

THE VACCINE  
ALLIANCE  
—  
RISK & ASSURANCE  
REPORT 2020





## Risk & Assurance Report 2020

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## 1. Introduction

### 1.1. Purpose of this report

This year has been an extraordinarily disruptive year with a significant impact on Gavi's risk profile. The COVID-19 pandemic is putting years of progress at risk by disrupting immunisation programmes and Alliance operations and has led to a highly uncertain operating environment with still many unknowns around the evolution of the pandemic and its potential impact. To successfully navigate today's highly uncertain environment, robust risk management is needed more than ever to help the Alliance to continuously assess what might happen, manage expectations, reduce vulnerabilities, and secure success. It enables a proactive and resilient Alliance to safely face the risks posed by the current environment and confidently take the risks required to achieve the Gavi mission.

Gavi stands at the start of its "Gavi 5.0" strategic period with a new strategy that, as flagged in last year's Risk & Assurance Report<sup>1</sup>, is inherently more risky as it represents a very aspirational ambition requiring more and novel support to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments. On top of that, the pandemic is now exposing Gavi to new, heightened and rapidly changing risks as Gavi responds to it by supporting countries to maintain, restore and strengthen their immunisation services, and by administrating the COVAX Facility, which is being established in record time and has to navigate uncharted territory in securing equitable access to potential COVID-19 vaccines. Establishing the COVAX Facility and COVID-19 vaccine delivery in-country may also pose risk to and distract from Gavi's core mission. Moreover, while inherently risks are heightened, mitigating these risks and obtaining assurance over the effectiveness of mitigation is now more complicated due to COVID-19 related restrictions and affected capacities. As a result, the Gavi Board needs to acknowledge that Gavi will need to accept some of this higher risk exposure as it is pursuing a riskier strategy in a riskier world, and faces limitations in its ability to mitigate some of these. It will be critical to reflect this in a recalibrated risk appetite (i.e. consciously accepting for some risks that they may materialise as part of pursuing our mission) and to continue to actively monitor and re-assess risks as they change or our understanding of them evolves. The Secretariat has therefore interpreted what kind of risk appetite would be appropriate in pursuit of the Gavi mission under the current circumstances, and Section 2.3 of this report includes suggestions for a recalibrated risk appetite, which can serve (together with the Board's guidance on this) as the basis for a subsequent update of Gavi's Risk Appetite Statement.

This annual Risk & Assurance Report discusses the most critical risks that could potentially have an impact on the ability of the Alliance to achieve its mission and strategic goals. This year's report presents a reframed set of 16 top risks in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility. It shows that Gavi's overall risk profile has increased across the board, with 9 top risks from last year having increased, one new top risk and one having decreased. Detailed information including analysis of each top risk and corresponding mitigation is included in the annexes. Where applicable, links are made with findings from audits, evaluations and other reviews if these provided insights or assurance on the effectiveness of existing mitigation measures or identified new risks. The report provides an update on risk management across the Alliance, an analysis of macro-trends affecting Gavi's risk profile, an overview of key changes in top risks compared to last year, and an overview of how current levels of risk compare to Gavi's risk appetite (i.e. the willingness to accept being exposed). It also includes a separate section with a risk assessment of the COVAX Facility (see Section 3 of this report).

<sup>1</sup> See Section 3 of the 2019 Risk & Assurance Report: <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2019>

## 1.2. Progress made on Alliance-wide risk management

As the pandemic is putting the concept of risk and the importance of proactive risk management front and centre in many people's professional and personal lives, the Risk function continues to foster a risk-aware culture across the Alliance. Over the course of the year the Risk function engaged in many Secretariat meetings to encourage staff to think about potential risks from the outset of activities and to put adequate measures in place proportionate to levels of risk. As such, the Risk team participated in country programme monitoring meetings and various working groups, e.g. on the redesign of country portfolio management processes, channelling of funds and supply chain insurance. The Risk team also supported the development of business continuity and crisis management policies, risk-based due diligence as part of the new corporate procurement policy and an updated internal control framework for the Finance function. The risk lens also continues to be integrated into the Secretariat's biannual priority-setting, budgeting and performance management process, requiring all teams to identify risks associated with their priorities in their team risk registers and to ensure mitigation of key risks is included as part of team objectives.

From the start of the first COVID-19 outbreak earlier this year, the Risk function has engaged actively with the business on pandemic preparedness to ensure that COVID-19 related risks were timely identified, managed and monitored. As part of the initial Secretariat's preparedness group (established before the outbreak developed into a pandemic and a crisis management team was set up), corporate risks to business continuity and staff health and safety were identified and measures put in place based on an escalation plan with a defined set of risk triggers. The Risk function also conducted a broader COVID-19 risk assessment<sup>2</sup>, which informed planning assumptions for Gavi's broader programmatic response. The Risk function furthermore continues to engage actively in several workstreams on the design and operationalisation of the COVAX Facility to monitor and identify risks. It also conducted a COVAX Facility risk assessment (see Section 3 of this report).

The Secretariat's Risk Committee (chaired by the CEO with senior leadership from across the organisation) has discussed both the COVID-19 and COVAX Facility risk assessments and aligned on the changes in Gavi's risk profile. It has continued to review several top risks over the year based on in-depth presentations from risk owners in the Secretariat. The Risk Committee also had an initial discussion on the Three Lines of Defence<sup>3</sup> model in Gavi, rethinking its scope, structure and roles, and capacity and capabilities. It examined the potential need to differentiate between defining three lines based on risks related to the Secretariat's role in grant management versus defining three lines based on risks related to in-country immunisation programmes. There was also recognition that the model may need to be expanded to include multiple types of risks (including corporate risks), with risk themes as the basis for structuring rather than assigning existing teams to different lines of defence. The review of the model will continue and take into account newly published guidance<sup>4</sup> and any organisational changes following the organisational review. The Risk function is also exploring linkages between top risks and the Gavi 5.0 Theory of Change and Learning System being developed by the Monitoring & Evaluations team, and is collaborating with the Internal Audit team on their efforts to leverage the top risk assessment and provide assurance on the effectiveness of top risk mitigation.

<sup>2</sup> See: <https://www.gavi.org/news/document-library/03-annex-c-afc-update-risk-management-pdf>

<sup>3</sup> The best practice Three Lines of Defence model separates roles and responsibilities across first line functions to understand, monitor and actively manage risks, second line functions to provide objective specialist advice and appropriate checks and balances, and a third line audit function to provide independent assurance on the effectiveness of risk management by the first and second lines.

<sup>4</sup> The Institute of Internal Auditors (IIA) recently published updated guidance on the model: <https://na.theiia.org/about-ia/PublicDocuments/Three-Lines-Model-Updated.pdf>

## 2. Alliance-wide risk exposure

### 2.1. Macro trends affecting Gavi's risk profile

The Alliance normally already operates in a volatile global environment and is exposed to continuously changing exogenous factors which could affect Gavi's risk profile. This year however, the COVID-19 pandemic has led to an extraordinarily uncertain environment with a significant impact on Gavi's risk profile. The Secretariat reviews various independent reports<sup>5</sup> on global trends and risks identified in other organisations to evaluate the extent to which these factors could represent important drivers of risk to the Gavi mission and strategic objectives. Where applicable, the trends and developments summarised below have been captured as risk factors for Gavi's top risks.

The most serious global pandemic in over 100 years has spread across the world at an unprecedented speed. It can undo a decade worth of gains in poverty reduction, exacerbating inequalities and deepening gender disparities in lower income countries. Many countries are using social distancing measures and (recurring) lockdowns to control the virus and prevent health systems from being overwhelmed. Disruptions in immunisation services due to lockdown measures, supply chain disruptions, fears and rumours continue to risk millions of children missing on-time immunisation services, raising the risk of diseases and child deaths, particularly among the poor who lack resources to access health care. The further spread, severity and duration of the pandemic and the corresponding need for control measures continues to be uncertain, depending on whether suitable exit strategies can be found (e.g. effective vaccines or treatments becoming widely available, or roll-out of large-scale testing and targeted isolation of cases), and whether the virus may die out (e.g. due to natural immunity or weakening of the virus through mutations) or will continue to resurge (e.g. due to pandemic fatigue and inability to cope with the economic and social costs, reinfections due to waning immunity, or a virus mutation increasing infectiousness or undermining vaccine effectiveness). Depending on how it evolves, the pandemic has the potential to significantly affect performance against Gavi's mission and strategic goals (with increased child mortality, reduced immunisation coverage and a potentially enlarged number of under-immunised or zero-dose communities), as well as the capacity and operations of the Secretariat and Alliance Partners, both during the acute crisis and the eventual recovery phase<sup>6</sup>.

Before the crisis, the global economy was already under strain from trade tensions, low investment, weak confidence and high debt, and it is now expected to moderate significantly. COVID-19 diminished economic activity with restrictions on the movement of people and goods, required trillions of dollars in response packages, and may cause structural shifts in global economic relationships and supply chains. Although the global economy recovered somewhat since the global lockdown in April, the ascent will likely be long, uneven, and uncertain as the virus continues to spread and many countries have slowed reopening and reinstated partial lockdowns. Until vaccines and treatments are widely available, the risk of a prolonged deep recession with rising bankruptcies, deeper inequality and structural unemployment remains sizable. As countries deploy massive assistance and stimulus packages, public debt is now reaching new records. While low interest rates are currently supportive, servicing debt may become harder with a potentially smaller tax base going forward. Also, deteriorating financial sentiment could trigger a sudden stop in new lending (or failure to roll over existing debt) to vulnerable economies. Most governments are likely to face increasingly burdened budgets and structural weakening of their fiscal positions, and some could become at risk of defaulting. Economic disruptions are likely to be more severe and protracted in those countries with larger domestic outbreaks, greater exposure to international spill-overs (particularly through exposure to global commodity and financial markets, global value chains, and tourism), and larger pre-existing challenges such as informal economies.

<sup>5</sup> Amongst others World Economic Forum COVID-19 Risks Outlook; World Economic Forum Global Risks Report 2020; IMF World Economic Outlook 2020; World Bank Global Economic Prospects 2020; Eurasia Group Top Risks 2020 Coronavirus edition; Uppsala Conflict Data Program

<sup>6</sup> See also: <https://www.gavi.org/news/document-library/03-annex-c-afc-update-risk-management-pdf>

This would significantly affect risks for Gavi related to domestic immunisation financing, and while for many countries the pandemic has underlined the importance of investments in health and immunisation, some countries may reprioritise work on transitioning out of Gavi support or already transitioned countries may see backsliding or regain eligibility.

Severe economic crises in Gavi countries can furthermore lead to political instability, social unrest and conflicts (with violence already on the rise in Africa, as jihadist groups relocated there after the defeat of Islamic State in Syria and Iraq). Societal cohesion may also be affected as the pandemic continues to challenge people's well-being and mental health due to uncertainty, stress and social isolation during confinements. The already existing trend of populism and waning trust in institutions risks being exacerbated by ambiguous information from official channels on COVID-19 threats and measures as well as an increasing amount of disinformation and conspiracy theories circulating on social media. While COVID-19 highlights the need for global cooperation to address global challenges, there are heightened risks around politicisation of the pandemic response, with unilateral agendas being pursued (e.g. through vaccine nationalism or vaccine diplomacy) as uneven COVID-19 impact and recoveries could accelerate the reshuffling of geopolitical influence. This could potentially also result in reputational and political risks for Gavi, given its role in providing equitable access to COVID-19 vaccines.

The increase in work-from-home arrangements globally has resulted in a greater dependence on technology and heightens cybersecurity risks. Cybercriminals are exploiting the use of more vulnerable home-based systems and take advantage of fear and demand for information on the new virus to deliver malware, ransomware and phishing scams. A blurring of the line separating corporate and personal systems also heightens the risk of exposing sensitive information on personal devices.

The unprecedented lockdown measures to contain coronavirus transmission have had positive short-term effects on the environment, but the last five years are still on track to be the warmest on record. Natural disasters are becoming more intense and more frequent, and last year witnessed unprecedented extreme weather, floods and bushfires throughout the world. Climate change is intimately linked to the risk of future pandemics, e.g. as pathogens spread more easily to new hosts due to deforestation and agricultural and urban expansion, or as viruses stored in permafrost or polar ice shields get released due to global warming. While there are opportunities to ensure the sustainability agenda is part of a green COVID-19 recovery, there is a risk that it becomes lower priority in the face of the immediate health and economic crises, raising the risk of disease outbreaks and future pandemics.

## 2.2. Changes to the Alliance-wide top risks in 2020

Last year's report<sup>7</sup> prioritised 16 top risks. This year's report presents a reframed set of 16 top risks in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility. It shows that Gavi's overall risk profile has increased across the board, with 9 top risks from last year having increased, one new top risk and one having decreased. Some top risk definitions have been redefined, the levels of individual risks have evolved as illustrated by the arrows next to each top risk below, and the understanding of existing risks has been enhanced through work by risk owners and colleagues across the Alliance and reviews in the Secretariat's Risk Committee (see Annex IV for detailed information including analysis of each top risk and corresponding mitigation plans). While many top risks have increased this year, many are deemed *just within*<sup>8</sup> risk appetite when a recalibrated risk appetite is applied (i.e. consciously accepting for some risks that they may materialise as part of pursuing our mission)<sup>9</sup>. This year's top risks also include a new top risk to capture the aggregate risk associated with the successful establishment of the COVAX Facility, which are described in more detail in Section 3 of this report<sup>10</sup>. Where establishing the COVAX Facility and COVID-19 vaccine delivery in-country also have a potential effect on Gavi's core mission, these feature as risk factors for Gavi's other top risks<sup>11</sup>.

The 4 top risks rated as **very high** are:

- a) **Country management capacity ▲**  
Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities
- b) **COVAX Facility NEW**  
Failure to establish a successful COVAX Facility
- c) **Data on zero-dose<sup>12</sup>**  
Poor or lacking data may affect the ability of the Alliance to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact
- d) **Sustainable transition ▲**  
Some countries may fail to sustain progress of their immunisation programmes after transition

The 12 top risks rated as **high** are:

- e) **Insufficient demand ▲**  
Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation
- f) **VPD outbreaks<sup>13</sup> ▲**  
Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries
- g) **Misuse by countries ▲**  
Deliberate misuse of Gavi support in many Gavi-supported countries
- h) **Polio disrupting immunisation ▲**  
Polio resurgence may adversely affect routine immunisation
- i) **Cyber-attack<sup>14</sup>**  
Large cyber-attack significantly compromising critical information systems or data

<sup>7</sup> See for the 2019 Risk & Assurance Report: <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2019>

<sup>8</sup> "*Just within*" risk appetite is defined as close to getting outside of risk appetite, still requiring attention and ongoing mitigation to bring risk exposures more broadly within risk appetite.

<sup>9</sup> It is important for the Gavi Board to acknowledge that Gavi will need to accept some of this higher risk exposure as it is pursuing a riskier strategy in a riskier world, and faces limitations in its ability to mitigate some of these. The Secretariat has interpreted what kind of risk appetite would be appropriate in pursuit of the Gavi mission under the current circumstances, and Section 2.3 of this report therefore includes suggestions for a recalibrated risk appetite.

<sup>10</sup> As the COVAX Facility is still being established, this top risk will continue to be further refined, in line with changes in COVAX Facility risks and our understanding of them, as well as the impact of mitigation measures actively being implemented.

<sup>11</sup> See e.g. top risk descriptions for Country management capacity, Partner capacity, Insufficient demand, Misuse by countries, Secretariat disruption, Cyber-attack, Donor support, Conflicting Board priorities.

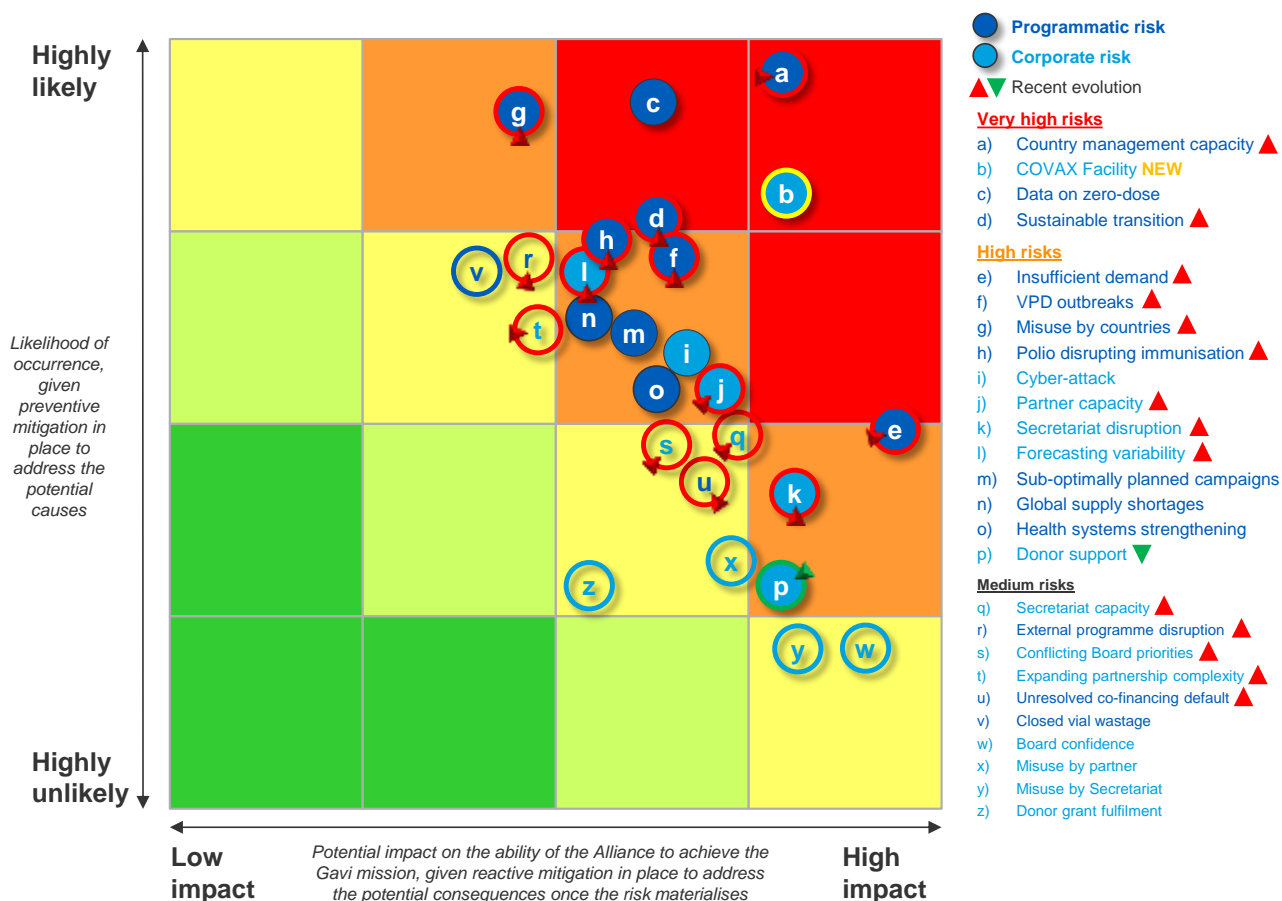
<sup>12</sup> Previously called "Data quality"

<sup>13</sup> Previously called "Outbreaks disrupting immunisation"

<sup>14</sup> Previously called "IT disruption"

- j) **Partner capacity** ▲  
Sum of comparative advantages of Alliance partners may be inadequate to effectively deliver required technical support to countries
- k) **Secretariat disruption** ▲  
Significant disruption of Secretariat operations
- l) **Forecasting variability** ▲  
Significant forecasting variability may drive inappropriate decision-making
- m) **Sub-optimally planned campaigns**  
Multiple large preventive vaccination campaigns that are often sub-optimally planned may undermine capacity to manage and deliver routine health and immunisation services
- n) **Global supply shortages**  
Significant shortages in the global vaccine supply
- o) **Health systems strengthening**  
HSS investments may not materially improve programmatic outcomes
- p) **Donor support** ▼  
Significant reduction in donor support to Gavi

## Alliance top risks ranked against likelihood and impact 2020 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2020 top risks in the red and orange zones on two dimensions, likelihood of occurrence and potential impact. These ratings represent the residual exposure to these risks, taking into account the effectiveness of already existing mitigation strategies to prevent these risks from occurring (thereby reducing the likelihood), as well as to detect and be prepared to react once they materialise (thereby reducing the potential impact). The levels of some individual risks have evolved since last year's report, as illustrated by the arrows next to each top risk. Risks are not strictly ranked within each segment as any ranking is subjective depending on how the relative importance of impact and likelihood are weighted. The



## Alliance-wide top risks summary

Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a <b>Country management capacity</b> Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption (conflict, natural disasters, disease outbreaks, political change/devolution)</li> </ul>	VH		JUST WITHIN		
b <b>COVAX Facility</b> Failure to establish a successful COVAX Facility	<ul style="list-style-type: none"> <li>Competition from bilateral deals</li> <li>Inability to secure deals in time</li> <li>(Perception of) inequitable allocation and distribution</li> <li>Insufficient funding, liquidity, risk management</li> <li>Overstretched people, processes, systems</li> <li>Ineffective coordination, project management, governance</li> </ul>	VH		OUTSIDE	NEW	
c <b>Data on zero-dose</b> Poor or lacking data may affect the ability of the Alliance to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact	<ul style="list-style-type: none"> <li>More precise data is not available</li> <li>Existing data is not shared</li> <li>Data is not timely</li> <li>Data is not used effectively to identify children</li> <li>Poor data culture, capacity and systems</li> </ul>	VH		JUST WITHIN		
d <b>Sustainable transition</b> Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> <li>Lack of (subnational) ability/capacity/fiscal space</li> <li>Poor preparation for transition by Alliance</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Overreliance on external support</li> <li>Lack of access to global markets and expertise</li> <li>External programme disruption (economic, outbreaks)</li> </ul>	VH		JUST WITHIN		
e <b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation	<ul style="list-style-type: none"> <li>Lack of knowledge / information about immunisation</li> <li>Hesitancy due to mistrust/fear</li> <li>Anti-vax sentiment, politicization, fake vaccines</li> <li>Logistical barriers, lack of motivation, prioritisation</li> <li>Poor quality services / experience</li> <li>Weak government systems for generating demand</li> </ul>	H		JUST WITHIN		
f <b>VPD outbreaks</b> Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries	<ul style="list-style-type: none"> <li>Low population immunity, vaccine hesitancy</li> <li>Climate change, urbanisation, deforestation, globalisation, migration and human displacement, population growth</li> <li>Lack of capacity/tools to detect, prevent and respond</li> <li>External programme disruption (conflict, disasters)</li> </ul>	H		JUST WITHIN		
g <b>Misuse by countries</b> Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Culture of gifts/corruption</li> <li>Opportunity for personal gain</li> <li>Weak monitoring/deterrence</li> <li>Weak institutions and systems</li> </ul>	H		JUST WITHIN		
Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
h <b>Polio disrupting immunisation</b> Polio resurgence may adversely affect routine immunisation	<ul style="list-style-type: none"> <li>Eradication challenges / Vaccine-derived outbreaks</li> <li>Reliance on GPEI staff/assets, weak national systems</li> <li>Delayed transition plans, incomplete polio asset mapping</li> <li>GPEI funding cuts / uncertain fund-raising for new strategy</li> </ul>	H		JUST WITHIN		
i <b>Cyber-attack</b> Large cyber-attack significantly compromising critical information systems or data	<ul style="list-style-type: none"> <li>Cyber-attack, phishing and malware</li> <li>Internal or external data breach</li> <li>Systems failure and data loss</li> </ul>	H		JUST WITHIN		
j <b>Partner capacity</b> Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> <li>Lack of accountability / performance</li> </ul>	H		JUST WITHIN		
k <b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>Loss of workplace and facilities</li> <li>Incident or loss of life in the workplace</li> <li>Security threats and kidnapping during travel</li> <li>Departures of key staff with critical knowledge</li> <li>Unforeseen catastrophic event or crisis situation</li> </ul>	H		JUST WITHIN		
l <b>Forecasting variability</b> Gavi forecasting variability drives inappropriate decision-making	<ul style="list-style-type: none"> <li>Uncertainty over vaccine demand</li> <li>Financial uncertainties (e.g., prices, FX)</li> <li>Complexity of process</li> <li>Sub-optimal systems</li> </ul>	H		JUST WITHIN		
m <b>Sub-optimally planned campaigns</b> Multiple large preventive vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>	H		JUST WITHIN		
n <b>Global supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption (epidemiological, political, technical)</li> </ul>	H		JUST WITHIN		
o <b>Health systems strengthening</b> HSS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSS</li> <li>HSS grants not designed to target key bottlenecks</li> <li>HSS grants duplicative with other donor funding</li> <li>HSS grants not large enough to have significant impact</li> <li>HSS not disbursed in timely fashion</li> <li>Programmes funded by HSS not well-managed</li> <li>Misuse of HSS resources</li> </ul>	H		BROADLY WITHIN		
p <b>Donor support</b> Significant reduction in donor support to Gavi	<ul style="list-style-type: none"> <li>Reduction in development budgets</li> <li>Competing priorities in development</li> <li>Competing priorities within health</li> <li>Loss of donor confidence in Gavi</li> </ul>	H		BROADLY WITHIN		

next segment of risks in the yellow zone are medium<sup>15</sup> risks (depicted with hollow circles), shown for comparison purposes only and not designated as top risks. The Secretariat also maintains a register containing a broader set of lower risks and their associated mitigation strategies, which are identified and managed at a team level. Annex III shows the trajectory of the evolved top risks since last year in more detail.

Annex IV contains a detailed description of each top risk, existing mitigation, current exposure and risk appetite. The major changes since last year are summarised below:

**a) Country management capacity<sup>16</sup> ▲** – The risk that many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities has increased. While between 2017 and 2019 institutional capacity scores have improved with 50% less countries having “weak” capacity and twice as much having “satisfactory” capacity, maintaining the gains is a challenge with EPI staff turnover, external disruption and stronger countries transitioning out of Gavi support. With the current pandemic we have seen delays in implementing Leadership, Management and Coordination (LMC) programmes, and existing capacity may be diverted to respond to COVID-19 or may suffer from absenteeism and fatalities, and may get diverted by the delivery of a potential COVID-19 vaccine. Moreover, increased capacity may be needed to plan and coordinate a large amount of catch-up campaigns to restore coverage levels after vaccine introductions and campaigns were suspended during lockdowns. Reaching missed communities and zero-dose children under Gavi 5.0 will also likely require greater country management capacity, including sub-nationally and in challenging environments. The Secretariat is proposing to the Board to make additional funding available (up to US\$ 500 million in HSS grants and increased PEF funding) as part of a comprehensive approach to reach zero-dose children and missed communities. It is also proposed to institutionalise the approach to financial management capacity-building to ensure timely funding of activities at sub-national level to reach zero-dose communities.

**b) COVAX Facility<sup>17</sup> NEW** – The risk of a failure to establish a successful COVAX Facility is very high as the COVAX Facility is being established in record time and has to navigate uncharted territory in securing equitable access to potential COVID-19 vaccines. It is a large, unique and structurally complex undertaking which requires new processes, capacities and capabilities, and will involve increased volumes of activities and transactions compared to Gavi’s regular business. It also requires extensive coordination, collaboration, stakeholder engagement and outreach with many partners involved with varying interests, as well as engagement with many new economies with which Gavi does not yet have established relationships (including economies under economic sanctions). To mitigate operational risks associated with overstretched people, systems and processes (which could also affect broader Secretariat capacity and distract from Gavi’s core mission), the Office of the COVAX Facility is developing a full end-to-end operations plan, is hiring additional and dedicated resources, and has a dedicated Managing Director. Outsourcing of treasury, accounting and

<sup>15</sup> The medium risks are defined as follows: **q) Secretariat capacity**: Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy; **r) External programme disruption**: Major external events disrupt programmes in some Gavi-supported countries; **s) Conflicting Board priorities**: Changes in Alliance Board may result in conflicting or inconsistent decisions or disagreements; **t) Expanding partnership complexity**: Growth in number of new partners may increase transaction costs and complexity; **u) Unresolved co-financing default**: Lasting co-financing default leading to suspension; **v) Closed vial wastage**: Excessive closed vial vaccine wastage; **w) Board confidence**: Board losing confidence in Gavi management; **x) Misuse by partners**: Deliberate misuse of Gavi funds by partners; **y) Misuse by Secretariat**: Deliberate misuse of Gavi funds by Secretariat; **z) Donor grant fulfilment**: Donors failing to fully pay pledged contributions

<sup>16</sup> This risk has been reframed to focus it more specifically on those areas of country management capacity that are critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities; and focus mitigation on where Gavi has a comparative advantage over other actors to make a real difference with targeted, scalable and sustainable interventions.

<sup>17</sup> This new top risk captures the aggregate risk associated with the successful establishment of the COVAX Facility, highlighting key operational and financial risks. As the COVAX Facility is still being established, this top risk will continue to be further refined, in line with changes in COVAX Facility risks and our understanding of them, as well as the impact of mitigation measures actively being implemented. See Section 3 of this report for a comprehensive risk assessment of the COVAX Facility, highlighting also other types of risk. The focus going forward will likely move from risks around establishment to operationalisation and programmatic risks around vaccine delivery and roll-out.

banking services is also being explored. A tailored Governance structure ensures multi-stakeholder coordination and decision-making. Furthermore, since Gavi is the legal entity administering the Facility, Gavi will ultimately be assuming the financial risk exposure of the Facility and needs to protect its balance sheet and minimise risks to Gavi core resources and programmes. In order to protect Gavi's balance sheet, Gavi will not enter into firm order commitments with manufacturers in excess of the cash it has received and to the extent further commitments from participants (i.e. outstanding payments to Gavi) are secured (e.g. by robust guarantees, insurance or financial risk instruments), until residual financial risks are well understood and mitigated to the extent possible. This operating principle will considerably limit financial risk exposure and liabilities for Gavi, however there is a risk that this results in delays for deal-making (due to financial backing being insufficient at the time deals need to be signed), which may pose a risk to the success of the Facility. There may not be sufficient financial backing for deals due to liquidity gaps (e.g. due to cash flow mismatches, insufficient upfront funding or slow cash inflows from COVAX AMC donor pledges); an inability to secure and therefore leverage commitments from participants because they expose Gavi's balance sheet to credit risk (i.e. the risk of countries defaulting leaving them unable to pay or breaching contractual commitments and being unwilling to pay); actual prices turning out higher than the estimated weighted average price used for participant cost calculations; or by a potential COVAX AMC funding shortfall (see also below). To enable deal-making, solutions are being explored with an external financial risk advisor to ensure that sufficient financial backing is available through financial guarantees, sovereign default risk insurance and a liquidity facility. The advisor has created a high level framework to compartmentalise sovereign credit risk into four segments, based on credit ratings and a decision tree to determine viable risk mitigation strategies for each segment by utilising financial instruments and structures made available by Multilateral Development Banks (MDBs) and International Financial Institutions (IFIs). Solutions are also being explored for countries without high credit ratings which have not provided bank guarantees (including countries under the optional purchase arrangement once they opt in) or which provided guarantees which are not acceptable for MDBs/IFIs. Based on materiality, cost, and Gavi's cash absorption layer, Gavi could also decide to absorb some sovereign risk. Furthermore, a comprehensive operational cash flow model will help to understand liquidity needs, and the need for liquidity providers.

**c) Data on zero-dose<sup>18</sup>** – The risk that poor or lacking data may affect the ability of the Alliance to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact is very high due to the shift from using data to measure coverage in Gavi 4.0 to needing to use (different types of) data to target interventions in Gavi 5.0, which requires more granular, sub-national and geospatial data. It also requires timely data, which was already a challenge during Gavi 4.0 with WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) being highly lagged and subject to retrospective revision. An analysis of data needs required in Gavi 5.0 has identified significant gaps in the data required for identification of missed communities. The hypothesis that zero-dose children are clustered in pockets also still needs to be tested.

**d) Sustainable transition ▲** – The risk that some countries may fail to sustain progress of their immunisation programmes after transition has increased again (after decreasing last year given the positive trend of successful transitions, post-transition support being rolled-out and an increased focus on programmatic sustainability under Gavi 5.0). The continued worldwide spread of COVID-19 has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' transition trajectories, their fiscal space for co-financing and risks of backsliding in already transitioned countries. To ensure

<sup>18</sup> Previously called "Data quality". This risk has been reframed to focus it more specifically on the critical types of data that if poor or lacking will affect the ability to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact; and which are addressable within Gavi's sphere of influence.

With the reframing of Country management capacity and Data on zero-dose with a specific focus on their consequences for the ability to reach zero-dose children and missed communities, previous years' risk *Ability to reach the under-immunised* has been removed.

immunisation services were not disrupted, the Board exceptionally approved flexibility to provide co-financing waivers in 2020 and 2021 on a case-by-case basis. At the same time, Gavi and its Alliance partners, in particular the World Bank, have been engaging with countries to mitigate the impact of the pandemic on their ability to co-finance and protect the significant gains achieved in strengthening the financial sustainability of immunisation programmes. As a result, despite fiscal constraints related to COVID-19, countries so far show good progress on co-financing payments in 2020. Risks however continue to be heightened as the economic context remains unpredictable, creating uncertainty around the magnitude and duration of the current downturn. Going forward, immunisation financing, including vaccine financing, will likely be affected by a shrinking fiscal space and stronger competition from other sectors for scarce resources, with fewer resources being available to countries due to lower government revenues following the economic contraction during the pandemic, accompanied by higher sovereign debt and withdrawal of the COVID-related external support.

**e) Insufficient demand ▲** – The risk of a significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation has increased due to COVID-19 lock-down measures and fear of visiting health clinics (~80% of countries are reporting reductions in demand for services), as well as vaccine hesitancy due to mis- and disinformation about vaccines (with surveys pointing to widespread reluctance to accept a COVID-19 vaccine and COVID-19 rumours and conspiracy theories potentially spilling over into routine vaccines). The risk also becomes more important under Gavi 5.0 with demand generation being critical to reach missed communities, including through strategies to overcome gender-related barriers and increased civil society and community engagement. As the Alliance looks to extend immunisation services and more children will get a first dose of pentavalent vaccine, Gavi will have to ensure drop-out does not increase through an intensified focus on demand, to ensure that caregivers are fully aware of the need and motivated to bring their children back for all required vaccines.

**f) VPD outbreaks<sup>19</sup> ▲** – The risk of sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries has increased with COVID-19 disrupting routine immunisation services (which is reported to have dropped significantly in ~40% of countries). This is resulting in decreased coverage rates for vaccines against outbreak prone diseases and threatening population level immunity which in turn increases the risk of vaccine-preventable disease (VPD) outbreaks. Furthermore, most planned preventive campaigns and several approved outbreak response activities have been postponed along with routine vaccine introductions. Disease surveillance systems have also been disrupted, which is likely to impact the ability of countries to quickly detect and respond to outbreaks. To reduce the risk of VPD outbreaks, the Alliance is working to support countries with the safe resumption of delayed preventive campaigns along with the maintenance of routine immunisation services as a key essential health service throughout the duration of the pandemic as stressed in WHO guidance and Gavi's efforts to Maintain, Restore and Strengthen immunisation in the context of COVID-19. This includes ensuring available funding to ensure children missed before, during and after the pandemic are quickly caught, primarily through routine immunisation services. Furthermore, the Secretariat is considering proposing to the Board increased investments in disease surveillance, which if approved may assist with earlier detection and response to VPD outbreaks

**g) Misuse by countries ▲** – The risk of deliberate misuse of Gavi support in some Gavi-supported countries has increased during the pandemic. In times of crisis, economic uncertainty, low morale and financial pressures may drive more wrongdoers to commit and rationalise fraud as more opportunities arise due to a weakened internal control environment and possibilities to take advantage of people's fear and distraction.

<sup>19</sup> Previously called "Outbreaks disrupting immunisation". This risk has been reframed to focus it more specifically on the risk of VPD outbreaks occurring, for which mitigation falls more clearly within Gavi's mandate, especially since Gavi 5.0 recognises a stronger role in Global Health Security (GHS) with enhancing outbreak response through stockpiles as a deliberate focus of the strategic goals. The more exogenous risk of non-VPD outbreaks disrupting immunisation services (with COVID-19 as a clear example) fits better under the medium risk of external programme disruption, which would also include other sources of disruption (e.g. conflicts, natural disasters).

Gavi also provided increased (emergency) funding to help countries respond to the pandemic and maintain, restore and strengthen immunisation programmes, using a fast-tracked application and review process. At the same time, travel restrictions continue to impair grant oversight and assurance in Gavi-supported countries. Programme Audits have been suspended until January 2021 and in-country assurance providers such as fiduciary and monitoring agents are often restricted in the scope of their activities due to social distancing measures. To protect Gavi investments during the COVID-19 crisis, the Secretariat is maintaining standard fiduciary requirements with some flexibilities applied on a case-by-case basis. Where possible, Gavi-funded assurance providers are adapting their procedures through remote working options and e-solutions. Furthermore, some de-risking of programmes is taking place by curtailing risky activities or moving them to lower risk implementers. The Secretariat also remains closely aligned with other agencies on their approaches to fiduciary risk and sharing intelligence. Furthermore, a Financial Management Working Group is focussing on the 5.0 approach to accelerate the movement of funds back to government systems while at the same time keeping fiduciary risk at an acceptable level. The Secretariat is also proposing to the Board to institutionalise the approach to fiduciary risk assurance and financial management capacity-building introduced in Gavi 4.0 through the creation of a discrete fund, clear portfolio targets and enhanced accountability. Finally, the distribution of COVID-19 vaccines in countries may be associated with a higher risk of theft and diversion than traditional Gavi-supported vaccines, given these are in low supply with potentially high demand and secondary markets exist (although they still require a sophisticated cold chain). They could also be diverted to non-target groups within countries or be used in exploitative transactions. The Secretariat is actively working on managing these risks and will closely monitor the utilisation of vaccines in COVAX AMC-eligible economies through country monitoring and reporting from an early stage. Through the vaccine request form that countries have to submit, target groups are agreed (as much as possible in line with WHO-SAGE guidance) and countries agree to reimburse all funding amounts (cash or the value of equipment, supplies or vaccine) that Gavi determines not to have been used for the programme or otherwise misused. The “COVID-19 Vaccine and Therapeutics Traceability Expert Advisory Board” (on which Gavi sits) has also started to address traceability to reduce diversion.

**h) Polio disrupting immunisation ▲** – The risk that polio resurgence may adversely affect routine immunisation has increased as the pre-COVID-19 resurgence of wild polio virus (WPV) and vaccine-derived polio virus (cVDPV) have been exacerbated by the programme pauses and disruptions of preventive and outbreak response campaigns, resulting in even lower population immunity and increased transmission. There is now more transmission of WPV in the endemics (Afghanistan and Pakistan), further spread of cVDPV2 and emergence of cVDPV1. Of particular concern is the spread of cVDPV2 given the low levels of type 2 protection and risk of the vaccine used for outbreak response (mOPV2) seeding further transmission until nOPV2 (novel oral poliovirus vaccine type 2), a more genetically stable live-attenuated oral vaccine, is rolled out in early 2021 (just having received Emergency Use Listing approval).

**i) Cyber-attack<sup>20</sup>** – The risk of a large cyber-attack significantly compromising critical information systems or data remains high despite progress in mitigation. There is a general increase in cyber-attacks globally, aiming to take advantage of the current crisis situation. Cybercriminals are exploiting the use of more vulnerable home-based systems and take advantage of fear and demand for information on the new virus to deliver malware, ransomware and phishing scams. A blurring of the line separating corporate and personal systems also heightens the risk of exposing sensitive information on personal devices. Gavi furthermore risks being targeted specifically due to increased visibility after the successful replenishment and as a prominent player in the COVID-19 response administering the COVAX Facility, potentially attracting anti-vaccine extremists and espionage on the COVAX Facility’s information assets. Recently, COVID-19 vaccine companies, government

<sup>20</sup> Previously called “IT disruption”. This risk has been reframed to focus more specifically on the aspects of data theft and disruption due to cyber-attacks, given that the Secretariat has made much progress in mitigating general IT disruption risk following past audit findings, and having stress-tested systems during the pandemic enabling all staff to keep working from home virtually.

organisations and cold chain infrastructure players have been targeted with phishing attacks by state or non-state actors, potentially aiming to steal technology, demand ransom or sabotage how vaccines are shipped, stored, kept cold and delivered. Gavi has strong policies and processes in place to prevent such phishing attacks and hacking attempts. The Secretariat is also working closely with core and expanded partners, CEPI and the Global Fund on security awareness and coordination of cyber-defence efforts, and seeks to intensify collaboration with external threat intelligence teams. A cyber security page has been added on the Gavi website including a link for external users to alert Gavi of suspicious activities and spoofing with the use of Gavi's identity.

**j) Partner capacity ▲** – The risk that the sum of comparative advantages of Alliance partners may be inadequate to effectively deliver required technical support to countries has increased with partner organisations being affected by the COVID-19 crisis with increased risk to staff well-being, mental health and productivity. Their capacity to deliver technical assistance in-country may also be impaired due to social distancing and travel restrictions, and delivery of a potential COVID-19 vaccine may divert attention and resources away from routine immunisation. As an indication, this year partners have only met 66% of agreed milestones overall, and in only 19% of countries they achieved 80% or more of all milestones, some of which might be explained by stretched partner capacities due to COVID-19. Furthermore, the Gavi 5.0 strategy may pose risks around changing partners' traditional technical assistance (TA) approaches in line with the strategic shifts, as well as risks related to accountability, coordination and measurability of cross-cutting TA priorities like equity in a broader partnership that is more complex to manage with more expanded and private sector partners and new types of partners, including humanitarian actors in conflict settings, civil society organisations (CSOs) and other local institutions. While WHO and UNICEF will remain the primary partners of the Alliance, it will be necessary to continue to diversify provision of TCA and scale-up technical assistance at subnational level to complement HSS. Over time, the aim is for up to 30% of TCA to be used to engage and build capacity of local partners with a focus on the zero-dose agenda.

**k) Secretariat disruption ▲** – The risk of significant disruption of Secretariat operations has now materialised with the COVID-19 pandemic and current risk exposure has increased as it could still have further impact if the pandemic continues or worsens. Although the ongoing work-from-home situation since the beginning of the pandemic is relatively manageable for most of the staff, an extended period of lockdowns will increase already mounting risks related to staff well-being, mental health and productivity. It may also become harder to maintain engagement and corporate cohesion with the lack of informal interactions, an increasing number of new staff and the introduction of new complex processes and approaches to our business in a new strategic period with an increased organisational mandate. At the same time, travel and security risk have virtually reduced to zero given the travel restrictions. Furthermore, being part of a COVID-19 vaccine roll-out will likely attract global attention on Gavi which can come with reputational and security risks in case of failures, AEFIs, or due to geopolitical tensions, social unrest and anti-vaccine sentiment and conspiracy theories surrounding COVID-19. Secretariat capacity issues have also become more critical (reflected in the increasing medium risk of *Secretariat capacity*) with a heightened workload across the Secretariat to respond to the COVID-19 impact on immunisation, to design and operationalise the COVAX Facility at record speed, and to prepare for the delivery of a potential COVID-19 vaccine. This is compounded with the corresponding need to service many additional governance meetings (with new bodies set up as part of the COVAX Facility governance structure, as well as robust governance engagement and oversight given the major strategic impacts and decisions) and intensive multi-stakeholder engagement. Staff capacity and institutional knowledge is also still at risk from potential COVID-19 related sick leaves or even deaths, combined with hiring and onboarding difficulties given travel restrictions. Furthermore, for Gavi 5.0, the increased focus on working in emergency, conflict and otherwise difficult operating contexts; providing more differentiated, tailored and targeted support for countries; ensuring coordination and collaboration with other health actors; and strengthening accountability, oversight and risk management across the Alliance all have the potential to significantly increase transaction costs and workload, and may require different competencies and expertise.

**l) Forecasting variability ▲** – The risk that Gavi forecasting variability drives inappropriate decision-making has increased. Greater uncertainty in the context of COVID-19 creates a higher risk of variability as compared to previously, with the exact trajectory of disease and its ultimate impact on immunisation programmes in Gavi supported countries difficult to predict. A “medium-risk scenario” was assumed for the vaccine forecast, defined as six months of an acute pandemic period, 12-24 months recovery with COVID-19 resurgence in some countries, a medium economic downturn and Gavi-supported countries substantially affected for 1-3 years. In the short term, there is increased uncertainty around new vaccine introductions and the pace of absorption of doses for ongoing programmes. In the longer-term, there is increased uncertainty around new vaccine introductions, resumption, and recovery of ongoing programmes to pre-COVID-19 levels, and delays in the Vaccine Investment Strategy (VIS) roll-out. Potential availability of a COVID-19 vaccine and its interaction with demand and supply of the existing portfolio of vaccines is also unclear for now. Some other areas of uncertainty have also the possibility to balance out, limiting the impact on the aggregate forecast, such as the implementation of the zero-dose strategy, or the targeted sub-national campaigns.

**p) Donor support ▼** – The risk of a significant reduction in donor support to Gavi has decreased since last year (but remains a top risk, with the potential to increase again going forward). Gavi’s successful replenishment at the Global Vaccine Summit in June 2020 had a result that exceeded the target, representing a huge vote of confidence in Gavi, Alliance partners and the collective mission. However, given the ongoing uncertainty and economic contractions in many Gavi donor countries due to the COVID-19 pandemic it is needed to remain vigilant to transform these pledges into full financial contributions. Furthermore, Gavi is now a prominent player in the global response to the COVID-19 pandemic, most notably as the administrator of the COVAX Facility and as such it is attracting global attention with global participation of 189 economies representing over 90% of the world’s population (making it the largest multilateral collaboration since the Paris Climate Agreement). This is a clear opportunity to further solidify and broaden donor support for Gavi, but in case of failures or (geo)political tensions related to COVID-19, Gavi could also be more vulnerable to reputational risk, including with potential consequences for donor support for core immunisation programmes. Furthermore, new fundraising efforts are being undertaken for the Gavi COVAX AMC. The risk that insufficient funding will be raised to fully capitalize the AMC is mitigated with a fundraising strategy that draws on carefully crafted advocacy campaign and on multiple funding sources, including ODA, innovative finance, working with MDBs as well as the private sector. More than US\$ 2 billion has been raised since mid-November. A further round of funding, at least US\$5 billion by the end of 2021, is required and a strategy being developed to fundraise for the next phase.

### 2.3. Applying a recalibrated risk appetite to Gavi’s top risk exposures

Being exposed to a high likelihood and/or potential impact of a risk can be acceptable, even if this does not mean the actual occurrence of the risk is desirable. This can be because the downside of the risk, if it were to materialise, is manageable or acceptable in light of the rewards being pursued, because exposure to the risk is required to achieve Gavi’s mission, or because the costs of mitigation or trade-offs with other risks are deemed too high. Gavi’s “risk appetite” defines its willingness to accept being exposed to risks in pursuit of its mission.

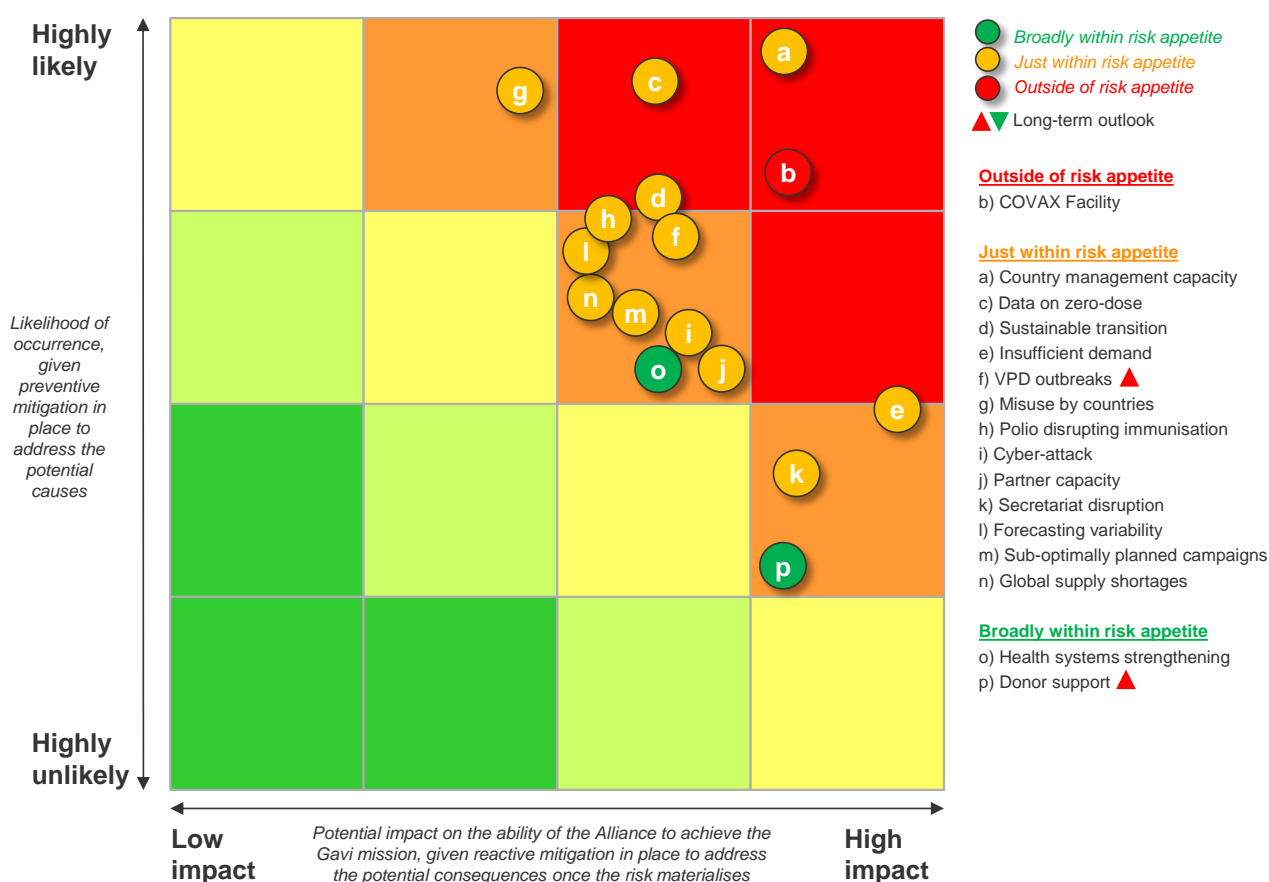
As per Gavi’s current Risk Appetite Statement<sup>21</sup> (based on the Gavi 4.0 strategic goals and enablers, see Annex II), the Alliance embraces the need to take programmatic risk given its ambitious mission and lean operating model, but it has a lower appetite for organisational risks affecting Alliance processes, systems and management, as well as for fiduciary oversight and control, and brand and stakeholder confidence. Gavi’s new strategy is inherently more risky as it represents a very aspirational ambition requiring more and novel support

<sup>21</sup> See: <https://www.gavi.org/sites/default/files/document/risk-appetite-statementpdf.pdf>

to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments<sup>22</sup>. Moreover, while inherently risks are heightened, mitigating these risks and obtaining assurance over the effectiveness of mitigation is now more complicated due to COVID-19 related restrictions and affected capacities. As a result, the Gavi Board needs to acknowledge that Gavi will need to accept some of this higher risk exposure as it is pursuing a riskier strategy in a riskier world, and faces limitations in its ability to mitigate some of these. It will be critical to reflect this in a recalibrated risk appetite (i.e. consciously accepting for some risks that they may materialise as part of pursuing our mission) and to continue to actively monitor and re-assess risks as they change or our understanding of them evolves. **This section includes (bolded) suggestions for such a recalibrated risk appetite**, which can serve (together with the Board’s guidance on this) as the basis for a subsequent update of Gavi’s Risk Appetite Statement to further specify and codify Gavi’s risk appetite for the Gavi 5.0 strategic period.

## Willingness to accept current top risk exposures

### Actual exposures reviewed against a recalibrated risk appetite



For each of the Alliance’s top risk exposures (as presented in the previous section), the Secretariat has interpreted what kind of risk appetite would be appropriate in pursuit of the Gavi mission under the current circumstances. While many top risks have increased this year, many are deemed just within risk appetite when a recalibrated risk appetite is applied, as described below (see bolded suggestions to recalibrate risk appetite) and in more detail in Annex IV. As depicted in the risk appetite heat map above, the top risks have been classified in three risk appetite categories where risks are clearly *outside of risk appetite* (i.e. risk exposures require intensive mitigation efforts or ceasing of activities that expose the Alliance to risk), *just within risk*

<sup>22</sup> See Section 3 of the 2019 Risk & Assurance Report: <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2019>



*appetite* (close to getting outside of risk appetite, requiring attention and ongoing mitigation), and *broadly within risk appetite* (current exposures are acceptable and risks only require monitoring). Where current exposures are not in line with risk appetite, further or more intensive mitigation measures are required to bring exposure (over time) within risk appetite (e.g. by enhancing existing or introducing new mitigation measures, changes in Gavi strategy or policies, or by ending certain activities that expose the Alliance to risk). Alternatively, the Board could choose to increase its risk appetite and acknowledge being exposed. The arrows next to each top risk in the risk appetite heat map show the expected long-term outlook of the risk exposures, which can increase (e.g. due to foreseeable trends in inherent or external risk factors), or decrease (due to trends in risk factors and / or due to the expected effect of ongoing or planned mitigation measures).

Annex IV contains a detailed description of each top risk and how current exposure compares to risk appetite.

### **Top risks outside of risk appetite – requiring intensive mitigation efforts**

**b) COVAX Facility** – The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, must find the right balance to successfully deliver on the promise of the Facility while minimising risks to Gavi core resources and programmes. Current risk exposure is however deemed outside of risk appetite until there is full clarity on the size of risks and possibilities to mitigate them. It therefore requires intensive mitigation efforts to bring the risk within risk appetite, including by continuing to surge capacity, implementing robust project and risk management and working with external advisors to fill critical skills and capacity gaps. Following the principle of safeguarding Gavi's assets and reputation, the Facility is being designed to avoid risk where possible, and residual risks are being actively monitored and mitigated. It is however also understood that operating at this magnitude and speed carries risks, and failure of establishing a successful Facility will also affect Gavi's overall reputation and have a negative effect on Gavi-supported countries.

### **Top risks just within risk appetite – requiring attention and ongoing mitigation**

Thirteen top risks are currently assessed as just within risk appetite. Three of these were deemed outside of risk appetite in previous years but are now deemed just within risk appetite given a reframing of the risks, progress in mitigation, and a recalibrated risk appetite. This is the case for **a) Country management capacity**, **c) Data on zero-dose** and **m) Sub-optimally planned campaigns**.

**a) Country management capacity** – This risk was previously defined more broadly and deemed outside of risk appetite. Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it was deemed not acceptable that EPI management capacity does not improve across the Gavi portfolio. It is now however proposed to **recalibrate Gavi's risk appetite** to more intentionally acknowledge that capacity-building takes a long time to take effect and sustainable mitigation depends on many factors outside of Gavi's control, such as government ownership, broader efforts across the health sector, turnover of staff, and external programme disruption such as conflict, natural disasters and disease outbreaks. Gavi will therefore need to accept some risk inherent in its mission and focus on those areas of country management capacity that are really critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities, and where Gavi has a comparative advantage over other actors to make a real difference with targeted, scalable and sustainable interventions. Current exposure is therefore deemed just within risk appetite and requires ongoing attention. To bring it more fully within appetite, an external evaluation of LMC is planned early next year to inform refinement of the approach and the ambition to scale-up and integrate LMC support as part of Gavi planning, programming and implementation processes. Gavi will also encourage LMC partners to work more explicitly and systematically with local institutions to build up strong local institutions capable of providing TA support, and will work with the Global Fund to address LMC beyond just EPI programmes. The Secretariat is furthermore proposing to the Board to make additional funding available (up

to US\$ 500 million in HSS grants and increased PEF funding) as part of a comprehensive approach to reach zero-dose children and missed communities. It is also proposed to institutionalise the approach to financial management capacity-building to ensure timely funding of activities at sub-national level to reach zero-dose communities.

**c) Data on zero-dose** – This risk was previously defined more broadly as *Data quality* and deemed outside of risk appetite. Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it was deemed not acceptable that data availability, quality and use do not improve across the Gavi portfolio. It is now however proposed to **recalibrate Gavi's risk appetite** to more intentionally acknowledge that parts of the broader data quality risk are not fully within Gavi's control and would likely remain a challenge for a long time. Gavi will therefore need to accept some risk inherent in its mission and focus on the critical types of data that if poor or lacking will affect the ability to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact; and which are addressable within Gavi's sphere of influence. Current exposure is therefore deemed just within risk appetite and requires ongoing attention. To bring it more fully within appetite, Gavi continues to rapidly scale up innovations on real-time data systems, triangulation of existing subnational data (both within immunisation and other sectors such as nutrition and education), enumeration of the distribution of zero-dose children, and geospatial mapping. It will also further optimise comparative advantages of the Alliance on data (e.g. through the roll-out of the Immunization Agenda 2030 data strategy in 2021) and ensure that disease surveillance and outbreak investigation data are used to identify, characterise, and reach unvaccinated populations, and available data from vaccine introductions and campaigns on missed communities will consistently translate into targeted and tailored strategies.

**m) Sub-optimally planned campaigns** – This risk was previously deemed outside of risk appetite as the Alliance normally has a low appetite for the risk of preventive immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term. As a result of COVID-19, the majority of planned campaigns have been postponed due to an initial SAGE recommendation to temporarily suspend these activities, followed by more nuanced guidance to carry out risk-benefit assessments when conducting mass immunisation activities. As more campaigns resume, it is expected that countries will need to spend more time planning to ensure adequate safety and effectiveness in the context of COVID-19, however, paradoxically the timing available between the decision to resume and the implementation may decrease driven by fear of outbreaks, thereby reducing the time to ensure all preparatory activities are conducted to a high standard. Once the immediate crisis abates, a large number of catch-up campaigns will likely be necessary in a short amount of time due to this backlog. The planning, implementation and resultant coverage in this context may be compromised along with the ability to conduct and ensure timely submission of post-campaign coverage surveys. In this current context it **may be necessary to accept** that not all campaigns will be optimally planned. Current exposure is therefore just within risk appetite and requires ongoing attention. The impact of COVID-19 on planned campaigns continues to be closely monitored together with partners.

One top risk has increased but remains just within risk appetite due to a suggested recalibration of risk appetite. This is the case for **g) Misuse by countries**.

**g) Misuse by countries** – The Alliance has kept a low appetite for the risk of deliberate fraudulent misuse occurring, or for any form of misuse occurring at scale. However, inherent risks are heightened in the current context and the ability to mitigate and obtain assurance is constrained. Since at the same time Gavi support is now more needed than ever, it is proposed to **recalibrate Gavi's risk appetite** to more intentionally acknowledge that misuse may increasingly occur despite best efforts to mitigate this risk. A differentiated

fiduciary risk appetite may also be needed in the context of Gavi 5.0, given the aspiration of reaching zero-dose children requiring to work more in challenging operating environments with very weak financial management capacity. Such a change will also help in striking a better balance between using and building country systems and staying within acceptable levels of fiduciary risk, enabling movement of funds back to government systems. With a differentiated risk appetite, the current exposure is just within risk appetite and requires ongoing attention. A differentiated risk appetite does not mean actual occurrence of the risk is desirable or the event should be tolerated once it actually occurs. In case of actual misuse, zero tolerance applies and Gavi will always require reimbursement as a condition of continued support.

Four risks were deemed broadly within risk appetite previous years, but now require more attention and ongoing mitigation as their risk levels have increased. This is the case for **f) VPD outbreaks**, **j) Partner capacity**, **k) Secretariat disruption**, and **l) Forecasting variability**.

**f) VPD outbreaks** – Fully addressing the significant gaps in Gavi-eligible countries' health systems and critical public health emergency preparedness and response capacities will require engagement beyond Gavi's current mission and resources. Furthermore, innovative efforts to increase routine coverage and reduce reliance on frequent and disruptive planned campaigns (see risk of "sub-optimally planned campaigns") **may also require a higher acceptance** of the risk of outbreaks. Current exposure is therefore just within risk appetite and requires ongoing attention. The Alliance accepts that there is significant risk that VPD outbreaks may continue to occur, so will continue to ensure that at-risk countries introduce Gavi-supported vaccines, and to emphasise the importance of preventive, rather than a reactive approach to outbreak-prone VPDs with in-country coordinating bodies and partners.

**j) Partner capacity** – The overall risk exposure is currently just within risk appetite and requires ongoing attention. The Alliance has overall a lower appetite for organisational risks that could impede its ability to deliver on the mission, for which partner capacity is critical. However, appetite for risks associated with the processes, systems and management of Alliance partners is moderately low, recognising that the Gavi Secretariat has less ability to directly influence this. Ensuring the right partners work at the right level with the right capacity and performance remains a key priority for Gavi. The vision for PEF in Gavi 5.0 is to sustain achieved gains in transparency, accountability, country focus and differentiation, and increasingly focus TA on zero-dose children and missed communities (the Secretariat is proposing to the Board to make additional PEF funding available for this), new partnerships (including increased engagement of local institutions and Civil Society Organisations) and sustainability.

**k) Secretariat disruption** – The Alliance has a low appetite for risks to Secretariat processes, facilities and people, since these are critical to coordinate the Alliance. Given the current situation, current exposure is just within risk appetite and requires ongoing attention. The Secretariat's crisis management team continues to monitor the evolution of the pandemic on a daily basis and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. Staff is kept informed and staff morale is supported through frequent newsletters, a dedicated intranet site, all-staff meetings, a staff survey to better understand challenges, radio breakfast shows and virtual wellness classes. The Secretariat also recalibrated its priorities for Gavi 5.0 and is bringing proposals for adjusting Secretariat resourcing to the Board as part of the ongoing organisational review of the Secretariat. Finally, a number of safety provisions were introduced in the Global Health Campus to be ready for a (gradual) return to the office once transmission rates allow this again.

**l) Forecasting variability** – Current exposure is just within risk appetite and therefore requires ongoing attention. More frequent updates to the forecast are being adopted this year to capture fast evolving assumptions, including greater integration of the forecast with various additional short-term data (e.g. shipments, disbursements, COVID-19 trackers). The Alliance has historically had a higher appetite for the risk

of forecasts being on the higher edge of the plausible range – to ensure availability of sufficient supply and funding. Recent forecasts have generally been consistent with this view. There is a lower appetite for the risk that such variability might reduce manufacturer or donor confidence and as forecasts reflecting higher scenarios will inherently have greater year-on-year variabilities in the forecast updates, assumptions, uncertainties and changes in forecasts are actively and regularly communicated.

Three other risks also increased a bit but are deemed to remain just within risk appetite. These are **d) Sustainable transition**, **e) Insufficient demand** and **h) Polio disrupting immunisation**.

**d) Sustainable transition** – Although the Alliance has a low appetite for the risk of *many* countries across the portfolio failing sustainable transition, it also recognises that it cannot completely guarantee that every country is ready to transition, in spite of its best efforts, and to avoid the risk of moral hazard. It is therefore willing to consider tailored approaches to support countries who are at high risk of not being ready for transition and have strong political commitment to immunisation, but it is also willing to consider a few countries failing where this is not the case (and therefore has a higher appetite for the risk that a *limited number of countries* may not transition successfully). The current high risk exposure for *some countries* failing sustainable transition is therefore just within risk appetite, and it continues to be needed to protect the significant gains made over the past years in increasing country ownership and financial sustainability of immunisation programmes. Safeguarding domestic financing for immunisation will remain a priority for Gavi in the next strategic period, together with the planned expanded focus on programmatic sustainability.

**e) Insufficient demand** – The Alliance has a low appetite for the risk of a sustained decline in demand and public confidence in vaccines in implementing countries, or in donor countries where this might impact their support to Gavi. Because current exposure is high mostly due to potential impact rather than likelihood, the risk is currently just within risk appetite and requires ongoing attention. It is important to monitor closely whether the risk increases in likelihood especially in Gavi countries, which may require further and more intensive mitigation efforts. Multi-stakeholder dialogues in Gavi-supported countries will inform how service delivery needs to be adapted to operate safely in the context of COVID-19, where intensified community engagement is required to rebuild trust and demand for services, and to identify children who have been missed and plan catch-up immunisation. Work underway to develop a more systematic approach to social listening and engagement through the Vaccine Demand Observatory that builds on UNICEF's global network and in-country communication capacity will help to understand specific reasons of vaccine hesitancy and define tailored responses.

**h) Polio disrupting immunisation** – The Alliance has a low appetite for the risk that routine immunisation is affected by polio resurgence or the loss of immunisation-critical assets due to polio transition in the weakest countries. As current exposure varies by country, the overall risk is just within risk appetite and requires ongoing attention. Continued proactive engagement with countries and partners is needed to determine the immunisation-critical functions most at risk, support transition planning with full country ownership and funding sources post bridge-funding, and incorporate aspects of polio transition into Joint Appraisals. New cVDPV outbreak response guidelines underline the need to address the root causes of the outbreak through improved microplanning, communication, service delivery quality as well as seek opportunities for integrated delivery of other vaccines and interventions. In Afghanistan and Pakistan there is now stronger coordination between polio eradication efforts and routine immunisation strengthening. As a core GPEI partner, Gavi is contributing to the revision of the Global GPEI strategy with the development of problem statements and will be engaged throughout the solution design phase. In addition, Gavi is the lead agency to help shape the Integrated Service Delivery workstream for both endemic and outbreak countries. This is an opportunity to shape an eradication programme that strategically and programmatically aligns on key areas related to Gavi 5.0 (i.e. essential immunisation strengthening and targeting of un- and under-vaccinated communities, government ownership and sustainable mechanisms of support).

Two other risks remained stable and remain just within risk appetite. These are **i) Cyber-attack** and **n) Global supply shortages**. See Annex IV for a detailed description of how current exposures compares to risk appetite.

#### Top risks broadly within risk appetite – to be monitored

Exposures for the remaining two top risks fall broadly within risk appetite. These are **o) Health Systems Strengthening**, and **p) Donor support**. It should be noted, however, that the long-term outlook is expected to increase for **p) Donor support** given the ongoing uncertainty and economic contractions in many Gavi donor countries due to COVID-19. It is important to continue to monitor whether the risk will move up again and continue strong advocacy efforts to secure donor pledges and to fundraise for the COVAX AMC in a constrained resource environment.

### 3. COVAX Facility risk assessment

In July 2020, the Gavi Board approved Gavi as the legal entity to administer the COVAX Facility, a global mechanism to pool resources and demand for COVID-19 vaccines with the goal of accelerating the availability of and equitable access to safe and efficacious vaccines. At its core, the COVAX Facility is a risk-management mechanism – reducing risk for countries concerned about failing to secure access to vaccines (or the candidates they have invested in bilaterally proving to be unsuccessful) and reducing risk for manufacturers concerned about investing without assured demand. The Board also approved the establishment of the Gavi COVAX Advance Market Commitment (AMC), a financing mechanism to ensure that low income and lower middle-income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as wealthier economies. The COVAX Facility has global participation of 189 economies (representing over 90% of the world’s population), consisting of both Self-Financing Participants (“SFP”) and 92 COVAX AMC-eligible economies (“AMC92”). Self-Financing Participants can choose a committed purchase arrangement, committing participants to purchase allocations of approved vaccines from the Facility, or an optional purchase arrangement, giving them the possibility to opt-out, either before Gavi enters into an agreement with a manufacturer (“window 1”) or later when Gavi provides purchase options for vaccines which have been allocated to the participant (“window 2”). With funding from both donors through the COVAX AMC and Self-Financing Participants, the Facility is reserving doses with manufacturers to build an actively managed portfolio of vaccine candidates based upon diverse technologies and geographies to maximise the chance of a successful outcome and accelerate access with up to two billion doses by the end of 2021. This shapes the vaccine market to expand supply and achieve economies of scale through aggregating demand and increasing availability simultaneously in developed and developing countries.

#### **Risks to the success of the Facility and Gavi’s reputation**

Without a successful COVAX Facility there is a very real risk that lower income countries will be left behind, and the majority of people in the world will go unprotected. This would allow the virus and the pandemic to continue unabated and continue to disrupt the global economy as well as Gavi’s core mission. The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, must therefore find the right balance to successfully deliver on the promise of the Facility while minimising risks to Gavi core resources and programmes. Following the principle of safeguarding Gavi’s assets and reputation, the Facility is being designed to avoid risk where possible, and residual risks are being actively monitored and mitigated. It is however also understood that operating at this magnitude and speed carries risks, and failure of establishing a successful Facility will also affect Gavi’s overall reputation and have a negative effect on Gavi-supported countries.

Entering into agreements with manufacturers rapidly is critical to reserve sufficient and timely volumes. There is a risk that **deal-making delays put the Facility at the back of the queue** with manufacturers. This could happen due to competition from bilateral deals or due to a lack of financial backing for deals. This risk is being mitigated by underlining the benefits of the Facility versus bilateral deals and exploring solutions together with an external financial risk advisor to ensure that sufficient financial backing is available (see also Financial risk below). Furthermore, all proposed deals with manufacturers are reviewed by the Market-Sensitive Decisions Committee (MSDC) to ensure reasonableness of terms and acceptable level of reputational risks, and the availability of resources to back proposed agreements.

Equitable access to safe and efficacious vaccines is the core objective of the Facility. There is a risk that **allocation and distribution of the vaccine is (perceived as) inequitable**. This could happen due to first available, most effective or safest vaccines being less suitable for lower income countries (e.g. requiring ultra cold chain, being expensive); using COVAX Facility funds too early for a less effective vaccine, when superior or cheaper products become available later; wealthy countries securing better deals bilaterally; or delivery

delays due to insufficient country readiness being perceived as inequitable access. This risk is being mitigated by a transparent and data-driven allocation mechanism (with validation by the Independent Allocation Validation Group (IAVG)) and a systematic approach to deciding which vaccine to make available in AMC countries balancing costs/feasibility versus equity (based on recommendations from the Independent Product Group (IPG) and with oversight from the Market-Sensitive Decisions Committee (MSDC)); keeping Facility deal information confidential and discouraging bilateral deals; and a proactive media and communications strategy globally and locally.

The COVAX Facility is a high-profile project with global participation. Running the Facility and the upcoming COVID-19 vaccine roll-out in countries will attract global attention on Gavi which can come with **reputational, political and security risks** in case of failures, serious adverse events following immunisation, or due to (geo)political tensions and conflicts of interest, social unrest and anti-vaccine sentiment and conspiracy theories surrounding COVID-19. There is also a heightened risk of **cyber-attacks and espionage** on the COVAX Facility's information assets and critical vaccine supply chain infrastructure in countries. This risk is being mitigated by enhanced cyber security, a proactive media and communications strategy globally and locally, proactive stakeholder management and a tailored COVAX Facility Governance structure (see also Governance risk below).

### **Financial risk**

As per the Gavi Board decision at its meeting in July 2020, Gavi is the legal entity administering the Facility. This means that Gavi will ultimately be assuming the financial risk exposure of the Facility. In order to protect Gavi's balance sheet, Gavi will not enter into firm order commitments with manufacturers in excess of the cash it has received and to the extent further commitments from participants (i.e. outstanding payments to Gavi) are secured (e.g. by robust guarantees, insurance or financial risk instruments), until residual financial risks are well understood and mitigated to the extent possible. This operating principle will considerably **limit financial risk exposure and liabilities** for Gavi, however there is a risk that this results in delays for deal-making (due to financial backing being insufficient at the time deals need to be signed), which may pose a risk to the success of the Facility (see also above). There may not be sufficient financial backing for deals due to **liquidity gaps** (e.g. due to cash flow mismatches, insufficient upfront funding or slow cash inflows from COVAX AMC donor pledges); an inability to secure and therefore leverage commitments from participants because they expose Gavi's balance sheet to **credit risk** (i.e. the risk of countries defaulting leaving them unable to pay or breaching contractual commitments and being unwilling to pay); actual prices turning out higher than the estimated weighted average price used for participant cost calculations; or by a potential COVAX AMC funding shortfall (see also below). To enable deal-making, solutions are being explored with an external financial risk advisor to ensure that sufficient financial backing is available through financial guarantees, sovereign default risk insurance and a liquidity facility. The advisor has created a high level framework to compartmentalise sovereign credit risk into four segments, based on credit ratings and a decision tree to determine viable risk mitigation strategies for each segment by utilising financial instruments and structures made available by Multilateral Development Banks (MDBs) and International Financial Institutions (IFIs). Solutions are also being explored for countries without high credit ratings which have not provided bank guarantees (including countries under the optional purchase arrangement once they opt in) or which provided guarantees which are not acceptable for MDBs/IFIs. Based on materiality, cost, and Gavi's cash absorption layer, Gavi could also decide to absorb some sovereign risk. Furthermore, a comprehensive operational cash flow model will help to understand liquidity needs, and the need for liquidity providers.

There is also a **risk of oversupply** resulting in financial liabilities in case manufacturer commitments exceed demand, which could happen when a higher proportion of vaccine candidates than anticipated achieve WHO prequalification (to protect against anticipated vaccine candidate failure the Facility will enter into agreements with manufacturers for additional doses beyond the 2 billion), or when a higher than anticipated number of SFPs with an optional purchase arrangement opt out at window 2 (after manufacturer agreements have been

signed and volumes committed). This is mitigated by a dynamic approach to managing the vaccine portfolio, i.e. having the possibility for each subsequent deal to adapt volumes and terms (e.g. by using optionality in manufacturer agreements, whereby Gavi has the option, rather than an obligation to purchase doses) based on latest vaccine efficacy data and known country opt-outs; countries losing their prepaid doses associated with the deal they opt out of; having received a risk sharing guarantee of US\$ 0.40/dose for optional purchase arrangements, which Gavi can draw on to cover liabilities in case of country opt-outs; and the possibility to absorb and reallocate oversupply to other participants via the allocation framework and the COVAX exchange.

There is also a risk of **insufficient funding being raised to fully capitalise the GAVI COVAX AMC**. This is mitigated with a fundraising strategy that draws on a carefully crafted advocacy campaign and on multiple funding sources, including ODA, innovative finance, working with MDBs as well as the private sector. More than US\$ 2 billion has been raised since mid-November. A further round of funding, at least US\$5 billion by the end of 2021, is required and a strategy is being developed to fundraise for the next phase.

### **Operational and Governance risk**

The COVAX Facility is a large, unique and structurally complex undertaking. It requires new processes, capacities and capabilities, and will involve increased volumes of activities and transactions compared to Gavi's regular business. It also requires extensive coordination, collaboration, stakeholder engagement and outreach with many partners involved with varying interests, as well as engagement with many new economies with which Gavi does not yet have established relationships (including economies under economic sanctions). To mitigate **operational risks associated with overstretched people, systems and processes** (which could also affect broader Secretariat capacity and distract from Gavi's core mission), the Office of the COVAX Facility is developing a full end-to-end operations plan, is hiring additional and dedicated resources, and has now a dedicated Managing Director. Outsourcing of treasury, accounting and banking services is also being explored. Furthermore, a tailored Governance structure ensures multi-stakeholder coordination and decision-making. The creation of many new governance bodies may however also further increase the burden on the Secretariat, including the Office of the COVAX Facility, to service these bodies. Changes in the Gavi governance structure (combined with political risk as described above) may also heighten risks regarding **conflicting or inconsistent Board decisions or disagreements**. This is mitigated by the Gavi Board being the ultimate decision-making body; having independent bodies providing non-politicised scientific and technical advice; the Audit and Finance Committee's (AFC) mandate extending over all of Gavi operations; and a COVAX Consensus group supporting consensus-based decision-making between various governing bodies, particularly in areas where disagreement may arise.

### **Programmatic risk**

Once COVID-19 vaccines will be available, countries need to be ready to receive, distribute and use the vaccines. Particularly in lower and middle-income countries, there is a risk of **delivery and roll-out delays due to insufficient country readiness**. This could happen due to vaccine licensing delays, countries' inability or unwillingness to take on liability for the vaccines (and indemnify manufacturers), or insufficient planning, financing or capacity for delivery (e.g. having inadequate cold chain capacity, especially in case of vaccines requiring ultra cold chain). Countries may also have limited management and service delivery capacity to roll this out broadly in a short amount of time. Furthermore, adapted delivery strategies to vaccinate COVID-19 specific target groups may not be well-established (e.g. for the elderly and people with comorbidities). The Gavi Board has approved the provision of US\$ 150 million in initial funding to jumpstart readiness support for COVAX AMC-eligible countries to deliver COVID-19 vaccines, to address the most urgent needs in terms of cold chain and technical assistance for planning vaccine introduction. However more support is needed from domestic budgets and the international community and the Alliance is coordinating with other donors, especially the multilateral development banks, to help countries secure these resources. Gavi is also proposing to the Board to set aside an additional US\$150 million that could be used in exceptional circumstances to cover critical gaps in some AMC countries that may not have access to alternative funding, and therefore are



at risk for a successful vaccine roll-out. Partners have worked intensely to develop integrated global frameworks, trainings, assessments, and planning and monitoring tools to guide countries (including a COVID-19 vaccine readiness assessment tool). Participants are also encouraged to promote and leverage regulatory convergence, collaboration and reliance to fast-track the path to vaccine licensure, and a Liability Task Force within COVAX is looking at ways to support countries with liability and indemnification issues.

Vaccines are currently seen as the ultimate way to end the acute phase of the pandemic and are therefore highly anticipated. There is however still a risk of **uncertain demand** related to the unknown evolution of the pandemic (countries' populations may have developed high levels of natural immunity by the time a vaccine is available or scale-up of diagnostics and therapeutics may reduce vaccine demand), political will and prioritisation (governments may prefer bilateral deals or may not prioritise addressing COVID-19 especially if it requires high levels of domestic funding) and public trust in the vaccine (people may distrust speedy development of new vaccines, mis- and disinformation on social media may affect confidence, a serious adverse event after immunisation may occur, or falsified vaccines may harm trust). This risk is being mitigated by advocacy, demand generation and building of community trust. UNICEF is developing a social listening and engagement approach and Alliance partners will support economies with information and advice to challenge misinformation and advocacy for vaccine benefits. UNICEF has also adapted the global interpersonal skills communication toolkit for COVID-19 response, and the Secretariat has stepped up cooperation with Alliance partners, Civil Society Organisations, private sector and others to amplify Gavi's voice and to increase impact. To mitigate **vaccine safety** risks (due to the speed and scale of both development and deployment), countries are being requested to adapt their surveillance and safety monitoring systems, considerations related to indemnification and consumer safety are being supported, and vaccines and delivery devices will be selected to minimise the risk of injuries from vaccines or handling and administration errors.

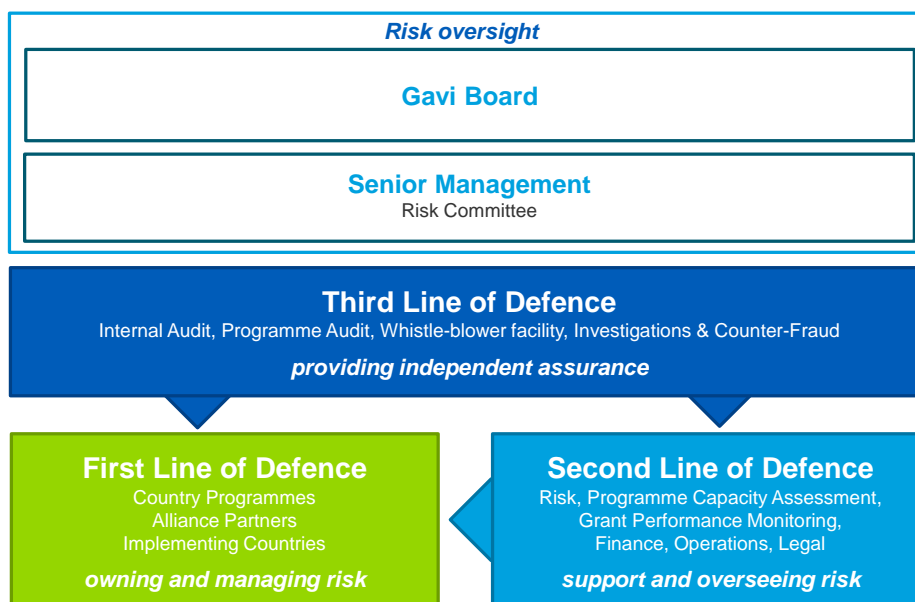
The distribution of COVID-19 vaccines in countries may be associated with a higher risk of **theft and diversion** than traditional Gavi-supported vaccines, given these are in low supply with potentially high demand and secondary markets exist (although they still require a sophisticated cold chain). They could also be diverted to non-target groups within countries or be used in exploitative transactions. There could also be a higher risk of **wastage** given the large amounts that will be flowing through the system, shorter shelf life initially and ultra cold chain requirements for some vaccines. The Secretariat is actively working on managing these risks and will closely monitor the utilisation of vaccines in COVAX AMC-eligible economies through country monitoring and reporting from an early stage. Through the vaccine request form that countries have to submit, target groups are agreed (as much as possible in line with WHO-SAGE guidance) and countries agree to reimburse all funding amounts (cash or the value of equipment, supplies or vaccine) that Gavi determines not to have been used for the programme or otherwise misused. The "COVID-19 Vaccine and Therapeutics Traceability Expert Advisory Board" (on which Gavi sits) has also started to address traceability to reduce diversion.

## Annex I – Gavi’s risk management and assurance model

Risk is everyone’s responsibility and risk management is an integral part of Gavi operations. Everyone working towards the Gavi mission is expected to pro-actively identify, assess, and manage risks. As stated in Gavi’s Risk Policy:

- The Gavi Board determines Gavi’s risk appetite, validates that effective risk management processes are established, and oversees that the most significant risks are being managed within Gavi’s risk appetite.
- The Secretariat translates the risk appetite into appropriate strategies and processes intended to anticipate and respond to risk, and implements these processes. Secretariat staff are responsible for identifying and managing risk in their daily work.
- Alliance partners are responsible for managing risks involved with Gavi activities and for alerting the Secretariat of risks that could affect Gavi’s mission.
- Implementing countries manage risks to the results being pursued with Gavi-funded programmes, and report these risks encountered in implementation.

Gavi has structured its risk management, control and assurance functions according to the Three Lines of Defence model, ensuring clear and distinct roles and objective checks, balances and controls. Its underlying premise is that, under the oversight and direction of senior management and the Board, three separate groups (or lines of defence) within the organisation are necessary for effective management of risk and control.



The responsibilities of each of the groups (or “lines”) are:

- **First line: owning and managing risk**  
Primary ownership sits with the business and process owners whose activities create and/or manage the risks that can facilitate or prevent an organisation’s objectives from being achieved. This includes taking the right risks. The first line owns the risk, and the design and execution of the organisation’s controls to respond to those risks.  
*Constituted by Country Programmes working with Alliance partners and implementing countries*
- **Second line: overseeing risk in support of management**  
The second line is put in place to support management by bringing specialised expertise, and coordinating, monitoring and overseeing risk management alongside the first line to help ensure that risk and control are effectively managed. While separate from the first line, they are still under the control and direction of senior management.  
*Constituted by the Risk function, Programme Capacity Assessment, Grant Performance Monitoring, Finance, Operations, and Legal*
- **Third line: providing independent assurance**  
An independent third line is providing objective assurance to the Board and senior management on the effectiveness of risk management and control by both the first and second line. Importantly, the third line has an independent reporting line to the Board – as well as senior management – to ensure its independence and objectivity.  
*Constituted by Audit & Investigations (Internal Audit, Programme Audit, Investigations & Counter-Fraud)*

*The current model is being reviewed based on learnings and in line with potential changes to the Secretariat structure.*

## Annex II – Gavi’s Risk Appetite Statement

Gavi’s Risk Appetite Statement defines on a broad level the amount of risk the Alliance is willing to take, accept, or tolerate in each area of its strategy.

### Gavi’s Risk Appetite Statement

The amount of risk the Alliance is willing to take, accept, or tolerate to achieve its goals

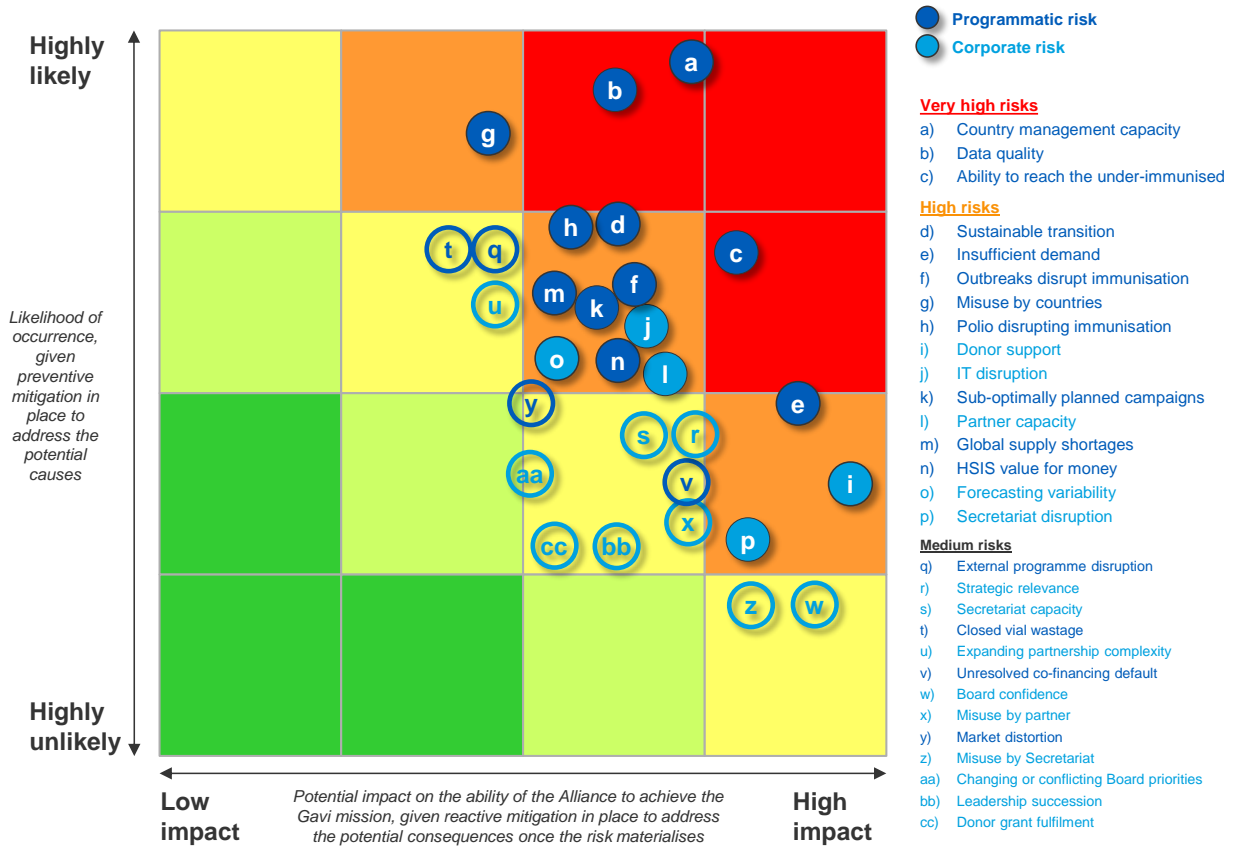
<b>Mission &amp; Organisation</b>	The Alliance embraces the need to take <b>programmatic risk</b> given its ambitious mission and operating model, but has a <b>lower appetite for organisational risks</b> impacting Alliance processes, systems and management; fiduciary oversight and control; and brand and stakeholder confidence.			
<b>Strategic Goals</b>	<b>1</b> Accelerate equitable uptake and coverage of vaccines	<b>2</b> Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems	<b>3</b> Improve sustainability of national immunisation programmes	<b>4</b> Shape markets for vaccines and other immunisation products
<b>High</b> <ul style="list-style-type: none"> <li>Risks required to increase C&amp;E and to accelerate introductions</li> <li>Risks required to respond to fragility and emergencies</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Vaccine introductions adversely impact routine immunisation</li> </ul>	<b>High</b> <ul style="list-style-type: none"> <li>Risks required to strengthen health systems</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Misuse of Gavi support</li> <li>Weak systems jeopardise vaccine / immunisation safety</li> </ul>	<b>Moderately low</b> <ul style="list-style-type: none"> <li>Significant reduction in performance post-transition</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Countries transition with low coverage and / or capacity</li> <li>Countries default on co-financing</li> </ul>	<b>High</b> <ul style="list-style-type: none"> <li>Risks required to create and sustain healthy markets</li> </ul> <b>Moderately low</b> <ul style="list-style-type: none"> <li>Supply shortages</li> </ul>	<b>Monitoring &amp; evaluation</b>
<b>Strategic enablers</b>	<b>Country leadership, management &amp; coordination</b>	<b>Resource mobilisation</b>	<b>Advocacy</b>	<b>Monitoring &amp; evaluation</b>
<b>High</b> <ul style="list-style-type: none"> <li>Risks required to strengthen country capacity</li> </ul> <b>Moderately high</b> <ul style="list-style-type: none"> <li>Risks of operating in countries with limited capacity</li> </ul>	<b>High</b> <ul style="list-style-type: none"> <li>Risks required for innovative financing and private sector partnerships</li> </ul> <b>Moderate</b> <ul style="list-style-type: none"> <li>Risks required to attract new donors</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Reduction in donor support</li> <li>Reputational risks or potential conflicts of interest</li> </ul>	<b>High</b> <ul style="list-style-type: none"> <li>Risks required to ensure recognition of value of vaccines</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Immunisation becoming lower priority on policy agendas</li> <li>Reputational risks</li> </ul>	<b>Moderately high</b> <ul style="list-style-type: none"> <li>Risks of working in settings with weak data systems</li> </ul> <b>Moderate</b> <ul style="list-style-type: none"> <li>Risks to grant monitoring and oversight at country level</li> </ul> <b>Low</b> <ul style="list-style-type: none"> <li>Risks impacting accountability and transparency in Alliance</li> </ul>	

See for the full statement: <http://www.gavi.org/library/gavi-documents/policies/risk-appetite-statement/>

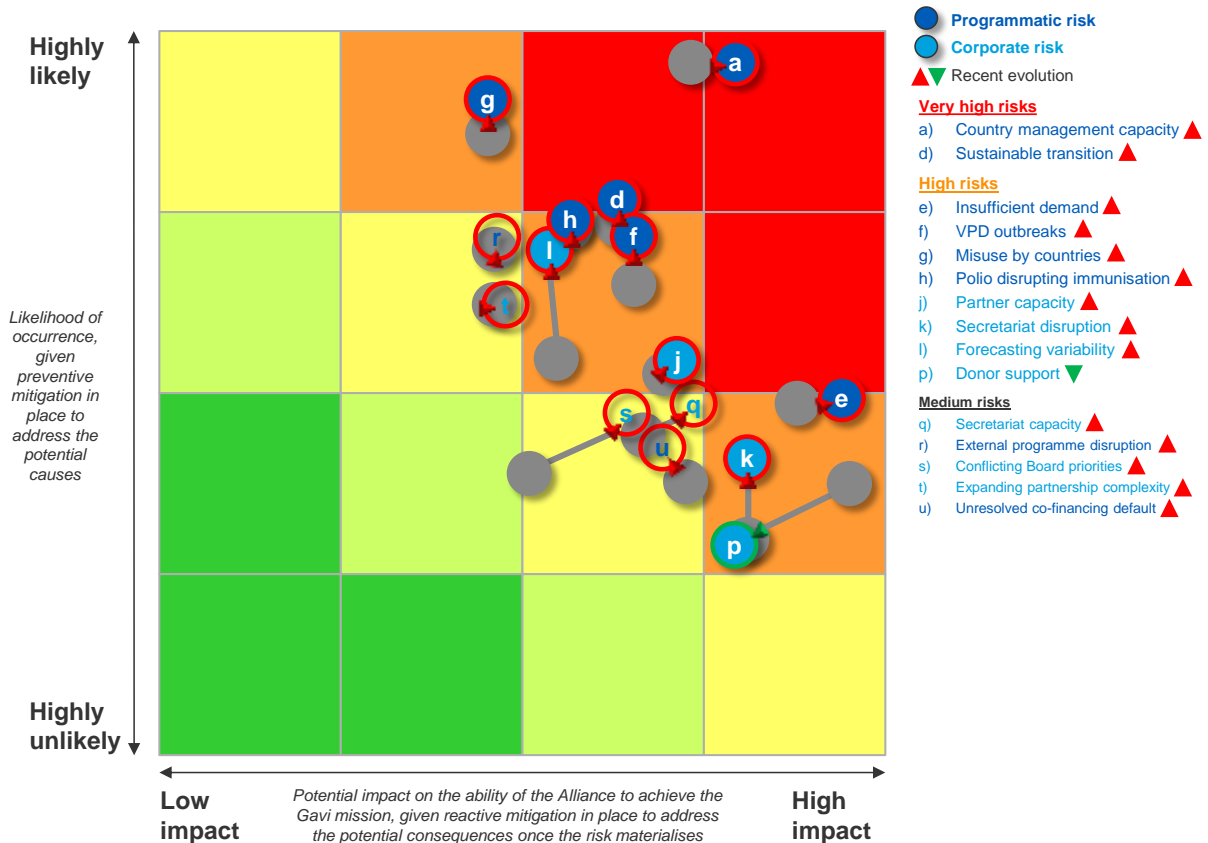
The current statement will be updated to bring it in line with the recalibrated risk appetite required for Gavi 5.0

## Annex III – Last year’s top risk profile and trajectory of changes this year

### 2019 residual risk exposure, taking into account existing mitigation



### Trajectory of the evolved top risks since last year



## Annex IV – Individual top risk descriptions

### a) Country management capacity

*Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Country management capacity</b> Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption (conflict, natural disasters, disease outbreaks, political change/devolution)</li> </ul>			JUST WITHIN		

During the Gavi 5.0 strategic period, there is a greater need to work more sub-nationally, in remote rural areas and in conflict settings, where most zero-dose children live. Naturally, many Gavi countries' Expanded Programme on Immunization (EPI) units have weak management capacity, even more so at subnational levels, and especially in fragile countries. Existing capacity can also easily be disrupted due to instability, shocks or political change (such as devolution), or due to retention challenges. Developing sufficient and resilient national and subnational capacity is crucial for countries to manage immunisation programmes and Gavi support, and to be ready for a sustainable transition out of Gavi support. The impact of weak capacity in areas such as leadership, management and coordination, financial management, and programme implementation cuts across all in-country work of the Alliance and can increase a number of other risks, such as misuse of Gavi support and poor data quality.

To manage this risk, Gavi assesses capacity-building needs through a range of tools including Joint Appraisals, Programme Capacity Assessments, Effective Vaccine Management assessments, Transition Assessments and country visits. Country management capacity gaps continue to be addressed with technical assistance targeted at improving leadership and management capacities in the EPI units; strengthening national Inter-Agency Co-ordinating Committees (ICCs) by revising their mandate, membership and oversight function; and enhancing financial management (a number of capacity building engagements are beginning to bear fruit). The most promising interventions include institutional restructuring of EPI units, embedded management support, data-use for decision making and performance management, and providing management training programmes (25 countries have taken the Yale EPI management training, and supply chain management training (STEP) is being developed jointly with the Global Fund).

Current exposure to this risk has increased. While between 2017 and 2019 institutional capacity scores have improved with 50% less countries having "weak" capacity and twice as much having "satisfactory" capacity, maintaining the gains is a challenge with EPI staff turnover, external disruption and stronger countries transitioning out of Gavi support. With the current pandemic we have seen delays in implementing Leadership, Management and Coordination (LMC) programmes, and existing capacity may be diverted to respond to COVID-19 or may suffer from absenteeism and fatalities, and may get diverted by the delivery of a potential COVID-19 vaccine. Moreover, increased capacity may be needed to plan and coordinate a large amount of catch-up campaigns to restore coverage levels after vaccine introductions and campaigns were suspended during lockdowns. Reaching missed communities and zero-dose children under Gavi 5.0 will also likely require greater country management capacity, including sub-nationally and in challenging environments.

Previous years this risk was defined more broadly and deemed outside of risk appetite. Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it was deemed not acceptable that EPI management capacity does not improve across the Gavi portfolio. It is now however proposed to

recalibrate Gavi's risk appetite to more intentionally acknowledge that capacity-building takes a long time to take effect and sustainable mitigation depends on many factors outside of Gavi's control, such as government ownership, broader efforts across the health sector, turnover of staff, and external programme disruption such as conflict, natural disasters and disease outbreaks. Gavi will therefore need to accept some risk inherent in its mission and focus on those areas of country management capacity that are really critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities, and where Gavi has a comparative advantage over other actors to make a real difference with targeted, scalable and sustainable interventions. Current exposure is therefore deemed just within risk appetite and requires ongoing attention. To bring it more fully within appetite, an external evaluation of LMC is planned early next year to inform refinement of the approach and the ambition to scale-up and integrate LMC support as part of Gavi planning, programming and implementation processes. Gavi will also encourage LMC partners to work more explicitly and systematically with local institutions to build up strong local institutions capable of providing TA support, and will work with the Global Fund to address LMC beyond just EPI programmes. The Secretariat is furthermore proposing to the Board to make additional funding available (up to US\$ 500 million in HSS grants and increased PEF funding) as part of a comprehensive approach to reach zero-dose children and missed communities. It is also proposed to institutionalise the approach to financial management capacity-building to ensure timely funding of activities at sub-national level to reach zero-dose communities.

## b) COVAX Facility

### *Failure to establish a successful COVAX Facility*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
b. <b>COVAX Facility</b> Failure to establish a successful COVAX Facility	<ul style="list-style-type: none"> <li>• Competition from bilateral deals</li> <li>• Inability to secure deals in time</li> <li>• (Perception of) inequitable allocation and distribution</li> <li>• Insufficient funding, liquidity, risk management</li> <li>• Overstretched people, processes, systems</li> <li>• Ineffective coordination, project management, governance</li> </ul>			<b>OUTSIDE</b>	<b>NEW</b>	

Gavi is the legal entity administering the COVAX Facility, a global mechanism to pool resources and demand for COVID-19 vaccines with the goal of accelerating the availability of and equitable access to safe and efficacious vaccines. The COVAX Facility has global participation of 189 economies (representing over 90% of the world's population), consisting of both Self-Financing Participants ("SFP") and 92 COVAX AMC-eligible economies ("AMC92"). With funding from both donors through the COVAX AMC and Self-Financing Participants, the Facility is reserving doses with manufacturers to build an actively managed portfolio of vaccine candidates based upon diverse technologies and geographies to maximise the chance of a successful outcome and accelerate access with up to two billion doses by the end of 2021. This shapes the vaccine market to expand supply and achieve economies of scale through aggregating demand and increasing availability simultaneously in developed and developing countries. Without a successful COVAX Facility there is a very real risk that lower income countries will be left behind, and the majority of people in the world will go unprotected. This would allow the virus and the pandemic to continue unabated and continue to disrupt the global economy as well as Gavi's core mission.

Current exposure to this risk is very high as the COVAX Facility is being established in record time and has to navigate uncharted territory in securing equitable access to potential COVID-19 vaccines. It is a large, unique and structurally complex undertaking which requires new processes, capacities and capabilities, and will involve increased volumes of activities and transactions compared to Gavi's regular business. It also requires extensive coordination, collaboration, stakeholder engagement and outreach with many partners involved with varying interests, as well as engagement with many new economies with which Gavi does not yet have established relationships (including economies under economic sanctions). To mitigate operational risks associated with overstretched people, systems and processes (which could also affect broader Secretariat

capacity and distract from Gavi's core mission), the Office of the COVAX Facility is developing a full end-to-end operations plan, is hiring additional and dedicated resources, and has a dedicated Managing Director. Outsourcing of treasury, accounting and banking services is also being explored. A tailored Governance structure ensures multi-stakeholder coordination and decision-making. Furthermore, since Gavi is the legal entity administering the Facility, Gavi will ultimately be assuming the financial risk exposure of the Facility and needs to protect its balance sheet and minimise risks to Gavi core resources and programmes. In order to protect Gavi's balance sheet, Gavi will not enter into firm order commitments with manufacturers in excess of the cash it has received and to the extent further commitments from participants (i.e. outstanding payments to Gavi) are secured (e.g. by robust guarantees, insurance or financial risk instruments), until residual financial risks are well understood and mitigated to the extent possible. This operating principle will considerably limit financial risk exposure and liabilities for Gavi, however there is a risk that this results in delays for deal-making (due to financial backing being insufficient at the time deals need to be signed), which may pose a risk to the success of the Facility (see also above). There may not be sufficient financial backing for deals due to liquidity gaps (e.g. due to cash flow mismatches, insufficient upfront funding or slow cash inflows from COVAX AMC donor pledges); an inability to secure and therefore leverage commitments from participants because they expose Gavi's balance sheet to credit risk (i.e. the risk of countries defaulting leaving them unable to pay or breaching contractual commitments and being unwilling to pay); actual prices turning out higher than the estimated weighted average price used for participant cost calculations; or by a potential COVAX AMC funding shortfall (see also below). To enable deal-making, solutions are being explored with an external financial risk advisor to ensure that sufficient financial backing is available through financial guarantees, sovereign default risk insurance and a liquidity facility. The advisor has created a high level framework to compartmentalise sovereign credit risk into four segments, based on credit ratings and a decision tree to determine viable risk mitigation strategies for each segment by utilising financial instruments and structures made available by Multilateral Development Banks (MDBs) and International Financial Institutions (IFIs). Solutions are also being explored for countries without high credit ratings which have not provided bank guarantees (including countries under the optional purchase arrangement once they opt in) or which provided guarantees which are not acceptable for MDBs/IFIs. Based on materiality, cost, and Gavi's cash absorption layer, Gavi could also decide to absorb some sovereign risk. Furthermore, a comprehensive operational cash flow model will help to understand liquidity needs, and the need for liquidity providers.

The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, must find the right balance to successfully deliver on the promise of the Facility while minimising risks to Gavi core resources and programmes. Current risk exposure is however deemed outside of risk appetite until there is full clarity on the size of risks and possibilities to mitigate them. It therefore requires intensive mitigation efforts to bring the risk within risk appetite, including by continuing to surge capacity, implementing robust project and risk management and working with external advisors to fill critical skills and capacity gaps. Following the principle of safeguarding Gavi's assets and reputation, the Facility is being designed to avoid risk where possible, and residual risks are being actively monitored and mitigated. It is however also understood that operating at this magnitude and speed carries risks, and failure of establishing a successful Facility will also affect Gavi's overall reputation and have a negative effect on Gavi-supported countries.

### c) Data on zero-dose

*Poor or lacking data may affect the ability of the Alliance to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Data on zero-dose</b> Poor or lacking data may affect the ability of the Alliance to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact	<ul style="list-style-type: none"> <li>• More precise data is not available</li> <li>• Existing data is not shared</li> <li>• Data is not timely</li> <li>• Data is not used effectively to identify children</li> <li>• Poor data culture, capacity and systems</li> </ul>			<b>JUST WITHIN</b>		

Reaching missed communities and zero-dose children requires more precise data to identify where unreached populations are and to measure the impact of interventions to reach them. Missed communities are often not visible through existing data systems and assessments, as they have limited or no access to health and social services, are often politically marginalised and may not be officially registered or recognised. A lack of cost-effective and quality data to identify and immunise zero-dose children would adversely impact the ability to prioritise, find and target missed communities, implement effective interventions, understand progress, and demonstrate impact on the equity agenda.

To manage this risk, Gavi continues to work with countries, core and expanded partners to strengthen the availability and use of quality data for immunisation, now with a specific focus on measuring whether children have been immunised, whether they have been brought into the routine health system, and why they are missed to design the right interventions to reach them. There is continued work towards a common Alliance view on how to identify missed communities and engagement with partners on sub-national data, advocacy of data needs, and data sharing (a data sharing agreement with GPEI is being finalised). Existing national level data work is being shifted to partners to free up Secretariat capacity to focus more on zero-dose data. Gavi is furthermore supporting countries to strengthen their capacity to triangulate data from multiple sources (e.g. health management information systems, logistic information systems, surveys, and geospatial mapping) to generate quality evidence to inform management of country EPI programmes. The CDC has developed guidance to support countries in their triangulation of data. The Secretariat also conducted several strategic analyses to explore possible use of subnational administrative and geospatial data to monitor immunisation coverage and equity more precisely and in real-time. The Secretariat furthermore generated a landscape analysis of all geographic information system (GIS) related evidence, supported the development of country guidance for use of GIS data, and is starting to identify partners for scale-up. WHO has been working to catalogue, summarise, and categorise the various equity tools and guidance documents for countries. Work on landscaping targeted survey methodologies is ongoing and aims to improve understanding of equity dimensions in targeted areas, improve zero-dose monitoring, and identify where efforts need to be targeted to maintain and restore immunisation services following COVID19. UNICEF is working on guidance for small area equity assessments through geospatial mapping with a focus on urban slums. Furthermore, several strategic analyses are ongoing to understand the distribution and characteristics of zero-dose children and missed communities, e.g. the link between zero-dose and poverty, geographical concentration of zero-dose children within a country, and the overlap between zero-dose children and other primary health care (PHC) services.

Current exposure to this risk is very high due to the shift from using data to measure coverage in Gavi 4.0 to needing to use (different types of) data to target interventions in Gavi 5.0, which requires more granular, sub-national and geospatial data. It also requires timely data, which was already a challenge during Gavi 4.0 with WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) being highly lagged and subject to retrospective revision. An analysis of data needs required in Gavi 5.0 has identified significant gaps in the data



required for identification of missed communities. The hypothesis that zero-dose children are clustered in pockets also still needs to be tested.

Previous years this risk was defined more broadly and deemed outside of risk appetite. Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it was deemed not acceptable that data availability, quality and use do not improve across the Gavi portfolio. It is now however proposed to recalibrate Gavi's risk appetite to more intentionally acknowledge that parts of the broader data quality risk are not fully within Gavi's control and would likely remain a challenge for a long time. Gavi will therefore need to accept some risk inherent in its mission and focus on the critical types of data that if poor or lacking will affect the ability to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact; and which are addressable within Gavi's sphere of influence. Current exposure is therefore deemed just within risk appetite and requires ongoing attention. To bring it more fully within appetite, Gavi continues to rapidly scale up innovations on real-time data systems, triangulation of existing subnational data (both within immunisation and other sectors such as nutrition and education), enumeration of the distribution of zero-dose children, and geospatial mapping. It will also further optimise comparative advantages of the Alliance on data (e.g. through the roll-out of the Immunization Agenda 2030 data strategy in 2021) and ensure that disease surveillance and outbreak investigation data are used to identify, characterise, and reach unvaccinated populations, and available data from vaccine introductions and campaigns on missed communities will consistently translate into targeted and tailored strategies.

#### d) Sustainable transition

*Some countries may fail to sustain progress of their immunisation programmes after transition*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Sustainable transition</b> Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> <li>Lack of (subnational) ability/capacity/fiscal space</li> <li>Poor preparation for transition by Alliance</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Overs reliance on external support</li> <li>Lack of access to global markets and expertise</li> <li>External programme disruption (economic, outbreaks)</li> </ul>			JUST WITHIN		

Gavi support is intended to be time-limited and catalytic. Countries are therefore expected to finance a growing share of the cost of their programmes as their gross national income (GNI) approaches the eligibility threshold, until they are fully self-financing. Both programmatic and financial sustainability are key elements to support successful transitions from Gavi support. Failure to successfully transition or a regression after transition would diminish the return on Gavi's investments and could have an impact on Gavi's reputation and the perceived viability of the model. Furthermore, it may affect manufacturers' pricing decisions for countries post-transition if they perceive a higher risk that countries will not sustain their programmes.

To manage this risk, Gavi's approach to sustainability continues to emphasise the importance of engaging early with countries to build and strengthen the financing, systems, and capacities needed to deliver on sustainable coverage and equity. This is also firmly embedded into different Gavi systems and processes (e.g., Joint Appraisals, TCA support, Full Portfolio Planning). Transitioning countries have a transition plan and countries at high risk for transition have tailored strategies with Accountability Frameworks in place or under development. Countries nearing transition undergoing Full Portfolio Planning are developing their transition plans as an integral part of this process. Countries also share their experiences and learn from each other through dedicated platforms, such as the Learning Network for Countries in Transition (LNCT), a peer-exchange network for transitioning and transitioned countries. Under the Sustainable Financing for Health Accelerator (SFHA) of the Global Action Plan for Healthy Lives and Wellbeing for All (GAP), there is enhanced collaboration with other global partners in the context of transition and financing on issues such as domestic

resource mobilisation for vaccines and PHC, addressing public financial management bottlenecks, alignment of national priorities and partners' engagement. As part of the ongoing policy review process, it is envisioned that in exceptional cases where countries are not on track for a successful transition, as defined by set coverage and equity criteria that are being developed, the accelerated transition phase can be tailored, allowing those countries for more time and tailored support to enhance country readiness for transition. Furthermore, the Alliance continues to provide time-limited, catalytic post-transition support in already transitioned countries to mitigate residual post-transition risks. In addition, in June the Board approved targeted support to former Gavi-eligible countries to address the risk of backsliding in the context of COVID-19 and the Secretariat is on track to operationalise the support. The Secretariat is also bringing forward a proposal for consideration by the Board regarding Gavi's Approach for engagement for middle-income countries (MICs).

Current exposure to this risk has increased again (after decreasing last year given the positive trend of successful transitions, post-transition support being rolled-out and an increased focus on programmatic sustainability under Gavi 5.0). The continued worldwide spread of COVID-19 has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' transition trajectories, their fiscal space for co-financing and risks of backsliding in already transitioned countries. To ensure immunisation services were not disrupted, the Board exceptionally approved flexibility to provide co-financing waivers in 2020 and 2021 on a case-by-case basis. At the same time, Gavi and its Alliance partners, in particular the World Bank, have been engaging with countries to mitigate the impact of the pandemic on their ability to co-finance and protect the significant gains achieved in strengthening the financial sustainability of immunisation programmes. As a result, despite fiscal constraints related to COVID-19, countries so far show good progress on co-financing payments in 2020. Risks however continue to be heightened as the economic context remains unpredictable, creating uncertainty around the magnitude and duration of the current downturn. Going forward, immunisation financing, including vaccine financing, will likely be affected by a shrinking fiscal space and stronger competition from other sectors for scarce resources, with fewer resources being available to countries due to lower government revenues following the economic contraction during the pandemic, accompanied by higher sovereign debt and withdrawal of the COVID-related external support.

Although the Alliance has a low appetite for the risk of *many* countries across the portfolio failing sustainable transition, it also recognises that it cannot completely guarantee that every country is ready to transition, in spite of its best efforts, and to avoid the risk of moral hazard. It is therefore willing to consider tailored approaches to support countries who are at high risk of not being ready for transition and have strong political commitment to immunisation, but it is also willing to consider a few countries failing where this is not the case (and therefore has a higher appetite for the risk that a *limited number of countries* may not transition successfully). The current high risk exposure for *some countries* failing sustainable transition is therefore just within risk appetite, and it continues to be needed to protect the significant gains made over the past years in increasing country ownership and financial sustainability of immunisation programmes. Safeguarding domestic financing for immunisation will remain a priority for Gavi in the next strategic period, together with the planned expanded focus on programmatic sustainability.

## e) Insufficient demand

*Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<p><b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation</p>	<ul style="list-style-type: none"> <li>Lack of knowledge / information about immunisation</li> <li>Hesitancy due to mistrust/fear</li> <li>Anti-vax sentiment, politicization, fake vaccines</li> <li>Logistical barriers, lack of motivation, prioritisation</li> <li>Poor quality services / experience</li> <li>Weak government systems for generating demand</li> </ul>			JUST WITHIN		

High levels of caregiver and community demand are critical to successfully reach every child and community with vaccines. It can be insufficient due to vaccine hesitancy (which ranges from accepting only some vaccines to delaying to outright refusal) or due to immunisation not being actively prioritised by parents as both a right and responsibility. Vaccine confidence depends on trust in the effectiveness and safety of vaccines, in the system that delivers them (including the reliability and competence of the health services and health professionals), and in the motivations of policymakers. It can also be rapidly undermined by adverse events following immunisation (AEFIs) as well as rumours and anti-vaccine sentiment, which are typically based on misinformation that can spread rapidly on social media and is often actively promoted by anti-vaccine movements driven by ideology, religion, false beliefs, and increasingly political and commercial motives. Demand can also be hindered by a lack of convenient access to health facilities. In areas that have been the focus for many immunisation campaigns, households may become accustomed to services being delivered at their doorstep and therefore less willing to actively seek immunisation at a health facility. Similarly, poor service quality, long waiting times, a lack of toilets or distance from facilities may deter some families from seeking immunisation. A significant drop in demand for vaccines or an insufficient increase in demand among those who are not yet actively seeking immunisation, would affect Gavi's ability to achieve its coverage and equity ambitions, including reaching missed communities. Lack of demand can adversely impact vaccine introductions and / or coverage, which in turn leads to increased morbidity and mortality and reduced programme impact. It can furthermore lead to programme delays and vaccine wastage. Gavi could also face reputational challenges and Alliance staff could become the target of extreme anti-vaccine movements. Ultimately, a significant and sustained loss of demand for vaccines could affect political will and reduce support among donor and implementing countries for Gavi's mission.

To manage this risk, the Alliance's demand generation framework includes building vaccine confidence and trust as a central component. In the context of COVID-19 and widespread disruptions to services at community level caused by lockdowns, partner coordination and engagement has been stepped up significantly through the Demand Hub, which clarifies partner roles and responsibilities and coordinates support to countries based on a roadmap with priority workstreams on social and behavioural data, service experience, behavioural interventions, digital engagement, and civil society and community engagement. To help understand the impacts of the pandemic on the demand side of immunisation, WHO has fast tracked the development of the new survey tools to assess the behavioural and social drivers for vaccination (BeSD) both for childhood vaccination and introduction of COVID-19 vaccine. UNICEF is supporting the development of an intensified approach to social listening and engagement, providing hands on support to four countries in West Africa, developing a field guide for addressing vaccine related misinformation and bringing the integrated approach together through the development of the Vaccine Demand Observatory. Core Alliance partners WHO, UNICEF and IFRC are supporting a unified risk communication and community engagement approach at country level which includes a focus on ensuring that demand for immunisation remains high in the context of COVID-19. UNICEF has also adapted the global interpersonal skills communication toolkit for COVID-19 response, and Sabin is rolling out an online version of their journalist training. To help tackle misinformation and vaccine hesitancy, the Secretariat has increased its media engagement through both proactive and reactive strategies, including increasing the frequency of undertaking interviews, social media, and harnessing Gavi's flagship VaccinesWork platform amongst other mediums. The Secretariat has also stepped up cooperation with Alliance partners, Civil Society Organisations, private sector and others to amplify Gavi's voice and to increase impact. There is increased engagement with new non-traditional partners and Private Sector Partnerships, and new demand generation work is undertaken in COVAX and ACT-A workstreams.

Current exposure to this risk has increased due to COVID-19 lock-down measures and fear of visiting health clinics (~80% of countries are reporting reductions in demand for services), as well as vaccine hesitancy due to mis- and disinformation about vaccines (with surveys pointing to widespread reluctance to accept a COVID-19 vaccine and COVID-19 rumours and conspiracy theories potentially spilling over into routine vaccines). The risk also becomes more important under Gavi 5.0 with demand generation being critical to reach missed

communities, including through strategies to overcome gender-related barriers and increased civil society and community engagement. As the Alliance looks to extend immunisation services and more children will get a first dose of pentavalent vaccine, Gavi will have to ensure drop-out does not increase through an intensified focus on demand, to ensure that caregivers are fully aware of the need and motivated to bring their children back for all required vaccines.

The Alliance has a low appetite for the risk of a sustained decline in demand and public confidence in vaccines in implementing countries, or in donor countries where this might impact their support to Gavi. Because current exposure is high mostly due to potential impact rather than likelihood, the risk is currently just within risk appetite and requires ongoing attention. It is important to monitor closely whether the risk increases in likelihood especially in Gavi countries, which may require further and more intensive mitigation efforts. Multi-stakeholder dialogues in Gavi-supported countries will inform how service delivery needs to be adapted to operate safely in the context of COVID-19, where intensified community engagement is required to rebuild trust and demand for services, and to identify children who have been missed and plan catch-up immunisation. Work underway to develop a more systematic approach to social listening and engagement through the Vaccine Demand Observatory that builds on UNICEF's global network and in-country communication capacity will help to understand specific reasons of vaccine hesitancy and define tailored responses.

## f) VPD outbreaks

### *Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>VPD outbreaks</b> Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries.	<ul style="list-style-type: none"> <li>• Low population immunity, vaccine hesitancy</li> <li>• Climate change, urbanisation, deforestation, globalization, migration and human displacement, population growth</li> <li>• Lack of capacity/tools to detect, prevent and respond</li> <li>• External programme disruption (conflict, disasters)</li> </ul>			JUST WITHIN		

Outbreaks of vaccine-preventable diseases can occur in Gavi-supported countries when immunisation coverage is low. They are also expected to occur more frequently in the future due to deforestation and urbanisation increasing human exposure to zoonotic disease reservoirs and urbanisation, globalisation, travel and population movement allowing for diseases to circulate quicker. Climate change may cause mosquitos who transmit diseases to change their geographical footprint and an increase in natural disasters from climate change may create the right conditions for outbreaks more frequently. Furthermore, weak country capacity for surveillance and disease diagnosis, and low routine coverage may exacerbate the effects of outbreaks, which, if uncontained, can also spread to neighbouring countries and beyond.

To manage this risk, Gavi provides vaccine support for many diseases with outbreak potential including measles, meningitis, cholera, yellow fever, typhoid, ebola and polio. For many of these diseases, Gavi supports multiple elements of disease control including routine immunisation, preventive campaigns, and outbreak response (including vaccine stockpiles). The Gavi 5.0 strategy recognises a stronger role and more deliberate focus on Global Health Security (GHS) and enhancing outbreak response through stockpiles. Gavi provides some support to countries for country-level disease surveillance and global and regional surveillance, as well as strengthening yellow fever diagnostic capacity in Africa. Gavi furthermore supports vaccine stockpiles and provides operational funding to implement outbreak response (Cholera, Yellow fever, Meningitis and Ebola stockpiles are managed by the ICG and an outbreak response fund for Measles is managed by MRI), including the undertaking of outbreak root cause analysis with linkages to RI planning and strengthening. To sustain population immunity Gavi provides routine and preventive campaign support for yellow fever, measles and meningococcal meningitis, targeted pre-emptive OCV campaigns in cholera hotspots, and HSS investments in RI strengthening. The Fragility, Emergencies and Refugees policy provides flexibilities to conduct preventive immunisation for refugees.

Current exposure to this risk has increased with COVID-19 disrupting routine immunisation services (which is reported to have dropped significantly in ~40% of countries). This is resulting in decreased coverage rates for vaccines against outbreak prone diseases and threatening population level immunity which in turn increases the risk of vaccine-preventable disease (VPD) outbreaks. Furthermore, most planned preventive campaigns and several approved outbreak response activities have been postponed along with routine vaccine introductions. Disease surveillance systems have also been disrupted, which is likely to impact the ability of countries to quickly detect and respond to outbreaks. To reduce the risk of VPD outbreaks, the Alliance is working to support countries with the safe resumption of delayed preventive campaigns along with the maintenance of routine immunisation services as a key essential health service throughout the duration of the pandemic as stressed in WHO guidance and Gavi's efforts to Maintain, Restore and Strengthen immunisation in the context of COVID-19. This includes ensuring available funding to ensure children missed before, during and after the pandemic are quickly caught, primarily through routine immunisation services. Furthermore, the Secretariat is considering proposing to the Board increased investments in disease surveillance, which if approved may assist with earlier detection and response to VPD outbreaks.

Fully addressing the significant gaps in Gavi-eligible countries' health systems and critical public health emergency preparedness and response capacities will require engagement beyond Gavi's current mission and resources. Furthermore, innovative efforts to increase routine coverage and reduce reliance on frequent and disruptive planned campaigns (see risk of "sub-optimally planned campaigns") may also require a higher acceptance of the risk of outbreaks. Current exposure is therefore just within risk appetite and requires ongoing attention. The Alliance accepts that there is significant risk that VPD outbreaks may continue to occur, so will continue to ensure that at-risk countries introduce Gavi-supported vaccines, and to emphasise the importance of preventive, rather than a reactive approach to outbreak-prone VPDs with in-country coordinating bodies and partners.

## g) Misuse by countries

### *Deliberate misuse of Gavi support in some Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
9 Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> <li>• Culture of gifts/corruption</li> <li>• Opportunity for personal gain</li> <li>• Weak monitoring/deterrence</li> <li>• Weak institutions and systems</li> </ul>			JUST WITHIN		

Gavi uses country systems (supply chains for vaccines and financial management systems for funds) whenever possible, in order to ensure country ownership of programmes (and encourage commitment, accountability, budget visibility, and domestic and donor funding harmonisation and alignment) and to build the sustainable capacity of countries to manage those programmes, which is critical for development especially as countries approach transition. However, as the Alliance works with the poorest countries in the world, many have weak systems, low capacity, poor governance and management, and / or prevailing corruption, and this exposes the Alliance to the risk of its support being misused (deliberately as well as by mistake). The inherent risk is particularly high for cash programmes which account for about 25% of Gavi's programmatic expenditure – the remainder being vaccines procured through UNICEF, which in general are less prone to theft and diversion, due to a lack of secondary markets and the need for a sophisticated cold chain to manage them. Inherent exposure is increasing – both due to the increase in the value of cash grants and the increasing concentration of those grants in countries with weaker systems (as stronger countries transition). Misuse can have a financial cost to Gavi if not reimbursed and it reduces the programmatic impact of its investments. It can result in the suspension of cash support to countries, undermining their programmes, and create significant transaction costs to manage that support and address fiduciary risks. Significant or sustained cases of misuse

can impact the reputation of the Alliance, potentially undermining donor and Board confidence. Misuse can also be an indicator of weak overall systems which may impede countries' ability to effectively manage their programmes and successfully transition out of Gavi support.

To manage this risk, the Secretariat has strengthened grant oversight by Senior Country Managers and budget, expenditure and support by a specialist Programme Finance team engaging with countries to fix fiduciary risk challenges and improve budgeting and reporting. Furthermore, before a new grant cycle starts, Programme Capacity Assessments (PCAs) assess a country's capacity to manage support which, together with other intelligence (internal knowledge of the country context and risks, internal and external audit reports, and external assessments if available) inform Gavi's grant management requirements (GMRs) and fiduciary measures. These can be conditional to disbursement and / or to be addressed during implementation. Key tools for fiduciary risk mitigation and assurance include annual independent external audits, the use of Program Management Units (PMUs) within Government implementing agencies, embedded Fiduciary Agents and independent Monitoring Agents. Many of these cases have been implemented in partnership with other donor agencies, in particular The Global Fund and World Bank. For the high-risk activity of procurement Gavi has frequently turned to UNICEF as the Alliance partner with core skills in this area. At a country and grant level, leveraging off PCA and audit findings, Gavi has engaged more effectively in addressing risks by ensuring countries strengthen their risk mitigation capabilities through grant inputs e.g. stronger human resources, removal of riskier activities and stricter budget discipline. For countries that lack basic capacity, Gavi can also decide to channel funds through alternative channels (historically Alliance partners, but alternative models that can provide more embedded fiduciary monitoring and assurance are being explored), while continuing to strengthen country systems with financial management capacity-building, so the Alliance can revert to using them ( number of capacity building initiatives have taken place which have seen countries such as Cote D'Ivoire and Tanzania move back to full use of Government systems in 2020). Furthermore, Programme Audits are conducted periodically with higher risk programmes being covered more frequently. Gavi also has an anonymous and confidential whistle-blower hotline to which anyone can report suspected wrongdoings, and has a dedicated fraud investigator to follow up on any suspected cases. In case of actual misuse, zero tolerance applies and Gavi will always require reimbursement as a condition of continued support (to date close to 95% payments have been received against scheduled reimbursement for misuse found by Programme Audits).

Current exposure to this risk has increased during the pandemic. In times of crisis, economic uncertainty, low morale and financial pressures may drive more wrongdoers to commit and rationalise fraud as more opportunities arise due to a weakened internal control environment and possibilities to take advantage of people's fear and distraction. Gavi also provided increased (emergency) funding to help countries respond to the pandemic and maintain, restore and strengthen immunisation programmes, using a fast-tracked application and review process. At the same time, travel restrictions continue to impair grant oversight and assurance in Gavi-supported countries. Programme Audits have been suspended until January 2021 and in-country assurance providers such as fiduciary and monitoring agents are often restricted in the scope of their activities due to social distancing measures. To protect Gavi investments during the COVID-19 crisis, the Secretariat is maintaining standard fiduciary requirements with some flexibilities applied on a case-by-case basis. Where possible, Gavi-funded assurance providers are adapting their procedures through remote working options and e-solutions. Furthermore, some de-risking of programmes is taking place by curtailing risky activities or moving them to lower risk implementers. The Secretariat also remains closely aligned with other agencies on their approaches to fiduciary risk and sharing intelligence. Furthermore, a Financial Management Working Group is focussing on the 5.0 approach to accelerate the movement of funds back to government systems while at the same time keeping fiduciary risk at an acceptable level. The Secretariat is also proposing to the Board to institutionalise the approach to fiduciary risk assurance and financial management capacity-building introduced in Gavi 4.0 through the creation of a discrete fund, clear portfolio targets and enhanced accountability. Finally, the distribution of COVID-19 vaccines in countries may be

associated with a higher risk of theft and diversion than traditional Gavi-supported vaccines, given these are in low supply with potentially high demand and secondary markets exist (although they still require a sophisticated cold chain). They could also be diverted to non-target groups within countries or be used in exploitative transactions. The Secretariat is actively working on managing these risks and will closely monitor the utilisation of vaccines in COVAX AMC-eligible economies through country monitoring and reporting from an early stage. Through the vaccine request form that countries have to submit, target groups are agreed (as much as possible in line with WHO-SAGE guidance) and countries agree to reimburse all funding amounts (cash or the value of equipment, supplies or vaccine) that Gavi determines not to have been used for the programme or otherwise misused. The “COVID-19 Vaccine and Therapeutics Traceability Expert Advisory Board” (on which Gavi sits) has also started to address traceability to reduce diversion.

The Alliance has kept a low appetite for the risk of deliberate fraudulent misuse occurring, or for any form of misuse occurring at scale. However, inherent risks are heightened in the current context and the ability to mitigate and obtain assurance is constrained. Since at the same time Gavi support is now more needed than ever, it is proposed to recalibrate Gavi’s risk appetite to more intentionally acknowledge that misuse may increasingly occur despite best efforts to mitigate this risk. A differentiated fiduciary risk appetite may also be needed in the context of Gavi 5.0, given the aspiration of reaching zero-dose children requiring to work more in challenging operating environments with very weak financial management capacity. Such a change will also help in striking a better balance between using and building country systems and staying within acceptable levels of fiduciary risk, enabling movement of funds back to government systems. With a differentiated risk appetite, the current exposure is just within risk appetite and requires ongoing attention. A differentiated risk appetite does not mean actual occurrence of the risk is desirable or the event should be tolerated once it actually occurs. In case of actual misuse, zero tolerance applies and Gavi will always require reimbursement as a condition of continued support.

## h) Polio disrupting immunisation

*Polio resurgence may adversely affect routine immunisation*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Polio disrupting immunisation</b> Polio resurgence may adversely affect routine immunisation	<ul style="list-style-type: none"> <li>• Eradication challenges / Vaccine-derived outbreaks</li> <li>• Reliance on GPEI staff/assets, weak national systems</li> <li>• Delayed transition plans, incomplete polio asset mapping</li> <li>• GPEI funding cuts / uncertain fund-raising for new strategy</li> </ul>			JUST WITHIN		

Over the last three decades, the Global Polio Eradication Initiative (GPEI) has built infrastructure for disease surveillance, social mobilisation, and vaccine delivery with the goal to eradicate polio worldwide. In many countries, especially those that have already eliminated polio, this infrastructure is also used beyond polio eradication, supporting routine immunisation, measles campaigns, maternal and child health programmes, disease surveillance, and outbreak response. GPEI has also pioneered capabilities and tools to improve micro-planning, use of data to drive programme management decisions, and population tracking, which is beneficial when mainstreamed into routine immunisation programmes. As eradication approaches, GPEI will sunset and ramp down its financial support for activities in countries that have eliminated polio. GPEI has therefore initiated planning with countries to map polio assets and determine the functions that can be repurposed to support broader health goals. A poorly managed transition of immunisation-critical assets (particularly related to disease surveillance, outbreak response and programme planning and management) would lead to public health capacity being lost in some countries that would have an adverse impact on national immunisation programmes including on efforts to improve coverage and equity and conduct high-quality supplemental immunisation activities. However, the eradication effort has experienced recent setbacks in Pakistan and Afghanistan where there has been a resurgence of wild poliovirus transmission. In addition, in an increasing number of countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2

(and some type 1) outbreaks are increasing due to low type 2 immunity following the global switch from trivalent to bivalent oral polio vaccine in 2016 (IPV provides individual protection but does not prevent the occurrence and spread of outbreaks). Outbreak response activities using monovalent oral polio type 2 vaccine risk themselves to cause further vaccine-derived poliovirus cases in under-immunised populations (especially in areas with poor sanitation and hygiene), until a new, more genetically stable vaccine is developed. Potential increased emergence and spread of wild and vaccine-derived poliovirus could divert public health capacity and resources away from routine immunisation, lead to a loss of confidence in vaccines (if people perceive the vaccine is reintroducing polio) and to increased resistance against polio immunisation from populations that see other diseases or primary needs as higher priorities. It could furthermore lead to reputational damage regarding immunisation (with Gavi now engaged through IPV and the Polio Oversight Board) if we fail to deliver the promise of a world free of polio.

To manage this risk, GPEI is assessing the contribution of polio assets to routine immunisation programmes and where gaps will arise if those activities cease (or where this presents an opportunity to strengthen routine immunisation by repurposing assets). Gavi's annual Joint Appraisals are including this information in country discussions to understand risks and opportunities to immunisation programmes associated with polio budget decreases and prioritise the functions they wish to maintain. GPEI's participation in Joint Appraisals, particularly in endemic and polio high-risk countries, is encouraged by both partnerships. Through HSIS and PEF TCA, Gavi can provide time-limited bridge-funding support to countries to mainstream key functional areas of polio into routine immunisation programmes. While priority countries now have mapped polio assets, they have not always realistically captured the range of immunisation functions that polio is performing on the ground, and numbers will need to be updated with the adoption of the new GPEI strategic plan. Important country-level polio budget information and the impact on immunisation-critical functions are still not systematically incorporated into Joint Appraisal preparations and planning discussions.

Current exposure to this risk has increased as the pre-COVID-19 resurgence of wild polio virus (WPV) and vaccine-derived polio virus (cVDPV) have been exacerbated by the programme pauses and disruptions of preventive and outbreak response campaigns, resulting in even lower population immunity and increased transmission. There is now more transmission of WPV in the endemics (Afghanistan and Pakistan), further spread of cVDPV2 and emergence of cVDPV1. Of particular concern is the spread of cVDPV2 given the low levels of type 2 protection and risk of the vaccine used for outbreak response (mOPV2) seeding further transmission until nOPV2 (novel oral poliovirus vaccine type 2), a more genetically stable live-attenuated oral vaccine, is rolled out in early 2021 (just having received Emergency Use Listing approval).

The Alliance has a low appetite for the risk that routine immunisation is affected by polio resurgence or the loss of immunisation-critical assets due to polio transition in the weakest countries. As current exposure varies by country, the overall risk is just within risk appetite and requires ongoing attention. Continued proactive engagement with countries and partners is needed to determine the immunisation-critical functions most at risk, support transition planning with full country ownership and funding sources post bridge-funding, and incorporate aspects of polio transition into Joint Appraisals. New cVDPV outbreak response guidelines underline the need to address the root causes of the outbreak through improved microplanning, communication, service delivery quality as well as seek opportunities for integrated delivery of other vaccines and interventions. In Afghanistan and Pakistan there is now stronger coordination between polio eradication efforts and routine immunisation strengthening. As a core GPEI partner, Gavi is contributing to the revision of the Global GPEI strategy with the development of problem statements and will be engaged throughout the solution design phase. In addition, Gavi is the lead agency to help shape the Integrated Service Delivery workstream for both endemic and outbreak countries. This is an opportunity to shape an eradication programme that strategically and programmatically aligns on key areas related to Gavi 5.0 (i.e. essential immunisation strengthening and targeting of un- and under-vaccinated communities, government ownership and sustainable mechanisms of support).



## i) Cyber-attack

### *Large cyber-attack significantly compromising critical information systems or data*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Cyber-attack</b> Large cyber-attack significantly compromising critical information systems or data	<ul style="list-style-type: none"> <li>• Cyber-attack, phishing and malware</li> <li>• Internal or external data breach</li> <li>• Systems failure and data loss</li> </ul>			JUST WITHIN		

The Secretariat increasingly makes use of automated systems and centralised cloud-based data repositories to support collaboration and maximise work efficiency. This mitigates risks related to human error and process delays, but the increasing reliance on technology also exposes the Secretariat to technology-related risks. A large cyber-attack, phishing and malware could lead to theft of sensitive data and business disruption due to IT systems failure and data loss. This could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and externally, an inability to complete disbursements to countries, partners or employees, or an inability to approve, manage, and monitor grants. It could also result in financial fraud or exploitation. Beyond its direct impact, it can lead to reputational impact and erode stakeholder trust.

To manage this risk, the Secretariat has implemented several measures which include internet traffic monitoring and filtering, single sign-on with multi-factor authentication, local file encryption, an improved network landscape in the Global Health Campus, and annual security scans. The Secretariat has furthermore implemented a Security Operations Centre and security incident and alerts monitoring (SIEM) on the Gavi network in collaboration with the Global Fund. Digital security training and awareness sessions have also been rolled out. Gavi's cloud-based systems provide a level of redundancy and back-up across key systems. In addition, the Secretariat has implemented an independent back-up solution which provides the ability to restore key data at a transactional level. A data classification project introduced a formal framework for data classification and tools and controls for information protection. Gavi is also implementing business continuity and IT disaster recovery plans, based on a business impact analysis of IT systems' unavailability on Gavi's operations. User awareness on security risks (including phishing and sharing of documents and data) continues to be enhanced based on a 2-year awareness plan with specific focus on high profile users, IT staff with elevated privileges and COVAX Facility users. Processes have been put in place to ensure swift response and recovery to security related attacks (e.g. incident response team; preparedness, response and recovery playbooks for malware and Gavi account, website and social media compromise) and additional controls will be delivered as part of the Security programme in 2021. A Business Continuity and IT Security Committee oversees the implementation of security policies, validates data classification and reviews incident response plans.

Current exposure to this risk remains high despite progress in mitigation. There is a general increase in cyber-attacks globally, aiming to take advantage of the current crisis situation. Cybercriminals are exploiting the use of more vulnerable home-based systems and take advantage of fear and demand for information on the new virus to deliver malware, ransomware and phishing scams. A blurring of the line separating corporate and personal systems also heightens the risk of exposing sensitive information on personal devices. Gavi furthermore risks being targeted specifically due to increased visibility after the successful replenishment and as a prominent player in the COVID-19 response administrating the COVAX Facility, potentially attracting anti-vaccine extremists and espionage on the COVAX Facility's information assets. Recently, COVID-19 vaccine companies, government organisations and cold chain infrastructure players have been targeted with phishing attacks by state or non-state actors, potentially aiming to steal technology, demand ransom or sabotage how vaccines are shipped, stored, kept cold and delivered. Gavi has strong policies and processes in place to prevent such phishing attacks and hacking attempts. The Secretariat is also working closely with core and

expanded partners, CEPI and the Global Fund on security awareness and coordination of cyber-defence efforts, and seeks to intensify collaboration with external threat intelligence teams. A cyber security page has been added on the Gavi website including a link for external users to alert Gavi of suspicious activities and spoofing with the use of Gavi's identity.

The Alliance has a low appetite for the risk of critical information systems or data being compromised, since these are critical to coordinate the Alliance. The current exposure is therefore just within appetite and requires ongoing attention. The Secretariat seeks to maintain robust processes and management, and reliable and secure systems, to prevent interruption of core systems and business-critical operations.

## j) Partner capacity

*Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Partner capacity</b> Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries.	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> <li>Lack of accountability / performance</li> </ul>			JUST WITHIN		

Alliance core and expanded partners play a critical role in the Alliance's ability to deliver on its mission and strategy, including by setting norms and standards in immunisation, procuring vaccines, providing technical information for Gavi policies and strategies, and providing technical and capacity-building support to countries to strengthen their immunisation programmes. Partners' collective capacity to provide the full range of support which countries require is therefore critical. The ambitious goals of the current strategy require intensified support to countries including assistance in areas that go beyond the traditional comparative advantages of core partners. It also requires that the support is truly country-owned and better coordinated across partners.

To manage this risk, the Partners' Engagement Framework (PEF) model leverages the comparative advantage of core partners (WHO, UNICEF, World Bank and CDC) as well as over 60 expanded partners, bringing new areas of comparative advantage. It has focussed on delivering more partner capacity directly to countries (with technical support now provided at subnational level in ~20 countries), and further enhanced the effectiveness, efficiency and transparency of collaboration with core partners. Technical Assistance (TA) guidance includes a specific section on 'Transfer of skills' detailing the objective and approach for it, and the PEF Management Team oversees TA delivery in 20 priority countries with continued attention to lessons learned based on independent reviews. Gavi is continuing to empower countries to assess their technical assistance needs and the quality of technical assistance provided, as well as expanding the pool of providers including local institutions, where appropriate. Furthermore, PEF milestones have been aligned with the countries' Theory of Change and the Grant Performance Framework indicators, to reinforce alignment of PEF Targeted Country Assistance (TCA) with Gavi's other in-country investments.

Current exposure to this risk has increased with partner organisations being affected by the COVID-19 crisis with increased risk to staff well-being, mental health and productivity. Their capacity to deliver technical assistance in-country may also be impaired due to social distancing and travel restrictions, and delivery of a potential COVID-19 vaccine may divert attention and resources away from routine immunisation. As an indication, this year partners have only met 66% of agreed milestones overall, and in only 19% of countries they achieved 80% or more of all milestones, some of which might be explained by stretched partner capacities due to COVID-19. Furthermore, the Gavi 5.0 strategy may pose risks around changing partners' traditional technical assistance (TA) approaches in line with the strategic shifts, as well as risks related to accountability, coordination and measurability of cross-cutting TA priorities like equity in a broader partnership that is more

complex to manage with more expanded and private sector partners and new types of partners, including humanitarian actors in conflict settings, civil society organisations (CSOs) and other local institutions. While WHO and UNICEF will remain the primary partners of the Alliance, it will be necessary to continue to diversify provision of TCA and scale-up technical assistance at subnational level to complement HSS. Over time, the aim is for up to 30% of TCA to be used to engage and build capacity of local partners with a focus on the zero-dose agenda.

The overall risk exposure is currently just within risk appetite and requires ongoing attention. The Alliance has overall a lower appetite for organisational risks that could impede its ability to deliver on the mission, for which partner capacity is critical. However, appetite for risks associated with the processes, systems and management of Alliance partners is moderately low, recognising that the Gavi Secretariat has less ability to directly influence this. Ensuring the right partners work at the right level with the right capacity and performance remains a key priority for Gavi. The vision for PEF in Gavi 5.0 is to sustain achieved gains in transparency, accountability, country focus and differentiation, and increasingly focus TA on zero-dose children and missed communities (the Secretariat is proposing to the Board to make additional PEF funding available for this), new partnerships (including increased engagement of local institutions and Civil Society Organisations) and sustainability.

## k) Secretariat disruption

### *Significant disruption of Secretariat operations*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>• Loss of workplace and facilities</li> <li>• Incident or loss of life in the workplace</li> <li>• Security threats and kidnapping during travel</li> <li>• Departures of key staff with critical knowledge</li> <li>• Unforeseen catastrophic event or crisis situation</li> </ul>			JUST WITHIN		

A catastrophic event significantly disrupting Secretariat operations could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and externally, an inability to complete disbursements to countries, partners or employees, or an inability to approve, manage, and monitor grants. This could manifest itself through the loss of access to a Gavi workplace facility, the loss of key infrastructure, or the loss of personnel. Potential causes include a natural or man-made disaster, a substantial security threat to staff, or the departure of a large number of key staff. The Secretariat is located in a place with limited exposure to natural disasters and terrorism, however staff are (normally) frequently travelling to countries with high security threat levels, and the growing profile of Gavi may attract more anti-vaccine extremists.

To manage this risk, there are ongoing building maintenance checks, fire and smoke detectors in all locations, and ongoing monitoring of local political and social events and weather forecasts. Fire evacuation plans exist, and drills are performed regularly. Business travel is subject to medical and security risk assessments and travellers' destinations are being monitored with a watch list. Travel to High and Extreme risk locations requires approval. Security training, security escorts, medical kits and vaccinations are available to travellers and there is a limitation on the number of team members or senior executives travelling together. Travel security processes are being reviewed jointly with The Global Fund, and audited for high and extreme destinations, with a bespoke plan by country produced, including thorough briefs and comprehensive safety and security manuals. Employees have also followed respectful workplace training to protect a culture of tolerance and respect, including training on ethical behaviour on Gavi missions. To enhance reactive mitigation measures for all areas, the Secretariat is developing a crisis management framework with emergency response plans and recovery arrangements to ensure crisis management and business continuity after a crisis.

This risk has now materialised with the COVID-19 pandemic and current risk exposure has increased as it could still have further impact if the pandemic continues or worsens. Although the ongoing work-from-home situation since the beginning of the pandemic is relatively manageable for most of the staff, an extended period of lockdowns will increase already mounting risks related to staff well-being, mental health and productivity. It may also become harder to maintain engagement and corporate cohesion with the lack of informal interactions, an increasing number of new staff and the introduction of new complex processes and approaches to our business in a new strategic period with an increased organisational mandate. At the same time, travel and security risk have virtually reduced to zero given the travel restrictions. Furthermore, being part of a COVID-19 vaccine roll-out will likely attract global attention on Gavi which can come with reputational and security risks in case of failures, AEFIs, or due to geopolitical tensions, social unrest and anti-vaccine sentiment and conspiracy theories surrounding COVID-19. Secretariat capacity issues have also become more critical (reflected in the increasing medium risk of *Secretariat capacity*) with a heightened workload across the Secretariat to respond to the COVID-19 impact on immunisation, to design and operationalise the COVAX Facility at record speed, and to prepare for the delivery of a potential COVID-19 vaccine. This is compounded with the need to service many additional governance meetings (with new bodies set up as part of the COVAX Facility governance structure, as well as robust governance engagement and oversight given the major strategic impacts and decisions) and intensive multi-stakeholder engagement. Staff capacity and institutional knowledge is also still at risk from potential COVID-19 related sick leaves or even deaths, combined with hiring and onboarding difficulties given travel restrictions. Furthermore, for Gavi 5.0, the increased focus on working in emergency, conflict and otherwise difficult operating contexts; providing more differentiated, tailored and targeted support for countries; ensuring coordination and collaboration with other health actors; and strengthening accountability, oversight and risk management across the Alliance all have the potential to significantly increase transaction costs and workload, and may require different competencies and expertise.

The Alliance has a low appetite for risks to Secretariat processes, facilities and people, since these are critical to coordinate the Alliance. Given the current situation, current exposure is just within risk appetite and requires ongoing attention. The Secretariat's crisis management team continues to monitor the evolution of the pandemic on a daily basis and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. Staff is kept informed and staff morale is supported through frequent newsletters, a dedicated intranet site, all-staff meetings, a staff survey to better understand challenges, radio breakfast shows and virtual wellness classes. The Secretariat also recalibrated its priorities for Gavi 5.0 and is bringing proposals for adjusting Secretariat resourcing to the Board as part of the ongoing organisational review of the Secretariat. Finally, a number of safety provisions were introduced in the Global Health Campus to be ready for a (gradual) return to the office once transmission rates allow this again.

## I) Forecasting variability

### *Gavi forecasting variability drives inappropriate decision-making*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>Forecasting variability</b> Gavi forecasting variability drives inappropriate decision-making	<ul style="list-style-type: none"> <li>• Uncertainty over vaccine demand</li> <li>• Financial uncertainties (e.g., prices, FX)</li> <li>• Complexity of process</li> <li>• Sub-optimal systems</li> </ul>			JUST WITHIN		

The Secretariat develops forecasts of future country demand, vaccine supply and pricing, and financial expenditure to inform annual procurement of vaccine doses and funding decisions. These also inform the Alliance's impact projections as well as key policy and strategy decisions (e.g., vaccine investment strategy). Forecasts are based on a number of inputs and assumptions including on vaccine demand (projected vaccine introduction dates and uptake, estimates of target population and immunisation coverage in each country, wastage estimates depending on product presentations, and countries' projected Gross National Income (GNI)

defining their co-financing share and transition date); on vaccine pricing (market dynamics, pipeline assumptions, and exchange rates); on vaccine supply (manufacturing capacity); on cash disbursements (country absorptive capacity, fiduciary risk conditions) and vaccine disbursement timing; on Partner and Secretariat operating costs; on resource inflows (donor contributions, innovative financing proceeds, and investment income); and on potential Gavi policy changes. Each of these has inherent uncertainties and, in some cases (e.g., for population and coverage estimates in some countries), challenges with data quality. Gavi's forecasts inform planning decisions by a range of stakeholders including countries (who plan introductions based on their understanding of availability of Gavi funding and vaccine supply), donors (demand and impact forecasts inform their decisions on the size and timing of their pledges), manufacturers (who use Gavi forecasts to plan their production schedules) and the Secretariat and Alliance partners (who use them for financial, strategic and operational planning). Significant deviation from forecasts could therefore result in Gavi having inadequate financial resources to fund country demand (or conversely being perceived to have "excess" funding), countries having to delay introductions (or conversely have excess supply potentially leading to wastage), and manufacturers producing inadequate or excess volumes of vaccine. It may also result in Gavi failing to deliver on its targets if these turn out to be overly aggressive.

To manage this risk, the Secretariat has strengthened forecasting processes and workflows with systematic collaboration across key teams responsible for vaccine supply, market shaping, co-financing and transition, and finance – informed by and validated with Alliance partners. Checks and balances are built into the process with systematic analysis of accuracy and variability being integrated into the vaccine forecasting cycle and Senior Country Manager (SCM) knowledge integrated into the vaccine renewals process. There is also systematic triangulation of renewal projections with other information sources (allowing dose allocations to be adjusted for accumulation of stock). In addition, efforts are made towards encouraging countries to adopt more realistic vaccine need planning and renewals requests. Key assumptions are pressure tested and variance drivers communicated. HSS and Cold Chain Equipment (CCE) forecasting has also been strengthened. Financial forecasting updates are regularly provided to senior management, the Audit & Finance Committee (AFC) and the Board with transparency on the key drivers of change between forecast versions. Potential financial impact is further mitigated with a cash and investments reserve, equivalent to eight months' future expenditure at least, and a surplus for expected future requests for programme funding. Gavi has also strengthened its vaccine forecasting process and increased scrutiny on the number of doses requested by countries, bringing a more robust analysis to its efforts to balance the risks of over- and undersupply. This includes more systematic triangulation of need estimates with other information sources, as well as review of all vaccine renewals by the HLRP (High Level Review Panel, composed of Gavi Secretariat, partners and independent members) prior to approval. There is also better integration of systems and processes within the Secretariat among key teams and following the implementation of a forecasting solution in SAP) and additional steps are being taken to improve processes and reporting solutions externally with partners and countries.

Current exposure to this risk has increased. Greater uncertainty in the context of COVID-19 creates a higher risk of variability as compared to previously, with the exact trajectory of disease and its ultimate impact on immunisation programmes in Gavi supported countries difficult to predict. A "medium-risk scenario" was assumed for the vaccine forecast, defined as six months of an acute pandemic period, 12-24 months recovery with COVID-19 resurgence in some countries, a medium economic downturn and Gavi-supported countries substantially affected for 1-3 years. In the short term, there is increased uncertainty around new vaccine introductions and the pace of absorption of doses for ongoing programmes. In the longer-term, there is increased uncertainty around new vaccine introductions, resumption, and recovery of ongoing programmes to pre-COVID-19 levels, and delays in the Vaccine Investment Strategy (VIS) roll-out. Potential availability of a COVID-19 vaccine and its interaction with demand and supply of the existing portfolio of vaccines is also unclear for now. Some other areas of uncertainty have also the possibility to balance out, limiting the impact on the aggregate forecast, such as the implementation of the zero-dose strategy, or the targeted sub-national campaigns.

Current exposure is just within risk appetite and therefore requires ongoing attention. More frequent updates to the forecast are being adopted this year to capture fast evolving assumptions, including greater integration of the forecast with various additional short-term data (e.g. shipments, disbursements, COVID-19 trackers). The Alliance has historically had a higher appetite for the risk of forecasts being on the higher edge of the plausible range – to ensure availability of sufficient supply and funding. Recent forecasts have generally been consistent with this view. There is a lower appetite for the risk that such variability might reduce manufacturer or donor confidence and as forecasts reflecting higher scenarios will inherently have greater year-on-year variabilities in the forecast updates, assumptions, uncertainties and changes in forecasts are actively and regularly communicated.

### m) Sub-optimally planned campaigns

*Multiple large preventive vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
m Sub-optimally planned campaigns Multiple large preventive vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services	<ul style="list-style-type: none"> <li>• Periodic very large cash inflows for campaigns</li> <li>• Front line workers diverted to implement campaigns</li> <li>• Management capacity diverted to manage campaigns</li> <li>• Infrastructure (e.g. supply chain, transport) repurposed for campaigns</li> <li>• Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>			JUST WITHIN		

By immunising a large target population in a short period of time, campaigns are meant to supplement routine immunisation and help to rapidly increase population immunity, and are thus an important tool for closing immunity gaps and preventing disease outbreaks. At the same time, countries that have scheduled multiple large campaigns for different infectious diseases risk disruptions to routine immunisation programmes and health systems by diverting health workers and resources away from routine services, potentially incentivised by providing financial “per diems” for participating in campaigns. This can undermine routine immunisation, especially when multiple campaigns occur in a short period. When the planning of the campaign is sub-optimal, the quality of implementation can vary significantly, resulting in the need to repeat campaigns due to a failure to achieve sufficient coverage among the target population. Campaigns are also expensive (with per diems for training, supervision, service delivery, and transport typically a major cost driver), resulting in large sums of money being disbursed in a short period of time, increasing the risk of misuse (especially in sub-optimally planned campaigns due to the lack of sufficient financial monitoring systems). Sub-optimal planning can furthermore increase risks of immunisation errors and without well planned risk communication strategies the expected increase in the absolute number of adverse events (due to the sheer number of children being vaccinated) may threaten confidence in broader immunisation programming. Well-planned, targeted and tailored campaigns, as part of a comprehensive immunisation delivery strategy, remain valuable and necessary to close immunity gaps, vaccinate missed populations, and mitigate risks of outbreaks. However, reliance on large periodic campaigns to close immunity gaps, resulting from inadequate routine immunisation coverage, is not sustainable given their cost and disruptive impact. All members of the Alliance are expected to work with countries to ensure that campaigns are justified, well-planned and executed in a manner that safeguards – and ideally strengthens – the broader immunisation programme.

To manage this risk, the Secretariat and Alliance partners are working to improve the quality of campaigns through more careful planning and preparation, including the mandatory use of readiness assessments before moving ahead with a campaign, and proper microplanning to assist with the targeting of zero dose or under-immunised children. An analysis of specific reasons for sub-optimal coverage in campaigns identified that delayed disbursement of funds from national to subnational level and from global to national level, and sub-optimal use of readiness assessment tools at subnational level compromised the quality of campaigns. The

Alliance ensures that the country receives quality technical assistance and conducts monitoring activities to guide mop up activities along with the required independent post-campaign coverage surveys to evaluate the success. However, ensuring completion and timely submission of technical reports and post-campaign coverage survey reports by countries remains an obstacle. Through the funding policy review (although currently paused), the Secretariat is working with partners to operationalise policies that will reduce reliance on nationwide non-selective measles campaigns in higher performing countries. Country-tailored strategies are promoted that reinforce routinised mechanisms to close immunity gaps (e.g., implementing immunisation catch-up policies and schedules, bolstered mobile and outreach, Periodic Intensification of Routine Immunisation) and integration of multiple antigens and health interventions in campaign and routine health services whenever possible. The health system and immunisation strengthening (HSIS) framework requires all countries to articulate how they will use operational cost support for campaigns and requests are reviewed to ensure alignment to the needs of the country as indicated in the campaign plans. The Secretariat is also reviewing campaign budgets before disbursing funds to minimise perverse incentives and misuse. Monitoring Agents are being used for higher risk planned campaigns to monitor programmatic and financial aspects of campaign preparations providing an additional level of assurance and risk mitigation.

Current exposure to this risk remains high. As a result of COVID-19, the majority of planned campaigns have been postponed due to an initial SAGE recommendation to temporarily suspend these activities, followed by more nuanced guidance to carry out risk-benefit assessments when conducting mass immunisation activities. As more campaigns resume, it is expected that countries will need to spend more time planning to ensure adequate safety and effectiveness in the context of COVID-19, however, paradoxically the timing available between the decision to resume and the implementation may decrease driven by fear of outbreaks, thereby reducing the time to ensure all preparatory activities are conducted to a high standard. Once the immediate crisis abates, a large number of catch-up campaigns will likely be necessary in a short amount of time due to this backlog. The planning, implementation and resultant coverage in this context may be compromised along with the ability to conduct and ensure timely submission of post-campaign coverage surveys.

Previous years this risk was deemed outside of risk appetite as the Alliance normally has a low appetite for the risk of preventive immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term. In the current context however it may be necessary to accept that not all campaigns will be optimally planned. Current exposure is therefore just within risk appetite and requires ongoing attention. The impact of COVID-19 on planned campaigns continues to be closely monitored together with partners.

## n) Global supply shortages

*Shortages in the global vaccine supply affect Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
n) <b>Global supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption (epidemiological, political, technical)</li> </ul>			JUST WITHIN		

Secure and reliable vaccine supply is essential for immunisation programmes to run uninterrupted, to enable new vaccine introductions, and to meet countries' vaccine presentation preferences. However, vaccine production is a technically challenging process and there are only a limited number of vaccine manufacturers for many of the Gavi-supported vaccines. Other factors are the total production buffer capacity for each market, manufacturers' engagement with global health and development aid, their assessment of commercial risks associated with investments, market entry barriers, and the strength of National Regulatory Authorities (NRAs).

Country demand may also delay or surge depending on country introduction readiness and disease outbreaks, conflict and natural disasters, while the production of vaccines and increasing production capacity is a long-term process. There is also natural volatility in demand, especially for newer vaccines and those with more sporadic use (e.g. with vaccines delivered for campaigns). The risk of supply shortages is generally decreasing for Gavi's more mature routine vaccine programmes (e.g., pentavalent and PCV) as supply capacity has increased over time and demand is more stable owing to more predictable usage patterns in countries where immunisation programmes are established. However, it remains a high risk for a number of vaccines and the inherent risk may grow when new vaccines will be supported in the future, especially for epidemic diseases. Also, as countries transition out of Gavi support, they may opt for self-procurement instead of procuring through UNICEF, potentially affecting demand predictability and making market shaping more complex.

To manage this risk, the Secretariat and Alliance partners work closely with industry to ensure engagement and confidence, and to improve the health of vaccine markets, which may entail incentivising increased production capacity to meet demand, through provision of long-term demand forecasts and other strategic information and incentives. This can involve encouraging existing manufacturers to expand capacity or new ones to enter the market to ensure competition and a diverse supply base. Annual base demand forecasts are updated to project demand for the next 10 years. Steps have been taken to increase accuracy of near-term forecasting integrated into grant renewal, using triangulation with other data sources to identify over-ambitious assumptions, and revising processes to ensure more opportunities for review of vaccine quantities prior to final approvals. Opportunities are being identified with partners to strengthen initial renewal requests from countries, via more realistic country level forecasting of needs and improved stock management. Longer-term strategic demand scenarios are also developed (usually with a 20-year horizon) based on strategic needs to model demand variation based on key strategic assumptions. Demand-side initiatives to improve predictability of demand or unpredictability of future product presentation preferences are also being explored (e.g., for Cholera, campaigns in hotspots will become more routinised, and easier to predict, as the program shifts from an outbreak control focused approach to a more integrated program in endemic countries). Secretariat and Alliance partners furthermore engage countries to understand needs and product preferences, introduction preparedness, and share information to facilitate country planning, budgeting, and decision making (including choosing product presentations with reliable supply). The Alliance secures required supply through long-term agreements with manufacturers, allowing them to plan production and development plans sufficiently far in advance. To facilitate market entry and vaccine licensing, WHO supports regulatory capacity-building of local NRAs and facilitates international harmonisation of vaccine production standards. Enhancements of the prequalification process and rationalising global regulatory barriers are also being explored. Finally, vaccine stockpiles are created for outbreak preparedness for epidemic diseases in case emergency response is needed after an unpredicted outbreak.

Current exposure to this risk remains high, with eight out of eleven vaccine markets continuing to be assessed as exhibiting low health. However, market dynamics are improving for inactivated polio vaccine (IPV), human papillomavirus vaccine (HPV) and pneumococcal conjugate vaccine (PCV). With the prequalification of two additional IPV manufacturers, supply security will be improved ahead of the introduction of a second dose of IPV in Gavi-supported countries from 2021. For HPV, increased supply from existing and new manufacturers is expected to materialise. A third HPV vaccine is currently undergoing WHO prequalification review and is expected to enter the market in 2021. A third supplier with lower prices was added for PCV. Lockdowns and closure of borders continue to pose a risk for delayed shipments and manufacturers potentially having to close businesses for social distancing purposes or resulting economic shocks. There have been disruptions in international logistics resulting in a few instances of country stockouts which have since been resolved by UNICEF. However, the main effect of the pandemic has been a drop in demand due to paused country vaccination activity, such that supply chain disruption in itself has not been rate-limiting. A severe drop in oral cholera vaccine (OCV) campaigns amid the pandemic has led to concerns around key supplier cashflow and sustainability, which has been mitigated with an advance payment to the main OCV supplier for the remainder



of the year's forecast. An isolated instance of pandemic impact on vaccine production leading to potential low stock scenarios was experienced by one PCV supplier; production will be normalised in 2021 and mitigating actions on potential programme interruption have been taken by Alliance partners. Status and sustainability of suppliers is being monitored closely and UNICEF is in constant contact with existing suppliers. While supply capacity from existing and new manufacturers is expected to increase in 5.0, the short- to medium-term impact of COVID-19 is still to be fully understood, meaning supply (and business continuity) planning will remain a challenge.

The Alliance has a moderately low appetite for the risk of supply shortages, especially if this may impact existing programmes. While ensuring sufficient and uninterrupted supply of vaccines is essential, it is also acknowledged that demand and supply are inherently volatile. Future supply security is dependent on assumptions of supplier production capacity scale-ups and new market entrants that introduce sufficient buffer capacity and supplier diversity into the markets. Also, mitigation is constrained by limitations in degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges. The overall risk exposure is therefore currently just within appetite and requires ongoing attention.

### o) Health systems strengthening

*HSS investments do not materially improve programmatic outcomes*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<ul style="list-style-type: none"> <li>Health systems strengthening</li> <li>HSS investments do not materially improve programmatic outcomes</li> </ul>	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSS</li> <li>HSS grants not designed to target key bottlenecks</li> <li>HSS grants duplicative with other donor funding</li> <li>HSS grants not large enough to have significant impact</li> <li>HSS not disbursed in timely fashion</li> <li>Programmes funded by HSS not well-managed</li> <li>Misuse of HSS resources</li> </ul>			BROADLY WITHIN		

HSS grants are one of the key financing tools for the Alliance to help strengthen coverage and equity and build sustainability in immunisation programmes, and are therefore critical to delivering the Gavi strategy. HSS includes grants for health system strengthening, vaccine introductions and operational support for campaigns. The Alliance is projected to invest over US\$ 2 billion in HSS between 2016 and 2020, including approximately US\$ 1.4 billion in health system strengthening grants. Nonetheless, Gavi's HSS support is intended to be catalytic and covers only a small proportion of the total financing required to implement sustainable programmes with high and equitable coverage, and the largest financing typically comes from governments. The value for money of HSS grants depends on them being well-designed and focused on the key bottlenecks, timely disbursed and well-implemented and utilised by countries, and delivering measurable results. Some of the key barriers to coverage and equity may not be addressable through HSS grants (e.g., design of the overall health system). Even when HSS grants are well-used, many factors impact the performance of immunisation programmes, so Gavi can contribute but not fully attribute its investments to outcomes and impact. Without robust management and oversight – including aligned technical support where required from Alliance partners – HSS funds could remain unspent, be channelled to low impact investments or misused. The inherent risk is likely to increase as stronger countries transition out of Gavi support and Gavi's grant portfolio is more concentrated in countries with weaker systems.

To manage this risk, Gavi has continued to strengthen its processes for the design, monitoring and improvement of grants. The approach to programming, planning and monitoring HSS is being fundamentally redesigned for Gavi 5.0. The allocation formula for funding has been revised to ensure that funding is more targeted towards countries with most zero-dose children, and there is a much greater programmatic focus on equity with dedicated equity funding and a new framework to help countries design programmes to sustainably reach zero-dose children. Operationally, the funding will be programmed through the new portfolio management processes with an integrated theory of change and budget across all Gavi support windows.





There is also a workplan to plan and track activities and a redesigned monitoring framework to better track progress. There is also an increasing focus on key systems areas which have historically been less of a focus (e.g., demand, gender, CSO engagement). Progress of the Full Portfolio Planning process is reviewed together with partners, and Joint Appraisals – annual reviews by all in-country stakeholders - have now become a valuable part of the annual EPI cycle in most countries, and are strengthening linkages between Gavi HSS, NVS and PEF grants. The Partners' Engagement Framework (PEF) has helped ensure that technical support is based on country needs, better connected to Gavi's other grants and has increased the transparency and accountability of partner support. As part of the annual cycle of review and monitoring of grants, there is a deliberate discussion on identifying technical support priorities for the next year, and consideration of whether adjustments are needed to ensure that grants are optimally targeted towards coverage and equity. This has also enabled countries to accelerate implementation of grants in countries that have experienced challenges in absorbing HSS funding. All HSS grants have performance frameworks with intermediate indicators measuring direct outputs as well as outcomes and a portfolio analysis reviewed the design of HSS grants and GPFs in priority countries. A unit cost and benchmarking database will be launched to ensure economy in HSS grants.

Current exposure to this risk remains high. There is continued growth in disbursement (following HSS flexibilities approved by the Board in June 2018). The Secretariat also provided countries with the flexibility to reprogramme support to meet urgent needs and protect frontline services in response to the COVID-19 pandemic, with nearly US\$ 80 million reprogrammed to date. While many countries were able to reprogramme funding from delayed activities or underspend, some core activities were deprioritised. However, these funds have played a critical role in the COVID-19 response with much of them invested in providing essential protective personal equipment and infection prevention control supplies. Countries are likely to reprogramme additional HSS funds as they work to maintain, restore and strengthen immunisation services, which will be essential as countries recover and catch-up. COVID-19 also resulted in some countries in delays in implementation of HSS grants and in many countries in delays in Full Portfolio Planning, which may slow down implementation of more zero-dose focused funding.

The current risk exposure is broadly within risk appetite. To achieve its zero-dose aspirations, the Alliance has to be ambitious and explore innovative strategies to strengthen health systems and immunisation programmes. It therefore has a moderately high appetite – where required – for the risk that HSS investments do not substantially improve outcomes as long as there is robust design, implementation and oversight of HSS grants.

## p) Donor support

### *Significant reduction in donor support to Gavi*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<p><b>Donor support</b> Significant reduction in donor support to Gavi</p>	<ul style="list-style-type: none"> <li>Reduction in development budgets</li> <li>Competing priorities in development</li> <li>Competing priorities within health</li> <li>Loss of donor confidence in Gavi</li> </ul>			<b>BROADLY WITHIN</b>		

Donor support is crucial to enable Gavi to sustain approved programmes and fund new activities and initiatives. However, economic challenges and uncertainty, shifting political ideologies, increasingly aid-hostile media in some countries, and competing priorities in development and health (such as refugees, security, climate, and education, but also the creation of other health initiatives) and domestically may pose risk to securing donor support. Elections in key donor markets are bringing new leaders who may take different directions from their predecessors, but at the same time will need to respond to a significant segment of discontented voters with increasing mistrust of established institutions. A reduced budget for Gavi programmes could lead to disruption of countries' immunisation programmes and therefore reduce impact. It could also prevent the Board from

opening support windows for new vaccines that are developed. Reduced donor support would likely also increase the effort and cost of mobilising resources and servicing donors.

To manage this risk, Gavi continues to diversify its donor base and ensure its support is broad based. The Secretariat invests significant efforts in engaging a variety of donors and ensuring their needs are met, including with financial instruments tailored to donors' budgetary processes and requirements, and by hedging currency risk whenever possible. Gavi showcases results and the effectiveness of Gavi's model through numerous multilateral reviews and evaluations, events, mid-term reviews and replenishments. Gavi also works to raise the Alliance's profile (through communications and advocacy organisations) in donor countries. There are tailored strategies for each market including bipartisan engagement, proactive outreach to political leadership and the creation of an expansive network of supporters in civil society and media, as well as private sector champions in key markets. More broadly, the Secretariat is working to increase private sector engagement in the Alliance and to leverage private sector investment, expertise and innovation. Furthermore, through the International Finance Facility for Immunisation (IFFIm) Gavi can frontload donor funds in a flexible manner, without being constrained by individual donor budgeting limitations.

The overall risk of a significant reduction in donor support has decreased since last year (but remains a top risk, with the potential to increase again going forward). Gavi's successful replenishment at the Global Vaccine Summit in June 2020 had a result that exceeded the target, representing a huge vote of confidence in Gavi, Alliance partners and the collective mission. However, given the ongoing uncertainty and economic contractions in many Gavi donor countries due to the COVID-19 pandemic it is needed to remain vigilant to transform these pledges into full financial contributions. Furthermore, Gavi is now a prominent player in the global response to the COVID-19 pandemic, most notably as the administrator of the COVAX Facility and as such it is attracting global attention with global participation of 189 economies representing over 90% of the world's population (making it the largest multilateral collaboration since the Paris Climate Agreement). This is a clear opportunity to further solidify and broaden donor support for Gavi, but in case of failures or (geo)political tensions related to COVID-19, Gavi could also be more vulnerable to reputational risk, including with potential consequences for donor support for core immunisation programmes. Furthermore, new fundraising efforts are being undertaken for the Gavi COVAX Advance Market Commitment (AMC). The risk that insufficient funding will be raised to fully capitalise the AMC is mitigated with a fundraising strategy that draws on a carefully crafted advocacy campaign and on multiple funding sources, including ODA, innovative finance, working with MDBs as well as the private sector. More than US\$ 2 billion has been raised since mid-November. A further round of funding, at least US\$5 billion by the end of 2021, is required and a strategy is being developed to fundraise for the next phase.

The Alliance has a low appetite for risks affecting the sustainability of donor funding in order to safeguard predictable financing of vaccines, as this is crucial to sustaining Gavi's existing programmes and the Alliance's ability to fund new vaccines. The current exposure is broadly within risk appetite but continues to require strong advocacy efforts to secure donor pledges and to fundraise for the COVAX AMC in a constrained resource environment.