexa  TCV  JE  MenA  M/MR  YF  IPV  PCV  CCE  Rota  HPV  Cholera  Malaria

Rotavirus downgraded: significant supply disruptions in seven countries necessitating product switches; Alliance working with suppliers to mitigate further risks.

HPV: unmet demand expected to resolve with imminent supply increases, adoption of single-dose schedule; anticipated positive impact on HPV vaccine programme revitalisation.

Cholera: despite supply increases in recent years, surge in outbreaks pushed limits of available oral cholera vaccine (OCV); 2022 outbreak demand is prioritised, delaying preventive campaigns.

Malaria: RTS,S supply limitation; speeding up access to additional supply through efforts to accelerate RTS,S tech transfer, access to forthcoming second vaccine (R21).

1. A total of three vaccine markets are now assessed as unacceptable, requiring further intervention: rotavirus, oral cholera vaccine (OCV) and malaria; the human papillomavirus (HPV) vaccine market is assessed as unacceptable with conditions for improvement.
Market shaping roadmaps

3 new market shaping roadmaps published in 2023

- OCV, malaria, cholera diagnostics

6 additional market shaping roadmaps under development in 2023

- HPV; yellow fever; diagnostics x 3 (measles, yellow fever, meningococcal); cold chain equipment (CCE): monitoring devices
VIPS partnership: accelerating three innovations for coverage, equity goals; global health security

**2018–2020**

**PRIORITISATION**

**ACCELERATION**
- MAPS – need incentive mechanism
- CTC – define use cases/demand
- Barcodes – pilot implementation

**INCREASED EQUITABLE COVERAGE**
- Zero-dose children
- Backsliding coverage
- Outbreak, epidemic, pandemic

**Prioritised innovations**
- Microarray patches (MAP)
- Heat-stable and controlled temperature chain (CTC) qualified vaccines
- Barcodes on primary packaging
Gavi 5.1 strategy update: evolving priorities based on learnings from COVID-19 pandemic

**RECALIBRATED GAVI 5.0 PRIORITIES**

Prevent **backsliding**; catch up **missed children**; and accelerate efforts to reach **zero-dose children**

Revitalisation of **HPV** vaccine programme

Launch of **malaria** vaccine programme

**TARGETED ADDITIONS**

Integration of **COVID-19 vaccination programme** into **routine immunisation** for 2024 and 2025

Evolution of Gavi’s role in **pandemic preparedness and response** (PPR), inc. support to **regional manufacturing**
From COVAX to COVID-19 vaccination programme in 2024–2025; VIS assessment for Gavi 6.0

2023: COVAX in transition

- COVAX committed to support countries’ COVID-19 vaccination programmes through end 2023
- PHEIC lifted; countries transitioning from pandemic response to routine disease management

2024–2025: COVID-19 vaccination programme

- Gavi Board approval in June 2023 to support countries to continue COVID-19 vaccination for high-priority groups in 2024–2025

2026 onwards: Routine COVID-19 vaccination programme – for consideration

- Gavi to revisit COVID-19 vaccination as longer-term programme beyond 2025 through Vaccine Investment Strategy 2024 (VIS 2024) process
**PPPR: critical role for Gavi; leveraging learnings, experience across Alliance**

**Gavi’s role in pandemic prevention, preparedness and response (PPPR)**

- Vaccines critical in outbreaks, epidemics, pandemics
- Vaccine Alliance: global health’s hub for vaccines and delivery
- Gavi core activities, capacity contributes to PPPR

**Key areas for Alliance PPPR plan**

1. Enhancing capabilities for readiness, response
2. Resilient health care systems, routine immunisation (RI) programmes
3. Diversification of regional manufacturing
4. Financial innovation
VIS 2024: multi-step process ending June 2024

1. **WHO landscape analysis:**
   WHO recommends longlist of vaccines for consideration in Vaccine Investment Strategy (VIS)

2. **VIS candidate list:**
   Determine which of the longlist vaccines are appropriate to evaluate

3. **Evaluation framework:**
   Define evaluation criteria, indicators and thresholds

4. **Vaccine analyses:**
   Evaluate vaccines along the indicators

5. **Prioritisation methodology:**
   Apply criteria towards shortlisting based on Board priorities

6. **Shortlist options:**
   Derive several shortlists based on prioritisation

7. **Investment Cases:**
   Develop investment cases for Board approval
Gavi-supported VIS 2018 and VIS 2024 vaccines

**Existing portfolio**
- **Routine vaccines**
  - Pregnant people
  - Newborns
  - Infants (<12 months)
  - 2nd year of life (13–23 months)
  - Older children (2–8 years)
  - Adolescents (9–19 years)
  - Adults
  - Older people
  - Health workers

**Emergency stockpiles**

**VIS 2018 vaccines**
- RSV
- MMCV**
- MCV2
- Hexavalent*
- Td Booster
- Rabies PEP

**VIS 2024**
- GBS, COVID-19, Others
- Shigella
- Dengue
- TB
- COVID-19
- COVID-19 Others

*Hexavalent approved at the same time as VIS 2018 vaccines
**Pending product and SAGE recommendation
† not all appropriate for newborns and infants.

Additional vaccines supported:
- Hepatitis E, mpox & chikungunya

*supported for periodic follow-up.
**supported with one-time catch-ups beyond infancy
***mass preventive campaign.
## VIS 2024 evaluation framework for vaccines for endemic disease

### Ranking criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health impact</td>
<td>Total future deaths averted 2026–2040, and per 100,000 vaccinated</td>
</tr>
<tr>
<td></td>
<td>Total future DALYs averted 2026–2040, and per 100,000 vaccinated</td>
</tr>
<tr>
<td>Value for money</td>
<td>Vaccine procurement cost per death averted</td>
</tr>
<tr>
<td></td>
<td>Vaccine procurement cost per DALY averted</td>
</tr>
<tr>
<td>Equity and social protection impact</td>
<td>Disproportionate impact of disease on vulnerable groups</td>
</tr>
<tr>
<td></td>
<td>Vaccination contributes to addressing underlying gender-related barriers faced by caregivers, adolescents and health workers; and/or gender-associated differences in immunisation coverage</td>
</tr>
<tr>
<td>Gavi comparative advantage</td>
<td>Degree of vaccine market challenges</td>
</tr>
<tr>
<td></td>
<td>Alliance role in addressing challenges</td>
</tr>
<tr>
<td>Economic impact</td>
<td>Direct medical cost averted</td>
</tr>
<tr>
<td></td>
<td>Indirect cost averted</td>
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</table>

### Modulating criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global health security impact</td>
<td>Epidemic potential of disease</td>
</tr>
<tr>
<td></td>
<td>Impact on antimicrobial resistance (AMR)</td>
</tr>
<tr>
<td></td>
<td>Climate change risks and mitigation</td>
</tr>
<tr>
<td>Other impact</td>
<td>Total U5 deaths averted 2026–2040, and per 100,000 vaccinated</td>
</tr>
<tr>
<td>Broader health system benefits</td>
<td>No specific indicator – evaluated case by case</td>
</tr>
<tr>
<td>Implementation feasibility</td>
<td>Ease of supply chain integration</td>
</tr>
<tr>
<td></td>
<td>Need for health care worker training/behaviour change</td>
</tr>
<tr>
<td></td>
<td>Requirements of vaccination timepoint</td>
</tr>
<tr>
<td></td>
<td>Need for demand promotion (e.g. acceptability, understanding of disease burden)</td>
</tr>
<tr>
<td></td>
<td>Availability of epidemiological data to inform programmes</td>
</tr>
<tr>
<td></td>
<td>Diagnostics availability/needs</td>
</tr>
<tr>
<td>Alternate interventions</td>
<td>Optimal use of current and future alternative interventions (prevention and treatment)</td>
</tr>
<tr>
<td>Contribution to global agenda</td>
<td>Fit with global development (SDGs), immunisation (IA2030) agendas and other relevant global targets</td>
</tr>
</tbody>
</table>
Four questions to structure assessment of vaccines for epidemic preparedness and response

1. Is the disease burden/epidemic potential sufficient to prioritise a stockpile or similar investment?

2. Would the vaccine be feasible to use and impactful as part of epidemic preparedness and response?

3. What is Gavi’s comparative advantage, and how can Gavi’s expertise contribute to the funding and delivery of this vaccine?

4. What is the appropriate scale of the stockpile (or related intervention), and what would be the financial implications of an investment?

VIS Phase 2 assessment
(Analyse longlist of diseases according to evaluation framework to determine shortlist)

Phase 3 assessment
(Develop investment cases of shortlist)
Looking ahead: Alliance operating in profoundly reshaped global health environment

- Catching up routine immunisation following COVID-19 pandemic: leaving no one behind
- Increased pressures on health systems (population growth, migration, fragility and conflicts)
- Innovation in immunisation systems and technology
- Climate emergency
- Reshaping of global health architecture

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Gavi 6.0 strategy design and replenishment timeline

Gavi 6.0 strategy design

1. Trends, Gavi 6.0 vision & high-level opportunities for impact
   - March 2023 Board retreat
   - June 2023 Board Vaccine Investment Strategy (VIS)
   - October 2023 Gavi 6.0 virtual Board mini-workshop
   - 6.0 deep dives/tech briefing on HSS and eligibility, transition, co-financing & MICs (early December TBD)

Gavi 6.0 consultations with Board/PPC members, Alliance partners, countries, global health community

2. Strategic options and initial trade-offs
   - December 2023 Gavi 6.0 Board retreat
   - Board VIS — shortlist

3. Finalise choices and “one-pager” framework
   - April 2024 – Gavi 6.0 Board retreat
   - June 2024 Board Gavi 6.0 approval & VIS

Resource mobilisation process

"Listening phase" & consultations

Drafting of the investment case

Public campaign

Gavi 6.0 operationalisation

2023

2024

2025

2026

Investment case launch

Replenishment

WHO, G7 May

TBC

Pandemic Fund replenishment

G20

UNGA Sep

Global Fund replenishment

IDA replenishment

WHA, G7 & VIS

Finalise choices and "one-pager" framework

2023

2024

2025

Gavi 6.0 start
Thank you