

THE VACCINE ALLIANCE — RISK & ASSURANCE REPORT 2021





Risk & Assurance Report 2021

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1. Introduction

1.1. Purpose of this report

The world continues to grapple with uncertainty and disruption from an enduring pandemic that creates a highly unpredictable operating environment with still many unknowns around its evolution and its potential impact. Gavi is pursuing an ambitious strategy in this risky world and faces limitations in its ability to anticipate, mitigate and monitor some risks due to the ongoing pandemic. The COVAX Facility's mission also continues to require navigating uncharted territory at unprecedented speed and scale, which naturally comes with new and heightened risks. Gavi acknowledges that many of these risks are worth taking, and it is able to do so by relying on robust risk management which helps 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.

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. 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. its willingness to accept being exposed to certain risks) as per the recently updated Risk Appetite Statement¹ which was approved by the Board at its June meeting. 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.

This year's report shows that Gavi's overall risk profile has remained stable with most top risks continuing to be elevated due to the current environment, Gavi's ambitious strategy and the mission of the COVAX Facility. Two top risks have decreased, two increased, and last year's single aggregate COVAX-related risk has now been disaggregated into four risks as the Facility has moved from design to operationalisation and delivery. Three risk exposures are deemed to be outside of Gavi's updated risk appetite as long as intensive mitigation is still ongoing.

1.2. Progress made on Alliance-wide risk management

The Risk function continues to engage actively with the business to identify and frame new risks, maintain awareness of existing risks and ensure progress in mitigation. The Secretariat's Risk Committee (chaired by the CEO with senior leadership from across the organisation) has had in-depth discussions on fraud risk (followed by a request to all Secretariat teams to think through fraud-related risks in their areas for inclusion on their team risk registers) and the risk of cyber-attacks, especially in the context of the increased public profile of Gavi due to COVAX and the additional finances associated with its operations. The Committee also had a meeting on Safeguarding risk to re-evaluate the Secretariat's exposure to sexual exploitation, abuse and harassment risks given the evolving context and to discuss whether existing measures remain fit for purpose.

The Risk Committee also reviewed the COVID-19 vaccine delivery risk framework, which continues to be discussed and further elaborated jointly with Alliance partners in the Country Readiness and Delivery (CRD)

¹ See <https://www.gavi.org/news/document-library/risk-appetite-statement> or in French: <https://www.gavi.org/fr/actualites/librairie-de-documents/declaration-de-gavi-alliance-sur-lappetit-pour-le-risque>

workstream of the COVAX Pillar. The Risk function furthermore assisted the Office of the COVAX Facility with the creation of a central COVAX Facility-wide risk register, bringing together all top risks across the COVAX Facility, clarifying risk ownership, and serving as an actionable management tool to stay abreast of new risks, track mitigation actions, and inform decisions, prioritisation and management attention. The Risk function is a standing member on many COVAX Facility meetings, including planning meetings and dedicated brainstorming sessions on special topics such as virus variants and scenarios for the new COVAX strategy. This allows for providing the risk perspective on new initiatives and latest developments and ensuring that new risk areas and potential implications are acknowledged early on in a fast-moving and dynamic context.

The Risk function has worked with the Governance team and the Board's Governance Committee to further define governance-related risks; worked with the Operations team to update Gavi's crisis and incident management policy and response plans incorporating learnings from the current crisis; and shared its experience on building out a comprehensive risk management approach with the Global Polio Eradication Initiative (GPEI). It also met with UNICEF in a workshop for both organisations to share their risk management approaches and key COVAX risks identified and to discuss how to develop a shared approach to end-to-end risk management. The Risk function also engages with the business through a newly established Treasury risk management committee and a Cybersecurity steering committee on corresponding risks.

Following the Board's approval of Gavi's updated Risk Appetite Statement at its June meeting, the Risk function facilitated a Risk Committee meeting on how to operationalise the higher risk appetite into Gavi's daily business and people's mindsets. This was a first discussion on what is needed for people to feel comfortable to take the right risks (equipped with adequate risk management capacities), and not be risk averse. It also explored where principles from the statement needed to be unpacked further to give practical guidance on how to strike the right balance in specific contexts, where to set limits and where to encourage taking more risk. Finally, the Risk function has hired new staff members, expanding from 1 FTE (Head of Risk) to a team of 3 FTEs (an additional permanent position as well as a temporary position on the COVAX budget).

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. Since last 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 reports² 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 COVID-19 pandemic continues to upend lives and economies across the world. While effective and safe vaccines are now available, these do not yet reach every country in sufficient volumes and with sufficient population coverage in order to protect against the more infectious Delta variant of the virus. The further spread, severity and duration of the pandemic continues to be uncertain given the potential of new virus variants emerging with increasing infectiousness, or increasing morbidity and mortality (e.g. also affecting younger age groups), or undermining vaccine effectiveness; given waning immunity after vaccination and the potential need for booster shots; and given evolving social behaviour and policy responses such as pandemic fatigue and premature lifting of still necessary non-pharmaceutical interventions. Depending on how the pandemic evolves, it has the potential to significantly affect performance against Gavi's mission and strategic goals (with increased child mortality, reduced immunisation coverage and an enlarged number of under-immunised and zero-dose communities), as well as the capacity and operations of the Secretariat, partners and implementing countries. Despite a drop in immunisation activity in Gavi-supported countries during spring last year, immunisation programmes appear to have bounced back. However, since the pandemic is not yet over, a real risk of backsliding remains from potential future waves of COVID-19 infections as well as from the diversion of resources to COVID-19 vaccine delivery.

Following last year's collapse, the global economy is experiencing a strong but uneven recovery, even as the pandemic resurges. While advanced economies are re-bounding, many of the world's poorest countries are being left behind. Vaccine access has emerged as the principal fault line along which the global recovery splits into two blocs: those that can look forward to further normalisation of activity next year (almost all advanced economies) and those that might still face resurgent infections and rising COVID-19 death tolls. The recovery's momentum, however, has already weakened due to the highly transmissible Delta variant and is not assured even in countries where infections are currently very low so long as the virus circulates elsewhere. The possibility remains that additional COVID-19 waves, further vaccination delays, longer-than-expected supply chain disruptions, debt crises, asset bubble bursts, or rising inflationary pressures deliver economic setbacks. Financial conditions could tighten rapidly, for instance from a reassessment of the monetary policy outlook in advanced economies if inflation expectations increase more rapidly than anticipated. A double hit to emerging market and developing economies from worsening pandemic dynamics and tighter external financial conditions would severely set back their recovery and drag global growth below the current outlook. Furthermore, the last decade saw the largest, fastest, and most broad-based increase in debt levels around the world. Half of the low-income countries faced debt distress or were at high risk of it even before the pandemic struck. There is therefore a risk that with increasing interest rates and elevated debt levels resources required to service debt may divert funds from investment in health and other critical development needs.

² Amongst others World Economic Forum Global Risks Report 2021; IMF World Economic Outlook 2021; World Bank Global Economic Prospects 2021; Eurasia Group Top Risks 2021; Uppsala Conflict Data Program

The number of active conflicts, both conflicts involving states and conflicts between non-state groups, has increased after five consecutive years of falling numbers. Several conflicts that had been inactive for a long time escalated again last year with a clear regional shift from the Middle East to the African continent (more than half of all the civil wars in the world now occur in Africa, partly due to IS shifting their focus to Africa after being severely weakened in Syria and Iraq). For Gavi this could lead to a further disruption of immunisation programmes and challenges to reaching zero-dose communities. Divisiveness had been increasing before the pandemic in many countries with growing perceptions of economic and political systems being rigged and unrepresentative, and fragmentation in many societies is being further exacerbated by the pandemic, with the young “pandemics” particularly at risk of losing faith in opportunities and institutions. The crisis has also challenged national policy-making and international relations in ways that threaten lasting impacts. Institutions and policies to support international coordination were already in decline, and responses to the pandemic have caused new geopolitical tensions. This puts equitable and effective vaccine distribution at risk from protectionist tendencies and makes public health a new frontier for geopolitical rivalry, impeding international coordination and the effectiveness of the multilateral system to address global concerns.

The latest UN IPCC climate change report sounded 'code red for humanity' warning the world is already certain to face further climate disruptions for decades, if not centuries, to come. The heat waves, hurricanes and other weather extremes that are already happening will only become more severe. As with COVID-19, climate change impacts are likely to play out disproportionately across countries, exacerbated by long-existing inequalities. 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, as rising temperatures increase vector habitats to regions that are currently free of disease 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.

COVID-19 has accelerated the digitalisation of human interaction and the workplace. Cybercriminals are exploiting the use of more vulnerable home-based systems and take advantage to deliver malware, ransomware and phishing scams. On average, ransomware claims a new victim every ten seconds worldwide, and cost businesses around \$20 billion last year, an increase of 75% over the previous year. Furthermore, the sheer volume of data available drives down the cost and ease of using algorithms for malicious or manipulative purposes. Individuals and non-state groups have access to algorithms that can spread dangerous content with unprecedented efficiency, speed and reach. Malicious actors are also becoming more capable of launching misinformation campaigns on a national and global scale—and because individuals and small groups are difficult to track and prosecute, it is harder for authorities to stop the spread of misinformation. The number of countries experiencing organised social media manipulation campaigns increased by 150% between 2017 and 2019. Misinformation could endanger a global recovery that hinges on widespread vaccination and a faith in science and institutions.

2.2. Changes to the Alliance-wide top risks in 2021

Last year's report³ presented a reframed set of 16 top risks in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility, with an increase in risk levels across the board. This year's report prioritises 19 top risks, disaggregating the single aggregate COVAX-related top risk from last year into four risks this year as the Facility has moved from design to operationalisation and delivery⁴. It shows that Gavi's overall risk profile has remained stable with most top risks continuing to be elevated, and with three risk exposures deemed to be outside of Gavi's updated risk appetite as long as intensive mitigation is still ongoing (see section 2.3 for more detail on risk appetite). Two risks have decreased, and two risks have increased as illustrated by the arrows next to each top risk below. 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 progress on mitigation). 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 risks⁵.

The 6 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 delivery** NEW
Significant COVID-19 delivery issues and impact on routine immunisation
- c) **COVAX supply** NEW
Significantly reduced and unpredictable COVID-19 vaccine supply
- d) **COVAX reputation** NEW
Reputational damage for the COVAX Facility and Gavi
- e) **COVAX Facility** ▼
Inability to adequately operationalise the COVAX Facility
- f) **Sustainable transition**
Some countries may fail to sustain progress of their immunisation programmes after transition

The 13 top risks rated as **high** are:

- g) **Insufficient demand**
Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation
- h) **VPD outbreaks**
Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries
- i) **Misuse by countries**
Deliberate misuse of Gavi support in many Gavi-supported countries
- j) **Cyber-attack** ▲
Large cyber-attack significantly compromising critical information systems or data
- k) **Data on zero-dose** ▼
Poor or lacking data may affect the ability of the Alliance to identify and reach zero-dose children, implement effective interventions, understand progress and demonstrate impact
- l) **Polio disrupting immunisation**
Polio ramp-down or resurgence may adversely affect routine immunisation
- m) **Secretariat disruption** ▲
Significant disruption of Secretariat operations

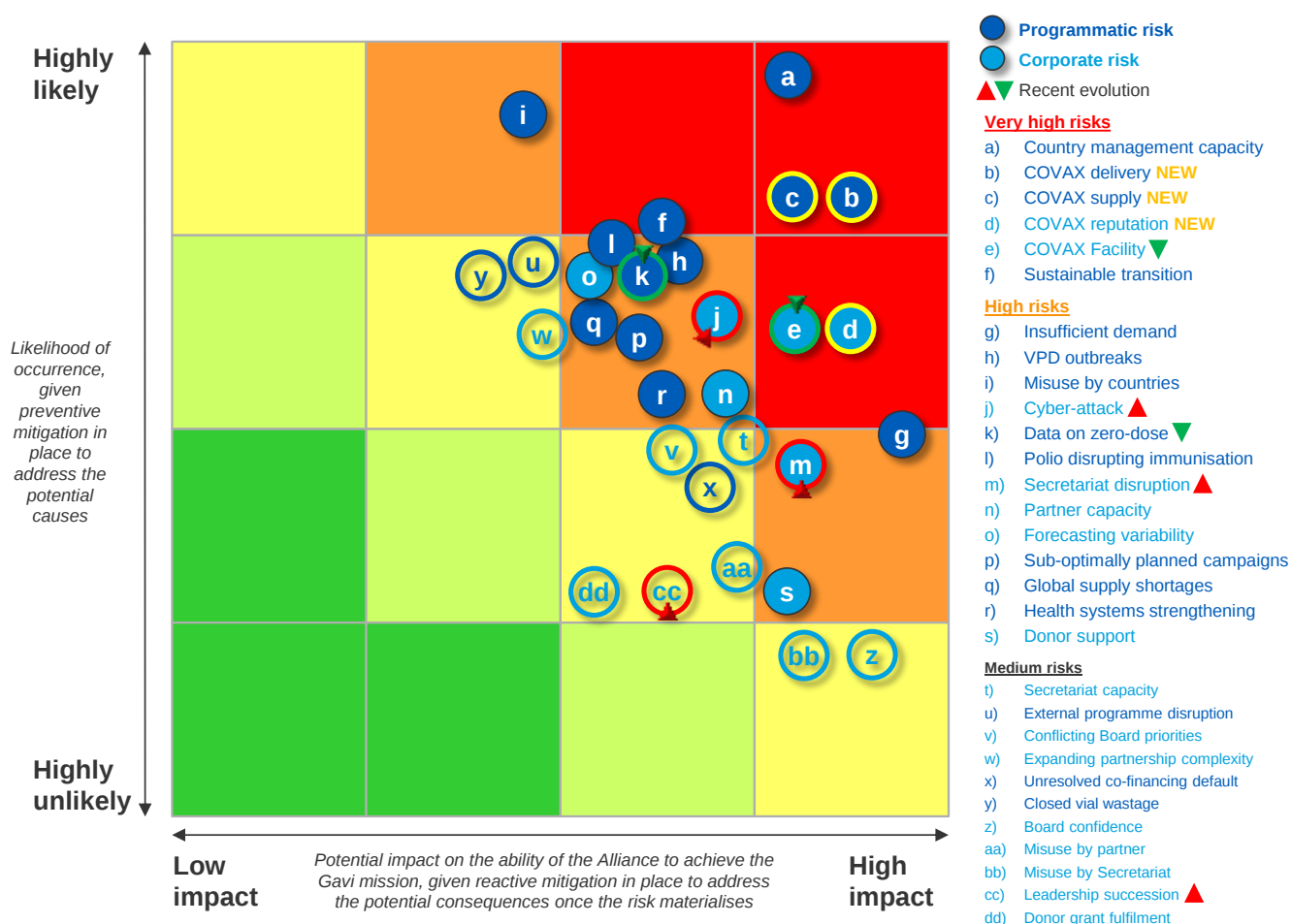
³ See for the 2020 Risk & Assurance Report: <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2020>

⁴ This report captures aggregate COVAX risks as part of the overall Gavi risk profile. COVAX risks have been reported in more detail in the COVAX risk report for the June Board: <https://www.gavi.org/news/document-library/06-annex-c-covax-risk-report-pdf>

⁵ See e.g. top risk descriptions for Country management capacity, Secretariat disruption, Partner capacity, Insufficient demand, Misuse by countries, Cyber-attack, Global supply shortages and Donor support.

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

Alliance top risks ranked against likelihood and impact 2021 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2021 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

Doc 09 - Annex A

Alliance-wide top risks			Risk assessment			Risk evolution	
	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
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	- Weak existing systems and technical capabilities - Weak management capabilities - Insufficient human resources or retention challenges - Insufficient prioritisation of health and immunisation - Inadequate support from Alliance to build capacity - External programme disruption (conflict, natural disasters, disease outbreaks, political change/devolution)	VH		OUTSIDE		
b	COVAX delivery Significant COVID-19 delivery issues and impact on routine immunisation	- Insufficient country readiness and absorption capacity - Lack of demand and vaccine hesitancy - Wastage due to expiry or cold chain failures - Adverse impact on RI or missed opportunity for synergies	VH		OUTSIDE	NEW	
c	COVAX supply Significantly reduced and unpredictable COVID-19 supply	- Competition from bilateral deals - Inability to secure deals in time - Export controls - Manufacturer prioritisation or production issues	VH		OUTSIDE	NEW	
d	COVAX reputation Reputational damage for the COVAX Facility and Gavi	- Inability to meet supply promises - Large-scale wastage or idle doses in-country (Perception of) inequitable allocation and distribution (Geo)political tensions and conflicts of interest	VH		JUST WITHIN	NEW	
e	COVAX Facility Inability to adequately operationalise the COVAX Facility	- Overstretched people, processes, systems - Ineffective coordination, project management, governance - Inadequate financial risk and liquidity management	VH		JUST WITHIN		
f	Sustainable transition Some countries may fail to sustain progress of their immunisation programmes after transition	- Lack of (subnational) ability/capacity/fiscal space - Poor preparation for transition by Alliance - Insufficient prioritisation of health and immunisation - Overreliance on external support - Lack of access to global markets and expertise - External programme disruption (economic, outbreaks)	VH		JUST WITHIN		
g	Insufficient demand Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation	- Lack of knowledge / information about immunisation - Hesitancy due to mistrust/fear - Anti-vax sentiment, politicization, fake vaccines - Logistical and gender barriers, lack of prioritisation - Poor quality services / experience - Weak government systems for generating demand	H		JUST WITHIN		
h	VPD outbreaks Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries	- Low population immunity, vaccine hesitancy - Climate change, urbanisation, deforestation, globalisation, migration and human displacement, population growth - Lack of capacity/tools to detect, prevent and respond - External programme disruption (conflict, disasters)	H		JUST WITHIN		
i	Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	- Culture of gifts/corruption - Opportunity for personal gain - Weak monitoring/deterrence - Weak institutions and systems	H		JUST WITHIN		
j	Cyber-attack Large cyber-attack significantly compromising critical information systems or data	- Increase in phishing, malware and ransomware - Work-from-home vulnerabilities - Increased target for cybercrime, antivax and espionage	H		JUST WITHIN		
k	Data on zero-dose Poor or lacking data may affect the ability of the Alliance to identify and reach zero-dose children, implement effective interventions, understand progress and demonstrate impact	- More precise data is not available - Existing data is not shared - Data is not timely - Data is not used effectively to identify children - Poor data culture, capacity and systems	H		JUST WITHIN		
l	Polio disrupting immunisation Polio ramp-down or resurgence may adversely affect routine immunisation	- Eradication challenges / Vaccine-derived outbreaks - Reliance on GPEI staff/assets, weak national systems - Delayed transition plans, incomplete polio asset mapping - GPEI funding cuts / uncertain fund-raising for new strategy	H		JUST WITHIN		
m	Secretariat disruption Significant disruption of Secretariat operations	- Stretched capacity and increased complexity of work - Pandemic impact on mental health and staff engagement - Leadership succession issues - Departures of key staff with critical knowledge - Incident or loss of life in the workplace or during travel	H		JUST WITHIN		
n	Partner capacity Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	- Lack of alignment and coordination - Lack of capacity / expertise - Lack of availability - Lack of accountability / performance	H		JUST WITHIN		
o	Forecasting variability Gavi forecasting variability drives inappropriate decision-making	- Uncertainty over vaccine demand - Financial uncertainties (e.g., prices, FX) - Complexity of process - Sub-optimal systems	H		JUST WITHIN		
p	Sub-optimally planned campaigns Multiple large disease focused vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services	- Periodic very large cash inflows for campaigns - Front line workers diverted to implement campaigns - Management capacity diverted to manage campaigns - Infrastructure (e.g., supply chain, transport) repurposed for campaigns - Poor planning and management undermine quality of the campaign, resulting in low coverage	H		JUST WITHIN		
q	Global supply shortages Shortages in the global vaccine supply affect Gavi-supported countries	- Manufacturing capacity inadequate to meet demand - Unable to meet country presentation preference - Lack of supply security - External disruption (epidemiological, political, technical)	H		JUST WITHIN		
r	Health systems strengthening HSS investments do not materially improve programmatic outcomes	- Key bottlenecks not addressable by HSS - HSS grants not designed to target key bottlenecks - HSS grants duplicative with other donor funding - HSS grants not large enough to have significant impact - HSS not disbursed in timely fashion - Programmes funded by HSS not well-managed - Misuse of HSS resources	H		BROADLY WITHIN		
s	Donor support Significant reduction in donor support to Gavi	- Reduction in development budgets - Competing priorities in development - Competing priorities within health - Loss of donor confidence in Gavi / COVAX Facility	H		BROADLY WITHIN		

next segment of risks in the yellow zone are medium⁶ 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. While the annex describes in more detail progress on mitigation against all risks, the major changes in risk levels since last year are summarised below:

b) COVAX delivery NEW – The risk of significant COVID-19 delivery issues and impact on routine immunisation is very high as the roll out of COVID-19 vaccine doses is expected to rapidly scale up in Q4 2021, and a substantial volume will be from Pfizer – the hardest to deliver given ultra cold chain and special syringe requirements, and through dose donations – the hardest to plan for as these often come with earmarking and little notice or in a staggered manner and in small volumes and with short shelf lives. The absorption of such volumes of vaccines is expected to represent a significant challenge for many countries, although the situation varies across countries, and up till now, most countries have been able to increase delivery as supply scales up and mitigate the risk of dose expiry. In the absence of consistent and predictable supply it remains difficult to gauge real absorptive capacity in many countries. The emergence of new virus variants and safety signals for some vaccines has also created further uncertainty for allocation and uptake, with the potential for refusals due to product preferences and vaccine confidence potentially affecting uptake in country populations due to (perceived) safety concerns. A shortage of syringes could also hinder effective roll-out as well as impact routine immunisation. Cold chain capacity may also prove insufficient in some places because of a steep increase in supply. To manage this risk, COVAX Pillar partners are actively monitoring key delivery risks through weekly ‘implementation monitoring reviews’ and defining targeted interventions for high risk countries (e.g. accelerating access to funding for delivery when there are gaps, adjusting future shipments and allocation based on absorption, informing the next allocation round with product preference, considering redeployment of doses within or outside the country, and providing specific technical assistance based on country implementation gaps). Furthermore, significant but fragmented funding is being made available by funders including UN partners, bilateral donors, private sector partners and the multilateral development banks to try and help mitigate these risks, including nearly ~\$1B in delivery support from Gavi. Initial Gavi funding has already supported >400 in-country positions (primarily through UNICEF and WHO) and procured and deployed cold chain equipment to fill critical gaps. Further Gavi funding is designed to be both expedient, needs based, and targeted on areas where it will have high impact. An initial tranche had been made available via an early access window, with significantly reduced transaction times, including an abbreviated application and waived IRC review to ensure funding is readily available in advance of increasing supply. Sufficient COVID-19 delivery funding will also help in mitigating the potential impact on routine immunisation and at the same time be used to exploit synergies where possible.

c) COVAX supply NEW – The risk of significantly reduced and unpredictable COVID-19 supply following signature of Advance Purchase Agreements (APAs) has materialised due to export restrictions and technical difficulties in manufacturing scale up which resulted in significant delays in supply of the COVAX Facility doses. A large portion of the doses originally forecasted to arrive throughout 2021 has been pushed into Q4 2021 and

⁶ The medium risks are defined as follows: **t) Secretariat capacity**: Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy; **u) External programme disruption**: Major external events disrupt programmes in some Gavi-supported countries; **v) Conflicting Board priorities**: Changes in Alliance Board may result in conflicting or inconsistent decisions or disagreements; **w) Expanding partnership complexity**: Growth in number of new partners may increase transaction costs and complexity; **x) Unresolved co-financing default**: Lasting co-financing default leading to suspension; **y) Closed vial wastage**: Excessive closed vial vaccine wastage; **z) Board confidence**: Board losing confidence in Gavi management; **aa) Misuse by partners**: Deliberate misuse of Gavi funds by partners; **bb) Misuse by Secretariat**: Deliberate misuse of Gavi funds by Secretariat; **cc) Leadership succession**: Failure to effectively plan for succession of key leadership at Gavi Board, Secretariat, or Alliance partners; **dd) Donor grant fulfilment**: Donors failing to fully pay pledged contributions

early 2022. Many countries and other procurement mechanisms have equally been affected by a highly unpredictable market. Due to the COVAX Facility's response to adapt and build resilience, including through the establishment of a dose sharing programme, portfolio diversification, new deals and options exercised, the pace of supply has now significantly accelerated and Q4 2021 is expected to outpace the first three quarters of the year combined. The key COVAX Facility milestone of 2 billion doses released for delivery is now expected to be reached before the end of Q1 2022. However, current exposure to this risk remains very high given an environment that remains highly uncertain and competitive. There are still many fundamental scientific uncertainties which may impact supply and the use of COVID-19 vaccines in the future, such as the duration of vaccine-induced protection and the need for boosters or addition of second or third doses to an existing primary vaccination regime; the public health case for paediatric vaccination strategies; the emergence, transmission and impacts of new variants of concern on vaccine efficacy; the role of mix and match strategies in the context of supply constraints and potential benefits in terms of population coverage; and the potential feasibility and impact of dose-sparing strategies such as fractional dosing in the context of supply constraints. Given the success of dose sharing, there is a risk that this takes preference over direct funding from donors, which would make it difficult to get a predictable supply for country planning purposes and achieve the right mix for the vaccine portfolio. To manage this risk, the COVAX Facility enters into agreements with options for volumes in excess of the targeted demand and advocates against export controls and prioritisation of bilateral deals. It also engages early with suppliers (together with CEPI) on supply chain challenges and seeks to compensate shortfalls with dose-sharing by countries with excess supply (e.g. significant work was done to secure donations to fill the acute supply gap due to the India export ban). The Facility also refreshed its portfolio strategy to respond to changing supply and demand risks (i.e. limited availability of Indian-manufactured vaccines due to export restrictions, emerging safety concerns and evolving recommendations, and emerging data on vaccine efficacy against specific variants), which resulted in a more diversified portfolio (all tech platforms account for <50% of volumes; less reliance on India as the source of vaccines; and with 11 vaccines the Facility now has the largest portfolio of COVID-19 vaccines in the world). Remaining doses available have also been prioritised for delivery in Q3/Q4.

d) COVAX reputation NEW – The risk of reputational damage for the COVAX Facility and Gavi is very high, due to varying interests of many stakeholders, a high need for information sharing, and frustration at the current slow pace of shipments. There was however positive feedback from the last round of communications and advocacy that was more transparent on challenges outside of COVAX's control that prevent it from being successful, with calls to action on donations, manufacturer transparency, manufacturer queue slot-swapping and ending of export bans to ease supplies. There was also strong political support at the UNGA. While the current reputational risks are mostly grounded in the supply challenges experienced by COVAX, going forward the risk may shift to be driven by delivery-related issues. Poor absorption, earmarked dose-sharing or the perception of dose-dumping of lesser vaccines by HICs may result in (the perception of) an uneven roll-out across countries, and wastage of vaccines in country could affect the COVAX Facility's and Gavi's reputation with donors, participants and the public. To manage this risk, a proactive media and communications strategy has been implemented that does not downplay the challenge of ending the pandemic or overstate the role of vaccines but supports the achievements of COVAX. There is strong global media monitoring as well as participation by the Communications team in internal discussions to ensure emerging risks can be assessed quickly and effectively. Systems are in place to facilitate information sharing and there is active engagement by focal points with governments on concerns, as well as monthly briefings on delivery and supply communications. Regarding dose-sharing, there are guardrails on earmarking of shared doses with only broad earmarking being encouraged and a scorecard to evaluate incoming offers including political risks and transaction costs. To combat the perception of dose-dumping, real-time sharing of doses that donors already use and donations of a variety of vaccines are being encouraged. Furthermore, adjustments to the allocation framework design are being explored to take into account criteria that could include total population coverage data, absorptive capacity and epidemiological considerations. Finally, since COVAX supply and delivery risks

are the main underlying contributors to reputational risk currently, mitigation strategies to address those will contribute primarily to reduce the derived reputational impact of those risks materialising.

e) COVAX Facility ▼ – The risk of an inability to adequately operationalise the COVAX Facility has decreased due to progress in mitigating operational and financial risks, but it remains high. The COVAX Facility is no longer in start-up mode and has effectively shifted its focus on operationalisation, with formalised processes, increased resourcing and a dedicated organisational structure. The new country participation model (“SFP 2.0”) as part of the 2022 strategy will also considerably reduce inherent financial risks with revised SFP terms and conditions relying more on upfront payments. The Facility however continues to operate in a dynamic, competitive and challenging external environment, continues to develop new initiatives such as dose-sharing, cost-sharing and the humanitarian buffer, and awaits a large scale-up of activities and transactions going forward after the smaller first wave of vaccine allocations and shipments (given the expectation of more supply availability going forward and in the context of contributing to a high global coverage target of 70% in 2022). The design and strategy of the Facility also needs to continue to adapt to the evolving pandemic and global strategy to remain fit for purpose, and may require further integration with Gavi core processes and routine immunisation programmes in the future. To manage this risk, the Office of the COVAX Facility has developed a full end-to-end operations plan and continues to document priority processes in SOPs. It also continues to hire additional and dedicated resources supported by onboarding programmes and mapping of roles and responsibilities, regular meetings to facilitate coordination across teams, co-creation of processes, problem-solving, work planning and sharing of information. IT systems have been developed to ensure reliable, accessible data for staff and participants including the COVAX Collaboration Portal, intranet and shared drive. A tailored Governance structure, a Pillar level Strategic Coordination Office and a dedicated Country Communications team ensure multi-stakeholder coordination, communication, and decision-making. Financial risk mitigation has been implemented actively with the help of financial advisors, including a decision-making framework and dashboard to optimise the choice of sovereign credit risk cover vis-à-vis particular participant country exposures, and actual insurance coverage with insurance providers for 32 countries. Furthermore, a comprehensive operational cash flow model has been developed to understand liquidity needs, and the need for liquidity buffers and providers. Treasury operations, accounting and banking services have also been reviewed and recommendations to enhance workflows, automate processes and optimise resources are being implemented.

j) Cyber-attack ▲ – The risk of a large cyber-attack significantly compromising critical information systems or data has increased 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 COVID-19. Phishing and other human-facing social engineering tactics remain the primary vectors of potentially successful attacks, but credential guessing leading to account compromise, malware and ransomware is also increasing. 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 a substantial increase in its financial resources 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. 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. To manage this risk, the Secretariat has implemented several measures which include single sign-on with multi-factor authentication, regular patching, local file encryption, and annual security scans. The Secretariat also implemented a Security Operations Centre and security incident and alerts monitoring (SIEM) on the Gavi network in collaboration with the Global Fund. Gavi’s cloud-based systems provide a level of redundancy and back-up across key systems, and allow reliance on the security resilience of large cloud providers. There is furthermore a formal framework for data classification and tools and controls for information protection. User awareness on security risks

(including phishing and sharing of documents and data) continues to be enhanced (e.g. through training and fake phishing campaigns) with a specific focus on high profile users, IT staff with elevated privileges and COVAX Facility users. Business continuity and IT disaster recovery plans have been created based on a business impact analysis of IT systems' unavailability on Gavi's operations. Processes have been put in place for early detection of malware and account compromise and to ensure a swift response and recovery to security related attacks. There is also a focus on enhanced threat intelligence (including an ongoing security forum with WHO, UNICEF and CEPI) and regular assessments and vulnerability testing. 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. An internal audit identified a few more issues for remediation and an ISO 27001 gap analysis is currently ongoing to gauge the effectiveness of mitigations and identify any further steps to improve.

k) Data on zero-dose ▼ – The risk that poor or lacking data may affect the ability of the Alliance to identify and reach zero-dose children, implement effective interventions, understand progress and demonstrate impact is decreasing due to progress in mitigation. It however remains 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, geospatial and qualitative 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 as lack of clustering sub-nationally would make it harder to intervene. Delays in implementation of Gavi levers such as HSS and the new EAF at country level due to the COVID-19 situation may slow down the scale-up of these data activities. To manage this risk, Gavi continues to work with countries and Alliance partners to strengthen the availability and use of quality data for immunisation, to ensure the systems are fit-for-purpose to identify, understand and design the right interventions to reach zero-dose children and missed communities. Building on the work of the Data Strategic Focus Area in Gavi 4.0, there is increasing experience and alignment on how to identify missed communities and engagement with partners on sub-national data, use of data to support advocacy, and data sharing across systems and programmes (e.g. with GPEI). Zero-dose is the focus of the Digital Health Information activities to support timely use of information and to strengthen country capacity to triangulate existing subnational data (both within immunisation and other sectors such as nutrition and education) from multiple sources (e.g. in health management information systems, logistic information systems, surveys, and geospatial mapping) to generate quality evidence to inform management of country EPI programmes. A request for proposals was recently launched for technical assistance (TA) providers to help countries identify zero-dose children and missed communities and prepare robust equity plans as well as a global learning partner to help identify and disseminate key learnings. A cross-Alliance community of practice was established, which includes an online platform to facilitate sharing of knowledge and experience across partners and countries, including for data. Gavi is also designing Learning Hubs in a few countries to be able to better measure progress, support cross-country synthesis and identify and share best practices. 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/religion/ethnicity, geographical concentration of zero-dose children within a country, distribution by Equity Reference Group (ERG) setting and the overlap between zero-dose children and other primary health care (PHC) services. The Alliance is also leveraging campaigns to include specific activities to identify and incorporate zero-dose children in campaign and routine immunisation planning.

m) Secretariat disruption ▲ – The risk of significant disruption of Secretariat operations is increasing due to the ongoing impact of the pandemic on the Secretariat by increasing complexity to the work on its core mission, adding COVAX and the delivery of COVID-19 vaccines to its priorities and changing its ways of working due to virtual and hybrid working and travel restrictions. While mitigation of the current disruption is taking effect,

further disruption could still occur if the pandemic continues or worsens, with increased workload due to COVID-19 delivery scaling up, and with continued organisational changes due to optimisation and integration of COVAX and Gavi core processes. 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 stress 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 substantially reduced given the travel restrictions. Furthermore, being part of a COVID-19 vaccine roll-out is attracting 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 also remains critical (reflected in the medium risk of *Secretariat capacity*) with a heightened workload across the Secretariat to respond to the COVID-19 impact on immunisation, to operationalise the COVAX Facility at record speed, and to support the delivery of 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 and virtual working. 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. Finally, with the current Chief Executive completing his term of appointment in 2023 and the Deputy CEO due to retire in the same year, the Secretariat may be exposed to disruption if the transition to new leadership does not go smoothly (as reflected in the medium risk of *Leadership succession*). To manage this risk, the Secretariat has rolled out the new organisational structure recommended through the organisational review that includes reinforcement of executive leadership and progress in recruitment is starting to alleviate Secretariat capacity constraints. The HR, Communications and Operations teams continue to engage staff and focus on wellbeing, finding ways to keep them connected. A Health and Wellness Committee has been launched with prominent participation from staff. Communication with staff has increased with exchange of regular information. 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. Throughout the remote working period Gavi has been collaborating and aligning safety measures with the other GHC partner organisations, with the joint goal to keep all employees as safe as possible at the Global Health Campus. A similar approach has been adopted in the Washington office. A Ways of Working project has redefined the role of the office once staff can return and physical adjustments to the Gavi offices have been made to enable hybrid working. A Crisis Management team remains deployed against the current crisis.

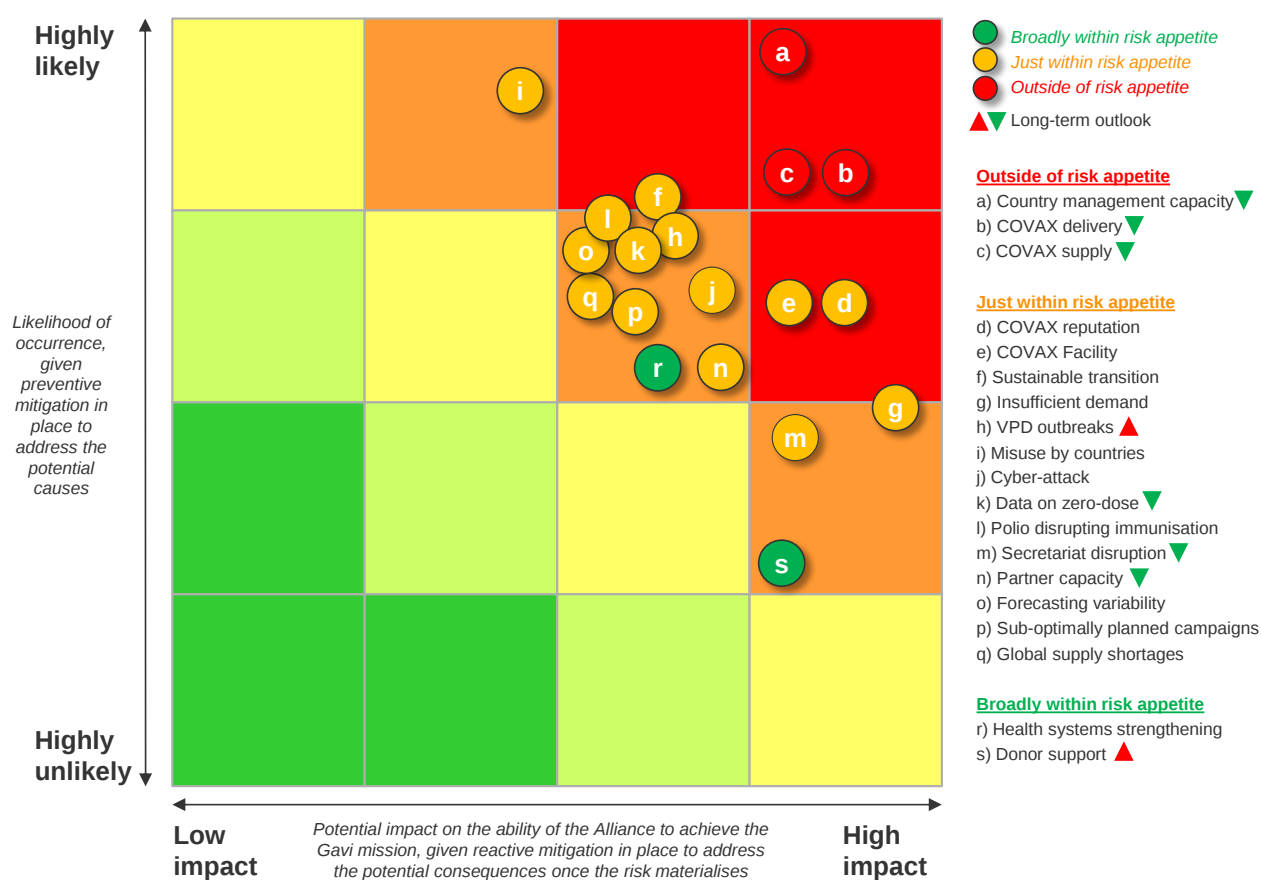
2.3. Gavi's willingness to accept the current top risk exposures

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 updated Risk Appetite Statement⁷, the Alliance embraces the need to take risk to achieve its ambitious mission of leaving no-one behind with immunisation in the world's poorest countries. It acknowledges the risks inherent in its distributed operating model, being an Alliance with a lean Secretariat without in-country presence and dependent on many partners. It also acknowledges the risks inherent in its business model, which requires working through still developing country systems and providing highly catalytic support to implementing countries to ensure country ownership and sustainability. Gavi's new strategy 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. It therefore adopts an overall high risk appetite to achieve its strategic goals.

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 how the high-level statement translates into an appetite for each of the Alliance's top risks as described below (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 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).

⁷ See: <https://www.gavi.org/news/document-library/risk-appetite-statement> or in French: <https://www.gavi.org/fr/actualites/librarie-de-documents/declaration-de-gavi-alliance-sur-lappetit-pour-le-risque>

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) towards being more outside of risk appetite, or decrease (due to trends in risk factors and / or due to the expected effect of ongoing or planned mitigation measures) towards being more within risk appetite.

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

a) Country management capacity – The risk that many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities remains very high. While interventions seem to have contributed to help advance EPI capacities during the pandemic along with support from the Alliance on the ground, existing capacity may continue to be diverted to respond to COVID-19 or may suffer from absenteeism and fatalities. Capacity may become more constrained as the delivery of COVID-19 vaccines scales up further. 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 an orientation of sub-national managers to 'leave no one behind with immunisation' and build greater country management capacity in challenging environments. Most countries do not have contingency plans for natural disasters, outbreaks or other disruptions to immunisation programmes and would need help to plan ahead for possible disruptions, especially in countries that are more prone to such risks. The Alliance is willing to face 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 acknowledges that building management capacity in-country 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 disruption such as conflict, natural disasters and disease outbreaks. It however has a lower appetite for risks to aspects of country management capacity that are critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities, and where the Alliance has a comparative advantage over other actors to make a real difference with targeted, scalable and sustainable interventions. Current exposure is therefore deemed outside of risk appetite as long as intensive mitigation is still ongoing. An external evaluation of Leadership, Management and Coordination (LMC) support found that LMC 'worked' in most situations, and made several recommendations to improve the relevance of the design and coherence of the support at country level to align with Gavi 5.0 principles. To bring this risk more fully within appetite, these recommendations will be taken on board to inform refinement of the approach (e.g. being selective in the type of LMC work we support) and the ambition to scale-up and integrate LMC support as part of Gavi planning, programming and implementation processes. Further mitigation is also required to mitigate against the COVID-19 vaccine roll-out putting pressure on EPI teams' management capacity. The Alliance is already supporting delivery in countries in close coordination with other donors through exceptional support and Covid Delivery Support (CDS) – this also includes a dedicated amount (US\$20 million) specifically targeting surge management support for key, high-risk countries. Discussions have been initiated with WHO and UNICEF regarding ways to synergize delivery of COVID-19 and routine vaccines as twin priorities.

b) COVAX delivery – The risk of significant COVID-19 delivery issues and impact on routine immunisation is very high as the roll out of COVID-19 vaccine doses is expected to rapidly scale up in Q4 2021. The Alliance has in general a high appetite for risks required to pursue timely delivery of COVID-19 vaccines to AMC countries, given the emergency needs during the pandemic. It acknowledges that COVID-19 vaccines have a heightened risk profile compared to routine childhood vaccines as these are new products with different target groups, have specific cold chain and shelf-life characteristics, and are subject to competition, high expectations and politicisation due to the supply-constraint environment. It uses best efforts to mitigate country readiness and roll-out risks in-country, but acknowledges that high levels of residual risk will likely remain and may require

ad-hoc reactive responses. The Alliance aims to reduce the risk that COVID-19 vaccine roll-out adversely affects routine immunisation programmes and capacities, as well as for risks of missed opportunities to exploit synergies and leverage momentum from the COVID-19 vaccine rollout for routine immunisation programmes and Gavi 5.0 objectives (e.g. establishing life course platforms, demand generation, zero-dose identification). It however recognises the dual burden on countries and systems and the need to balance this with an urgent roll-out of COVID-19 vaccine in a global pandemic. The current exposure is therefore outside of risk appetite as long as intensive mitigation is still ongoing. The COVAX Facility will continue to actively monitor and mitigate delivery risks, with a continued focus on highest risk countries and developing bespoke country specific plans to enhance delivery capacity; and by ensuring predictable, high quality, scaled supply that take country preferences and contexts into account. Furthermore, under a refreshed COVAX Pillar Strategy for 2022, the Pillar has started to frame its future role in delivery support. This will include a greater emphasis on strengthening in-country deployment of vaccines in AMC countries; a heightened effort to coordinate with other delivery funders to close the immediate and long-term delivery funding gaps; and a more operational posture with a more deliberate and systematic approach to coordinate with other partners supporting AMC countries.

c) COVAX supply – The risk of significantly reduced and unpredictable COVID-19 supply remains very high given an environment that remains highly uncertain and competitive. The Alliance takes a balanced approach to risks required for securing access to and sufficient supply of safe and efficacious COVID-19 vaccines. It aims to reduce the risk that deal-making delays put the Facility at the back of the queue with manufacturers, but acknowledges that it has no control over competition from bilateral deals and that it needs to minimise financial risk to Gavi's balance sheet. It understands that an actively managed portfolio of vaccine candidates based upon diverse technologies and geographies will maximise the chance of successful outcomes and accepts that some candidates in the portfolio may fail or represent less value for money than others. Current exposure is therefore outside of risk appetite as long as intensive mitigation is still ongoing. The COVAX Facility continues to closely monitor the scientific developments and the supply and demand landscape. It remains important to maintain a diversified portfolio for now, but when the supply situation eases and there is more scientific certainty, it will likely be necessary to narrow the number of products gradually to optimise the products for countries and reduce complexity in delivery. Monitoring the market and active signalling to manufacturers will be important to ensure reliable supply through sustainable competition. The COVAX AMC and COVAX Facility are examining scenarios to secure additional resources and supply to cover ~60% or ~70% of AMC populations plus an additional 500 million doses contingency pool to manage external risk factors e.g., paediatric use, variants and boosters.

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

d) COVAX reputation – The risk of Reputational damage for the COVAX Facility and Gavi is very high, due to varying interests of many stakeholders, a high need for information sharing, and frustration at the current slow pace of shipments. Since Gavi's reputation is critical to its ability to deliver on the mission, the Alliance has in general a low appetite for risks affecting its image and confidence of its stakeholders, including its governance bodies, but is also accepting that in administering the COVAX Facility it needs to assume new levels of reputational risk. Current exposure is deemed just within risk appetite and requires ongoing attention. The COVAX Facility continues to actively monitor and anticipate reputational risks and is balancing maintaining stakeholder relationships with the need to call out issues transparently where this is needed to protect its reputation and unlock barriers for its continued success.

e) COVAX Facility – The risk of an inability to adequately operationalise the COVAX Facility has decreased due to progress in mitigating operational and financial risks, but it remains high. The Alliance acknowledges that the administration of the COVAX Facility requires navigating uncharted territory at unprecedented speed and scale. It is understood that the risks that come with that are worth taking in an effort to end the acute phase of the pandemic, as inaction would leave lower income countries behind and the global economy and Gavi's core mission would continue to be disrupted by the pandemic. The Alliance therefore seeks to find the right

balance between successfully delivering on the promise of the Facility and minimising risks to Gavi core resources and programmes. The Alliance has overall a lower appetite for operational risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners. It also in general has a low appetite for risks affecting its finances and seeks to maintain low levels of accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk. Current exposure is now deemed just within risk appetite due to progress on mitigation and with better clarity on the size of risks and possibilities to mitigate them. It still requires ongoing attention and to bring it more fully within appetite, the COVAX Facility continues to surge capacity, implement robust project and risk management and fill critical skills and capacity gaps. The Facility is currently transitioning to the 'delivery at scale' mode, enhancing and formalising the design to support the expected ramp-up in supply. Looking ahead to 2023 and beyond, attention is likely to turn to integration of COVAX strategy and operations into Gavi's routine immunisation programmes.

f) Sustainable transition – The risk that some countries may fail to sustain progress of their immunisation programmes after transition remains high despite the positive trend of successful transitions, post-transition support having been rolled-out and an increased focus on programmatic sustainability under Gavi 5.0. The number of countries that have transitioned to self-financing remained stable in 2021 as a result of the eligibility freeze that has been approved by the Gavi Alliance Board in response to the pandemic. Penta3 coverage has dropped in Honduras and Bolivia, and the pandemic may further affect transitioned countries' programmatic performance. 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 domestic financing and risks of backsliding in already transitioned countries. Part of the success in preventing backsliding in transitioned countries has been achieved through an expansionary fiscal policy that has seen Governments taking on public debt to support their economies, increase health expenditure per Capita, and off-set reduced revenues due to COVID-19. Despite access to emergency financing, policy responses in low-income countries have been hindered by a lack of fiscal space and little room for monetary policy. While 90% of advanced economies are expected to regain their pre-pandemic per capita income levels by 2022, only one-third of emerging markets and developing economies are expected to do so. 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, despite 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 Alliance continues to engage after transition, but recognises that it will have less ability to fully mitigate performance stagnating or declining once it stops fully financing a country's programme. 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, together with the planned expanded focus on programmatic sustainability. To further mitigate this risk, Gavi is developing a "transition continuum framework" to prepare countries along their transition process with a set of minimum requirements and suitable interventions for each critical immunisation system component, adapted to each of these maturity levels with the aim of monitoring and supporting progress towards a healthy transition. Support to prevent and mitigate the risk of backsliding will continue to be part of the Middle-Income Countries (MICs) approach that has been approved by the Gavi Alliance Board in December 2020 and is now being

operationalised in several identified priority countries, although it has experienced some delays due to the COVID-19 pandemic and vaccine roll-out.

g) Insufficient demand – The risk of a significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation continues to be high due to COVID-19 restrictions and vaccine hesitancy given mis- and disinformation about vaccines (with COVID-19 rumours and conspiracy theories potentially spilling over into demand for routine vaccines). Real time data collection on vaccine confidence and uptake registered an increase in COVID-19 related vaccine hesitancy as vaccines were introduced in countries, and triangulation with social listening data suggested increased rumours started to circulate. Analysis of the BeSD data shows that there are more “doubters” than “resistors” suggesting there is an opportunity to rapidly increase demand by targeting those who are unsure and hence, potentially willing to shift preferences. Currently, despite efforts, demand remains stagnant, suggesting an urgent need to review strategies and implementation. 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 significant drop or insufficient increase in demand and public confidence in vaccines in implementing countries, including due to vaccine hesitancy and gender-related barriers, as this is critical for achieving the equity agenda and reaching missed communities. Current exposure is therefore just within risk appetite and requires ongoing attention. As COVID-19 vaccine introduction accelerates we need to understand the impact on demand and uptake for routine immunisation particularly where capacity is stretched and where there is disruption on the operation of routine services. Increased availability of social data will make it possible to understand trends, and to identify and address emerging issues as soon they emerge in countries.

h) VPD outbreaks – The risk of sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries remains high due to the disruption to routine vaccination services resulting in missed children (early lockdowns at the beginning of the pandemic appear to have led to a 37% reduction in Penta3 doses administered, which has been restored in later months but inconsistent reporting across countries makes it difficult to assess portfolio-level impacts). Another risk factor is the easing of transmission limiting COVID-19 restrictions such as international travel, hygiene promotion and mask wearing. Disease surveillance systems have also been disrupted, which is likely to impact the ability of countries to quickly detect and respond to outbreaks. While the number of outbreaks requiring vaccination responses since the start of the COVID-19 pandemic is relatively low, cholera outbreaks have been recently notified in Nigeria, Niger and Bangladesh and three vaccine requests for more than 10 million Oral Cholera Vaccine (OCV) doses have been received in the last weeks. These large requests have momentarily depleted the global OCV stockpile. Moreover, substantial pressure on OCV supply is anticipated to remain during the foreseeable future, partly due to capacity diversion to COVID-19 related activities. Additionally, 16 countries are experiencing a resurgence of measles, with Cameroon, DRC and Yemen preparing or having already submitted measles outbreak response support. The Alliance aims to reduce the risk of vaccine-preventable disease outbreaks through enhanced routine vaccine support for outbreak-prone diseases, funding of global stockpiles for outbreak response and investments in disease surveillance. It however accepts that disease outbreaks will continue to occur since fully addressing the significant gaps in health systems and preparedness and response capacities require engagement beyond its current mission and resources. It furthermore acknowledges that reducing reliance on frequent and disruptive planned campaigns (see risk of “sub-optimally planned campaigns”) may require a higher acceptance of the risk of outbreaks in the short-term. Current exposure is therefore just within risk appetite and requires ongoing attention. The Alliance accepts that there is significant risk that VPD outbreaks will continue to occur, and will continue to ensure that at-risk countries introduce Gavi-supported vaccines, and timely outbreak response interventions are implemented. A revised TCA grant to support timely ICG

applications is being developed and a full proposal on enhanced diagnostic support for disease surveillance is going to be submitted for the Board approval in December.

i) Misuse by countries – The risk of deliberate misuse of Gavi support in many Gavi-supported countries remains high during these times of crisis, economic uncertainty, low morale and financial pressures. This provides more opportunities to commit and rationalise fraud due to a weakened internal control environment and possibilities to take advantage of people's fear and distraction. Equally countries are under pressure during a health emergency to spend faster, and to set aside their usual processes for emergency procurements. At the same time, travel restrictions continue to impair grant oversight and assurance in Gavi-supported countries. Gavi also provided increased funding to help countries respond to the pandemic and maintain, restore and strengthen immunisation programmes, using a fast-tracked application and review process. Furthermore, to move quickly in response to COVAX delivery risks Gavi is making funds available with less up-front due diligence (however mitigated by post facto assurance mechanisms). 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 the existence of secondary markets (although they still require a cold chain). They could also be diverted to non-target groups within countries or be used in exploitative transactions. The Alliance has in general 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 pandemic context and the ability to mitigate and obtain assurance is constrained. The Alliance therefore acknowledges that, during the duration of the crisis, risks may increasingly materialise despite best efforts to mitigate them. The Alliance is also willing to take risk where this is needed to respond flexibly and quickly to evolving needs, recognising that Gavi support to maintain, restore and strengthen immunisation services is needed more than ever due to the impact of the pandemic on routine immunisation programmes. Risks furthermore need to be balanced when reaching zero-dose children requires working more sub-nationally and in challenging operating environments with very weak financial management capacity; and when building sustainable country capacity and ownership requires channelling support through government systems. Accepting to be exposed to fiduciary risk does not mean actual occurrence is desirable or it should be tolerated should it occur. In case of actual misuse, Gavi will always require reimbursement as a condition of continued support. Current exposure is therefore just within risk appetite and requires ongoing attention. Following the June Board's approval of the Gavi 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, additional support will be provided to help countries develop better systems. This Board decision also provided a ring-fenced source of funding for continued development of other risk mitigation and assurance options, institutionalising the approach to fiduciary risk assurance and financial management capacity-building introduced in Gavi 4.0. Other planned initiatives include deepening working relationships with other non-traditional partners to improve capacities, e.g. Supreme Audit Institutions (SAIs), Country Internal Audit Departments and the International Federation of Accountants (IFAC).

j) Cyber-attack – The risk of a large cyber-attack significantly compromising critical information systems or data is increasing despite progress in mitigation. 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. Additional security enhancements continue to be delivered as part of the Cybersecurity programme, overseen by a Cybersecurity Steering Committee. This includes continued enhancements to e-mail, mobile phone and cloud security; a security drill exercise; and further audit findings remediations and actions based on an ongoing ISO 27001 gap analysis.

k) Data on zero-dose – The risk that poor or lacking data may affect the ability of the Alliance to identify and reach zero-dose children, implement effective interventions, understand progress and demonstrate impact due

to progress in mitigation. It however remains 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, geospatial and qualitative data. The Alliance is willing to face 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 acknowledges that improving data availability, quality and use in-country is not fully within Gavi's control and would likely remain a challenge for a long time. It however has a lower appetite for risks to 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. The Alliance continues to improve measurement including through targeted sub-national surveys and assessments and building country capacity and tools for generating insights from monitoring dashboards and analytics (including provision of global analytics of local data to inform country conversations). This includes, for example, scaling up District Health Information Software 2 (DHIS-2) dashboards for district-level immunisation monitoring and increased use of DHIS-2 campaign monitoring module where post-campaign surveys cannot be completed. It is also strengthening data triangulation to utilize "imperfect" data and introducing real-time campaign monitoring. Gavi is also strengthening global level data, including a revision of WUENIC and refining the electronic Joint Reporting Form. 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. To better measure progress, support cross-country synthesis, inform key strategy and policy questions, and help identify best practices to share across countries, the Secretariat is planning to create a number of learning hubs, which will supplement routine monitoring with deeper measurement, analysis and understanding of factors influencing the performance of approaches to reach zero-dose children and missed communities.

I) Polio disrupting immunisation – The risk that polio ramp-down or resurgence may adversely affect routine immunisation remains high as the COVID-19 related programme pauses and disruptions of preventive and outbreak response campaigns have likely resulted in lower population immunity with potential for increased transmission. While the earlier setbacks in the eradication effort in Pakistan and Afghanistan have been followed by a significant downturn in transmission since beginning of this year (possibly due to the lockdowns, school closures, and attention to hygiene/hand-washing – but disease surveillance may also have missed low-lying chains of transmission), the political upheaval and population movement in Afghanistan risk a resurgence. In countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2 remain a large risk with widespread transmission in west Africa (with ongoing outbreaks in northern Nigeria) as well as cases detected in Tajikistan and now emergent in Ukraine. Outbreak response activities continue in a number of countries, primarily in Africa with Emergency Use Listed (EUL) novel OPV2, a more genetically stable vaccine, being increasingly used. While the impact of nOPV2 is still being assessed, data thus far indicate a high degree of genetic stability that would signal less potential seeding of vaccine-derived virus to type-2 immune naïve populations. However, as supply of nOPV2 is currently limited, countries will need to respond to outbreaks with monovalent oral polio type 2 vaccine (mOPV2), which risks causing further vaccine-derived poliovirus cases, or wait and risk further transmission and paralysis of children. 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. 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. As a core GPEI partner, Gavi continues to shape the Integrated Service Delivery workstream for both endemic and outbreak

countries in line with 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).

m) Secretariat disruption – The risk of significant disruption of Secretariat operations is increasing due to the ongoing impact of the pandemic on the Secretariat by increasing complexity to the work on its core mission, adding COVAX and the delivery of COVID-19 vaccines to its priorities and changing its ways of working due to virtual and hybrid working and travel restrictions. 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 and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. In preparation for business travel to resume, staff security training will be made mandatory and additional processes are being developed for managing travel in a COVID and post COVID world. Additional Secretariat resources approved by the Gavi Alliance Board in December 2020 and a rigorous focus on staff wellbeing are expected to improve conditions. The Secretariat is furthermore developing a new Incident Response Policy and procedures based on learnings from dealing with the current crisis. In addition, all Business Continuity and Incident Response plans will be revisited to fill any gaps.

n) Partner capacity – The risk that the sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries remains high 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 COVID-19 vaccines may divert attention and resources away from routine immunisation. As an indication, partner performance in countries remained below pre-pandemic levels with 69% of milestones achieved (a slight improvement from mid-2020, but still below 2019). 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. With PEF Targeted Country Assistance (TCA) design shifting its focus towards zero-dose children and missed communities, the ability to develop local partnerships to better serve these missed communities has been raised as a key challenge. Furthermore, currently only 6% of programmed TCA activities specifically mention zero-dose children, and especially fragile countries are seeing poor utilisation of TCA funds. While local partner engagement is improving overall, this is limited by local partners not being empowered to participate in government level discussions and planning of immunisation services, and insufficient capacity building and strengthening of local partners on the ground to ensure there is a wider pool of partners with local expertise to access TCA funds. The Alliance has overall a lower appetite for risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners. It seeks to reduce risks related to the capacity and performance of Alliance partners. As such, it is aiming to engage with a wider set of partners, including local organisations and CSOs, and to collaborate with other health actors to strengthen primary health care and multisectoral approaches. This broader engagement requires a constant trade-off with the increased complexity of managing many partners at country level. The Alliance also has a low appetite for risks which could undermine accountability and transparency within and between the Secretariat, Alliance partners and implementing countries. The Alliance has a high appetite for risks associated with working with new partners, including local organisations and CSOs, which have critical context-specific expertise and the ability to reach zero-dose children in humanitarian and conflict areas outside government reach. The current risk exposure is therefore just within risk appetite and requires ongoing attention. Ensuring that 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, new partnerships (including increased engagement of local institutions and Civil Society Organisations) and sustainability. Another key shift in Gavi 5.0 is the way Partner performance will be monitored. Milestone reporting (used to monitor Partner performance in Gavi 4.0) will become more results-focused and more strongly aligned with Gavi's overarching monitoring framework and 5.0 key performance indicators. A global Expression of Interest and prequalification process is underway to further engage local institutions and global partners with a comparative advantage for subnational work. US\$ 100 million of the EAF will be allocated to new multi-country partnerships to reach zero-dose children and missed communities in fragile, conflict and cross-border settings outside government reach. A call for proposals to find appropriate partners was launched in September 2021, with the selection of providers expected to conclude before the end of the year. In order to build momentum and cohesion across the Alliance, a cross-Alliance Community of Practice (COP) on the zero-dose agenda is being established.

o) Forecasting variability – The risk that Gavi forecasting variability drives inappropriate decision-making remains high with the ongoing uncertainty in the context of COVID-19 creating a higher risk of variability as compared to previously, with the exact trajectory of disease and its ultimate impact on immunisation programmes and vaccine introductions in Gavi supported countries difficult to predict. There is also a high level of dependency on procurement partners for vaccine purchases (around 50% of disbursements) and there is not yet sufficient clarity on their long-term forecasting and underlying arrangements with manufacturers. The successful and timely execution of Gavi programmes depends on appropriate capacity in the Secretariat, Alliance partners, Ministries of Health (MOH) and other in-country partners. It is also anticipated that additional donor contributions will be received over and above the pledges reflected in the forecast, particularly from donors that have not made multi-year pledges for the entire strategic period. While there is evolving information about suppliers adjusting to incorporate the impact of COVID-19, it is too early to reflect a major shift in supply capacity or price in the forecast with certainty. The forecast does furthermore incorporate the short-term economic impact of the pandemic on country eligibility and transition, but the long-term co-financing is based on a highly uncertain GNI projection outlook. Current exposure is just within risk appetite and therefore requires ongoing attention. More frequent updates to the forecast continue to capture fast evolving assumptions, including greater integration of the forecast with various additional short-term data (e.g. shipments, disbursements, COVID-19 trackers). Forecasting and planning processes need to continue to be strengthened and better integrated. 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.

p) Sub-optimally planned campaigns – The risk that multiple large disease focused vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services remains high. As a result of COVID-19, the majority of planned campaigns had 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. Many delayed campaigns have now been targeted for 2021 to clear the backlog created by the pandemic. As more campaigns resume, 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. COVID-19 may therefore impact the ability to implement high quality campaigns, and pressure to implement quickly may result in insufficient consideration of effective integration and focus on zero-dose communities. 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. The Alliance has in general a low appetite for the risk of preventive immunisation campaigns undermining the capacity to manage and deliver long-term sustainable routine health and immunisation services and bring zero-dose children into the routine health system. It also has in general a low appetite for the risk of such supplementary campaigns being of low quality due to sub-optimal planning and implementation. However, the Alliance may need to assume a higher level of risk in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term, and in emergency situations where immunity gaps need to be closed rapidly to prevent imminent disease outbreaks. 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. The Secretariat is strengthening its screening of campaign applications and piloting differentiated operational costs for M/MR campaigns. The Alliance is reimagining how to support countries to plan comprehensive immunisation services with appropriate delivery strategies and build back better with a focus on zero dose children and reaching them with all antigens as well as other essential health services.

q) Global supply shortages – The risk of shortages in the global vaccine supply affect Gavi-supported countries remains high, with six vaccine markets assessed to be of low health (Measles, MR, MenA, JE, HPV, OCV). Three markets (Measles, MenA, JE) were scored as such because of low supplier diversity but are considered within acceptable risk levels due to sufficient capacity and a strong track record of the dominant supplier. Global demand for HPV continues to outpace available supply, as well as the manufacturing capacity expansion efforts of a major supplier to Gavi, but overall HPV supply is expected to increase in Gavi 5.0. Rotavirus vaccine experienced an unexpected reduction in the volume outlook from the primary supplier (not pandemic related), resulting in a ~10 million annual dose gap versus future demand. The Secretariat and Alliance partners are working with six countries to provide planning and technical support to facilitate switches to alternative rotavirus vaccines starting in 2022. The risk to supply of Gavi-supported vaccines posed by Covid-19 may be receding, but still exists. The impact of a 2020 PCV disruption was successfully managed with partners into 2021, although the risk has not materialised beyond this so far. Some repurposing of primary and secondary production lines for Covid-19 vaccines is inevitable, but this has not resulted in any material trade-off with non-Covid-19 vaccine processes. Additionally, Gavi is also monitoring Covid-19's impact on development timelines of pipeline vaccines in Gavi-supported categories; some delays have been reported by manufacturers, which in two cases resulted in revisions to Roadmap assumptions. At present there are no pipeline delays considered to be critical to long-term market health outcomes. The Alliance takes a balanced approach to the risk of supply shortages and aims to ensure sufficient and uninterrupted supply of vaccines, especially if this may impact existing programmes. It however also acknowledges that demand and supply are inherently volatile and 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. Furthermore, mitigation is constrained by limitations in the degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges. Current risk exposure is therefore just within appetite and requires ongoing attention. Alliance partners are closely monitoring the Covid-19 situation, with regular engagement of manufacturers, and with the COVAX Manufacturing Task Force making progress in the CEPI-led effort to de-risk the environment for raw materials and consumables such as adjuvants, tubing, glass vials, filters, single-use bags, etc. This effort is initially focused on Covid-19 supply chains, but its applicability will be broader and is expected to be formally extended to non-Covid-19 vaccines in early 2022.

Top risks broadly within risk appetite – to be monitored

Exposures for the remaining two top risks fall broadly within risk appetite. These are **r) Health Systems Strengthening**, and **s) Donor support**. It should be noted, however, that the long-term outlook is expected to increase for **s) 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.

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 risks are effectively managed. While separate from the first line, they are still under the control and direction of senior management.
Constituted by Risk, Legal, Finance, Operations, Funding Design & Review, Portfolio Financial Management and Measurement Evaluation & Learning
- **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 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

The Alliance is accepting to face risks required to achieve its goals, enabled by robust risk management to ensure these stay within the Board-approved risk appetite

Mission	- The Alliance embraces the need to take risk to achieve its ambitious mission of leaving no-one behind with immunisation in the world's poorest countries - It acknowledges risks inherent in its operating model relying on many partners and in its business model requiring country ownership - It acknowledges that during the COVID-19 crisis risks may increasingly materialise, and is willing to take risk needed to respond flexibly and timely to special needs - It understands that operating the COVAX Facility carries risks worth taking, and seeks to find the right balance to minimise risks to core resources and programmes The Alliance adopts an overall high risk appetite to achieve its strategic goals, acknowledging the aspirational ambition of the Gavi 5.0 strategy, requiring more and novel support to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments			
Strategic Goals	1 INTRODUCE AND SCALE UP VACCINES 2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION 3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES 4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS	High - Risks required to introduce and scale up coverage in fragile/emergency settings - Risks required for equitable allocation and timely delivery of COVID-19 vaccines Balanced - Vaccine-preventable disease outbreaks Low - Vaccine introduction decisions exacerbating inequities or affecting sustainability - Campaigns undermining routine immunisation or being of low quality	High - Risks required to strengthen health systems and increase equity - Risks of working with new partners - Risks of exploring innovative strategies Balanced - Building immunisation-critical management capacity in-country - Improving data quality to find and target zero-dose children - COVID19 roll-out adversely affecting routine immunisation or missed opportunities for synergies Low - Fraudulent misuse of Gavi support - Drop or insufficient increase in vaccine demand and confidence - Weak systems jeopardising vaccine and immunisation safety	High - Risks required to transform markets - Risks required to incentivise innovation for vaccine development and scale up of related products Balanced - Supply shortages impacting existing programmes - Risks required for securing access to and sufficient supply of safe and efficacious COVID-19 vaccines
Organisation	The Alliance has overall a lower appetite for organisational risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners			

REPUTATIONAL, FUNDING AND FINANCIAL RISK

- High**
- Risks required for attracting new donors
- Balanced**
- Risks affecting Gavi's image and confidence of its stakeholders
- Low**
- Immunisation becoming a lower priority on policy agendas
 - Risks affecting the sustainability of donor funding
 - Risks affecting Gavi's finances (accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk)
 - Forecasting variability reducing manufacturer or donor confidence

PERFORMANCE RISK AND OVERSIGHT

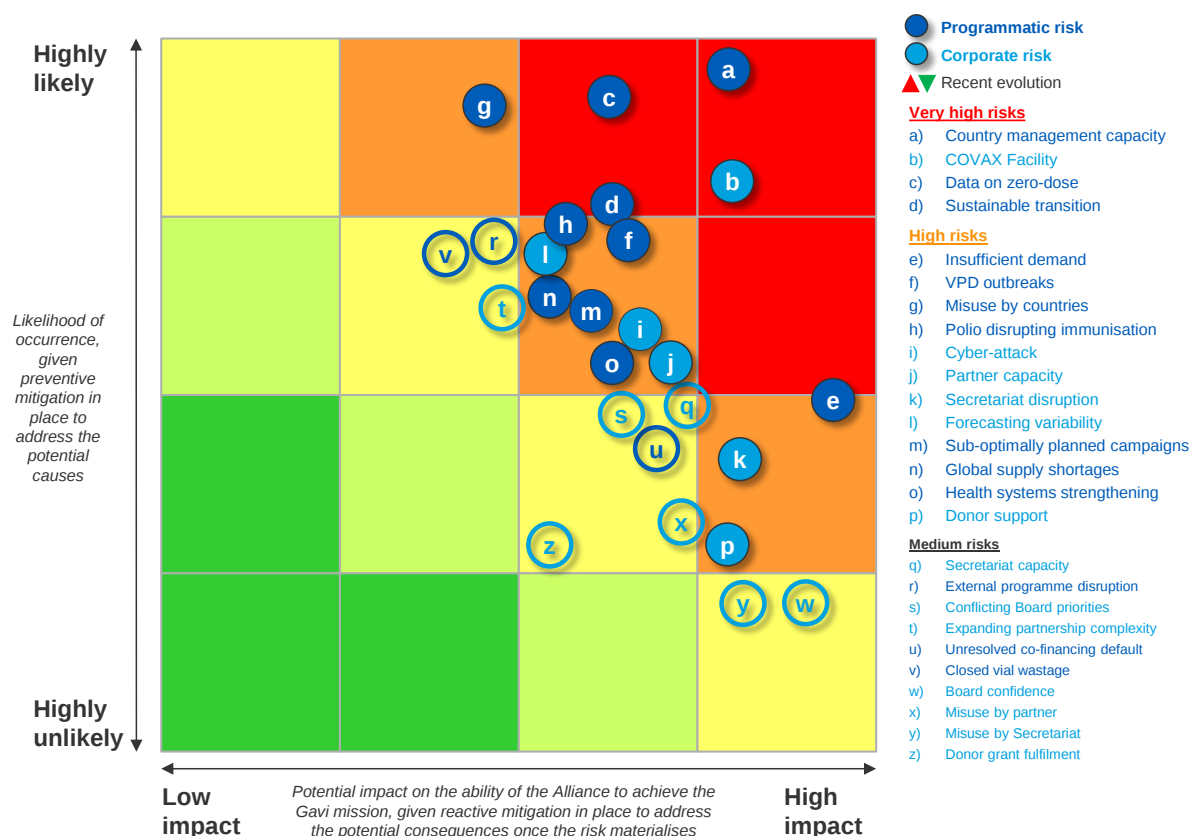
- Balanced**
- Risks related to the capacity and performance of Alliance partners
 - Risks related to the increasing complexity of managing many partners at country level
 - Risks related to grant performance in-country
- Low**
- Risks undermining accountability and transparency

OPERATIONAL RISK

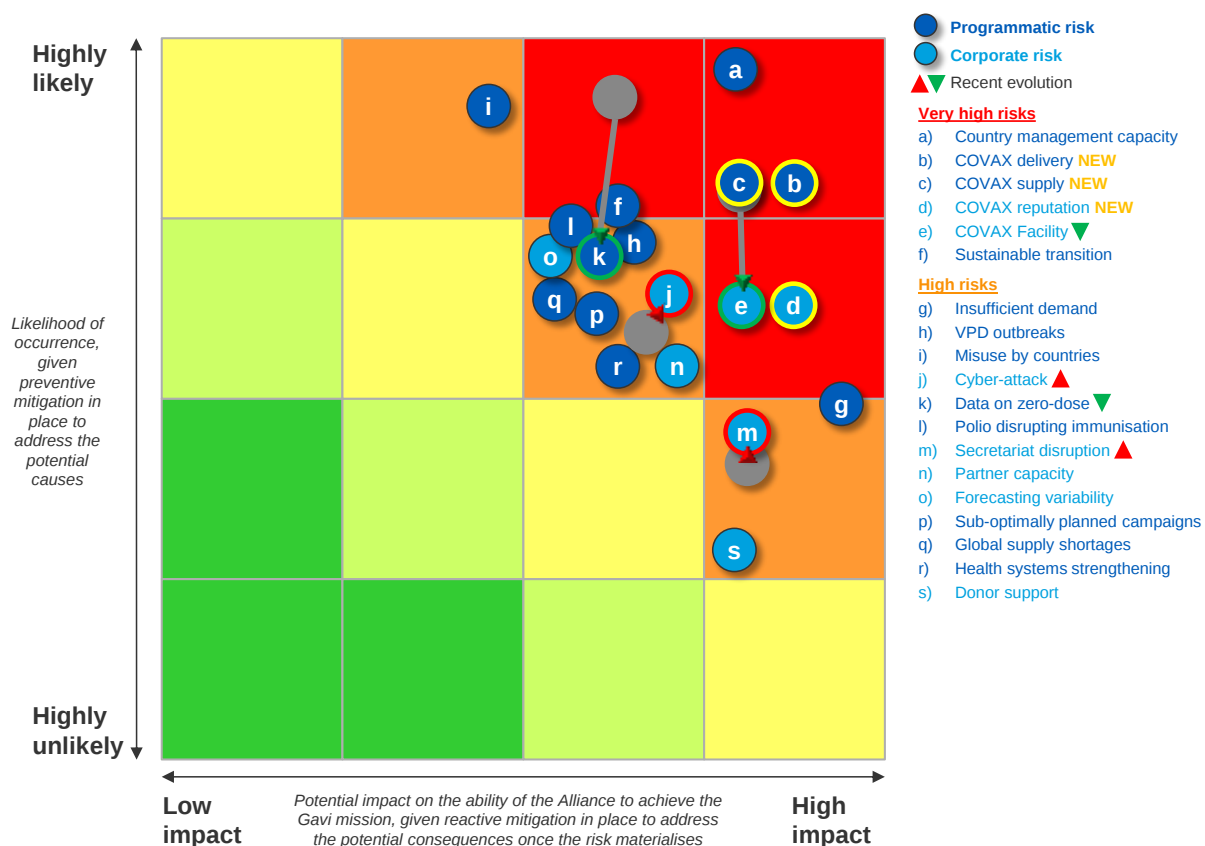
- Low**
- Quality and robustness of Secretariat processes, facilities and business continuity
 - Critical information systems or data being compromised
 - Risks related to staff health and safety, engagement and capacity, including harassment and exclusion

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

2020 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
Country management capacity Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities	- Weak existing systems and technical capabilities - Weak management capabilities - Insufficient human resources or retention challenges - Insufficient prioritisation of health and immunisation - Inadequate support from Alliance to build capacity - External programme disruption (conflict, natural disasters, disease outbreaks, political change/devolution)			OUTSIDE		

Risk description

During the Gavi 5.0 strategic period, there is a greater need to work more sub-nationally, in remote rural, urban and conflict settings, where almost half of zero-dose children live. 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), retention challenges and more recently – the Covid pandemic and the roll-out of Covid-19 vaccines. 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.

Existing mitigation

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. Several of these tools have been impacted by the pandemic – for instance, country visits have for the most part not taken place for the last 18 months, and joint appraisals have not been carried out as before. Nevertheless, country management capacity gaps continue to be addressed with technical assistance targeted at improving leadership, management and coordination (LMC) capacities in the EPI units; strengthening national Inter-Agency Co-ordinating Committees (ICCs) and Health Sector Coordination Committees (HSCC) by revising their mandate, membership and oversight function; and enhancing financial management. The most promising interventions include building sub national capacity for supervision, strategic use of data for local decision making and performance management, institutional restructuring of EPI units, embedded management support, and building effective teams through management training programmes such as the Yale EPI management training and supply chain management training (STEP) developed jointly with the Global Fund and USAID. Leadership, Management and Coordination (LMC) support has been adapted to match country needs during the pandemic with partners stepping up to help manage and provide oversight of EPI and other primary health care services, address gaps as necessary (e.g. multi-sectoral coordination and risk communication) and ensure a rapid response to issues on a daily basis. In addition, a peer learning platform was set up for the EPI Leadership and Management Programme (EPILAMP) alumni, covering 20-25 countries, to share lessons on managing and building back EPI services. The Board also approved additional HSS and PEF funding as part of a comprehensive approach to reach zero-dose children and missed communities, and to institutionalise the approach to financial management capacity-building to ensure timely funding of activities at sub-national level to reach zero-dose communities.

Current risk exposure

Current exposure to this risk remains very high. While interventions seem to have contributed to help advance EPI capacities during the pandemic along with support from the Alliance on the ground, existing capacity may continue to be diverted to respond to COVID-19 or may suffer from absenteeism and fatalities. Capacity may become more constrained as the delivery of COVID-19 vaccines scales up further. 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 an orientation of sub-national managers to 'leave no one behind with immunisation' and build greater country management capacity in challenging environments. Most countries do not have contingency plans for natural disasters, outbreaks or other disruptions to immunisation programmes and would need help to plan ahead for possible disruptions, especially in countries that are more prone to such risks.

Risk appetite and planned further mitigation

The Alliance is willing to face 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 acknowledges that building management capacity in-country 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 disruption such as conflict, natural disasters and disease outbreaks. It however has a lower appetite for risks to aspects of country management capacity that are critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities, and where the Alliance 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. An external evaluation of Leadership, Management and Coordination (LMC) support found that LMC 'worked' in most situations, and made several recommendations to improve the relevance of the design and coherence of the support at country level to align with Gavi 5.0 principles. To bring this risk more fully within appetite, these recommendations will be taken on board to inform refinement of the approach (e.g. being selective in the type of LMC work we support) and the ambition to scale-up and integrate LMC support as part of Gavi planning, programming and implementation processes. Further mitigation is also required to mitigate against the COVID-19 vaccine roll-out putting pressure on EPI teams' management capacity. The Alliance is already supporting delivery in countries in close coordination with other donors through exceptional support and Covid Delivery Support (CDS) – this also includes a dedicated amount (US\$20 million) specifically targeting surge management support for key, high-risk countries. Discussions have been initiated with WHO and UNICEF regarding ways to synergize delivery of COVID-19 and routine vaccines as twin priorities.

b) COVAX delivery

Significant COVID-19 delivery issues and impact on routine immunisation

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
b. COVAX delivery Significant COVID-19 delivery issues and impact on routine immunisation	• Insufficient country readiness and absorption capacity • Lack of demand and vaccine hesitancy • Wastage due to expiry or cold chain failures • Adverse impact on RI or missed opportunity for synergies			OUTSIDE	NEW	

Risk description

Now that the Facility is shipping vaccines to countries, and increasingly large volumes, risk exposures have also shifted towards delivery risks in-country. After COVID-19 vaccines are allocated, countries need to be ready to receive, distribute and use the vaccines. Particularly in lower and middle-income countries, there is a risk of insufficient absorption due to insufficient country readiness, driven by difficult or fragmented access to available delivery funding, limited predictability of short- and medium-term supply, insufficient workforce

capacity, gaps in cold chain, supply chain and service delivery or issues with demand and vaccine confidence in some countries. Vaccine hesitancy can persist due to misinformation, a perception of rushed vaccine development, substandard other COVID-19 vaccines, counterfeit vaccines, or a lack of product choice. Uptake can also be affected by an increased incidence of serious adverse events (SAEs) or evolving evidence on safety and efficacy (e.g., in light of variants) restricting appropriate use. Insufficient uptake can result in idle doses in-country, which represent an opportunity cost globally and could lead to wastage if these expire (especially given the short shelf life currently). Vaccine wastage can also happen due to poor handling, temperature excursions (given ultra cold chain requirements for some vaccines) or force majeure events. Large-scale COVID-19 vaccine delivery may also divert focus and capacity (across countries, partners and Secretariat) from routine immunisation, use RI resources such as syringes, and potential COVID-19 vaccine safety events may have a broader impact on routine vaccine confidence. However, there may equally be missed opportunities to exploit synergies and leverage momentum from the COVID-19 vaccine rollout for routine immunisation programmes and Gavi 5.0 objectives (e.g. establishing life course platforms, demand generation, and zero-dose identification).

Existing mitigation

To manage this risk, COVAX Pillar partners are actively monitoring key delivery risks through weekly 'implementation monitoring reviews' and defining targeted interventions for high risk countries (e.g. accelerating access to funding for delivery when there are gaps, adjusting future shipments and allocation based on absorption, informing the next allocation round with product preference, considering redeployment of doses within or outside the country, and providing specific technical assistance based on country implementation gaps). Furthermore, significant but fragmented funding is being made available by funders including UN partners, bilateral donors, private sector partners and the multilateral development banks to try and help mitigate these risks, including nearly ~\$1B in delivery support from Gavi. Initial Gavi funding has already supported >400 in-country positions (primarily through UNICEF and WHO) and procured and deployed cold chain equipment to fill critical gaps. Further Gavi funding is designed to be both expedient, needs based, and targeted on areas where it will have high impact. An initial tranche had been made available via an early access window, with significantly reduced transaction times, including an abbreviated application and waived IRC review to ensure funding is readily available in advance of increasing supply. Sufficient COVID-19 delivery funding will also help in mitigating the potential impact on routine immunisation and at the same time be used to exploit synergies where possible. Furthermore, there is a demand generation and building of community trust workstream where Alliance partners and CSOs provide information and advice to challenge misinformation, advocate for vaccine benefits, and engage communities. There is also a global assessment of safety of COVID-19 vaccines by WHO PQ and the Global Advisory Committee on Vaccine safety, as well as active surveillance for adverse events following immunisation. Moreover, the No Fault Compensation (NFC) scheme makes compensation available to eligible individuals in AMC countries for rare but serious adverse events associated with COVAX-distributed vaccines without the need to resort to law courts. To mitigate wastage, COVID-19 vaccines have been integrated into regular stock management and monitoring systems (eLMIS), technical assistance is provided through Alliance Partners to support vaccine management, and a COVAX CCE platform exists to strengthen supply chains. There are also enhanced monitoring solutions in development, through contracting Monitoring Agents in-country and funding CSOs to monitor COVAX implementation. All partners are supporting COVAX countries to advise how to avoid expired doses through national deployment and vaccination planning, microplanning, cold chain and logistic support, and guidance on delivery mode.

Current risk exposure

Current exposure to this risk is very high as the roll out of COVID-19 vaccine doses is expected to rapidly scale up in Q4 2021, and a substantial volume will be from Pfizer – the hardest to deliver given ultra cold chain and special syringe requirements, and through dose donations – the hardest to plan for as these often come with earmarking and little notice or in a staggered manner and in small volumes and with short shelf lives. The

absorption of such volumes of vaccines is expected to represent a significant challenge for many countries, although the situation varies across countries, and up till now, most countries have been able to increase delivery as supply scales up and mitigate the risk of dose expiry. In the absence of consistent and predictable supply it remains difficult to gauge real absorptive capacity in many countries. The emergence of new virus variants and safety signals for some vaccines has also created further uncertainty for allocation and uptake, with the potential for refusals due to product preferences and vaccine confidence potentially affecting uptake in country populations due to (perceived) safety concerns. A shortage of syringes could also hinder effective roll-out as well as impact routine immunisation. Cold chain capacity may also prove insufficient in some places because of a steep increase in supply.

Risk appetite and planned further mitigation

The Alliance has in general a high appetite for risks required to pursue timely delivery of COVID-19 vaccines to AMC countries, given the emergency needs during the pandemic. It acknowledges that COVID-19 vaccines have a heightened risk profile compared to routine childhood vaccines as these are new products with different target groups, have specific cold chain and shelf-life characteristics, and are subject to competition, high expectations and politicisation due to the current supply-constraint environment. It uses best efforts to mitigate country readiness and roll-out risks in-country, but acknowledges that high levels of residual risk will likely remain and may require ad-hoc reactive responses. The Alliance aims to reduce the risk that COVID-19 vaccine roll-out adversely affects routine immunisation programmes and capacities, as well as risks of missed opportunities to exploit synergies and leverage momentum from the COVID-19 vaccine rollout for routine immunisation programmes and Gavi 5.0 objectives (e.g. establishing life course platforms, demand generation, zero-dose identification). It however recognises the dual burden on countries and systems and the need to balance this with an urgent roll-out of COVID-19 vaccine in a global pandemic. The current exposure is therefore just within risk appetite and requires ongoing attention. The COVAX Facility will continue to actively monitor and mitigate delivery risks, with a continued focus on highest risk countries and developing bespoke country specific plans to enhance delivery capacity; and by ensuring predictable, high quality, scaled supply that take country preferences and contexts into account. Furthermore, under a refreshed COVAX Pillar Strategy for 2022, the Pillar has started to frame its future role in delivery support. This will include a greater emphasis on strengthening in-country deployment of vaccines in AMC countries; a heightened effort to coordinate with other delivery funders to close the immediate and long-term delivery funding gaps; and a more operational posture with a more deliberate and systematic approach to coordinate with other partners supporting AMC countries.

c) COVAX supply

Significantly reduced and unpredictable COVID-19 supply

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
c) COVAX supply Significantly reduced and unpredictable COVID-19 supply	• Competition from bilateral deals • Inability to secure deals in time • Export controls • Manufacturer prioritisation or production issues			OUTSIDE	NEW	

Risk description

With funding from both donors through the COVAX AMC and Self-Financing Participants, the Facility is contracting doses with manufacturers to accelerate access. It enables and encourages vaccine manufacturers to expand supply and achieve economies of scale through aggregating demand and increasing availability simultaneously in developed and developing countries. The risk of significantly reduced and unpredictable COVID-19 supply following signature of Advance Purchase Agreements (APAs) could be caused by manufacturer production issues, including a lack of raw materials (e.g. adjuvants, glass vials, filters), quality control bottlenecks (e.g. overwhelmed validation/testing labs), and logistical bottlenecks. It could also be

caused by a prioritisation of bilateral deals, export controls and vaccine nationalism; regulatory approval delays; or newly discovered safety or efficacy issues post approval. Without sufficient and predictable supply, lower income countries would continue to be left behind and the global economy and Gavi's core mission would continue to be disrupted by the pandemic. Furthermore, when supply arrives without sufficient notice or in a staggered manner (which often happens with dose donations), countries are unable to effectively plan and efficiently roll-out vaccines in-country.

Existing mitigation

To manage this risk, the COVAX Facility enters into agreements with options for volumes in excess of the targeted demand and advocates against export controls and prioritisation of bilateral deals. It also engages early with suppliers (together with CEPI) on supply chain challenges and seeks to compensate shortfalls with dose-sharing by countries with excess supply (significant work was done to secure donations to fill the acute supply gap due to the India export ban). It also refreshed its portfolio strategy to respond to changing supply and demand risks (limited availability of Indian-manufactured vaccines due to export restrictions, emerging safety concerns and evolving recommendations, and emerging data on vaccine efficacy against specific variants), which resulted in a more diversified portfolio (all tech platforms account for <50% of volumes; less reliance on India as the source of vaccines; and with 11 vaccines it now has the largest portfolio of vaccines in the world). Remaining doses available have also been prioritised for delivery in Q3/Q4.

Current risk exposure

This risk has materialised due to export restrictions and technical difficulties in manufacturing scale up which resulted in significant delays in supply of the COVAX Facility doses. A large portion of the doses originally forecasted to arrive throughout 2021 have been pushed into Q4 2021 and early 2022. Many countries and other procurement mechanisms have equally been affected by a highly unpredictable market. Due to the COVAX Facility's response to adapt and build resilience, including through the establishment of a dose sharing programme, portfolio diversification, new deals and options exercised, the pace of supply has now significantly accelerated and Q4 2021 is expected to outpace the first three quarters of the year combined. The key COVAX Facility milestone of 2 billion doses released for delivery is now expected to be reached before the end of Q1 2022. However, current exposure to this risk remains very high given an environment that remains highly uncertain and competitive. There are still many fundamental scientific uncertainties which may impact supply and the use of COVID-19 vaccines in the future, such as the duration of vaccine-induced protection and the need for boosters or addition of second or third doses to an existing primary vaccination regime; the public health case for paediatric vaccination strategies; the emergence, transmission and impacts of new variants of concern on vaccine efficacy; the role of mix and match strategies in the context of supply constraints and potential benefits in terms of population coverage; and the potential feasibility and impact of dose-sparing strategies in the context of supply constraints. Given the success of dose sharing, there is a risk that takes preference over direct funding, which would make it difficult get a predictable supply for country planning purposes and achieve the right mix for the vaccine portfolio.

Risk appetite and planned further mitigation

The Alliance takes a balanced approach to risks required for securing access to and sufficient supply of safe and efficacious COVID-19 vaccines. It aims to reduce the risk that deal-making delays put the Facility at the back of the queue with manufacturers, but acknowledges that it has no control over competition from bilateral deals and that it needs to minimise financial risk to Gavi's balance sheet. It understands that an actively managed portfolio of vaccine candidates based upon diverse technologies and geographies will maximise the chance of successful outcomes and accepts that some candidates in the portfolio may fail or represent less value for money than others. Current exposure is therefore deemed just within risk appetite and requires ongoing attention. The COVAX Facility continues to closely monitor the scientific developments and the supply and demand landscape. It remains important to maintain a diversified portfolio for now, but when the supply situation eases and there is more scientific certainty, it will likely be necessary to narrow the number of products

gradually to optimise the products for countries and reduce complexity in delivery. Monitoring the market and active signalling to manufacturers will be important to ensure reliable supply through sustainable competition. The COVAX AMC and COVAX Facility are examining scenarios to secure additional resources and supply to cover ~60% or ~70% of AMC populations plus an additional 500 million doses contingency pool to manage external risk factors e.g., paediatric use, variants and boosters.

d) COVAX reputation

Reputational damage for the COVAX Facility and Gavi

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
d COVAX reputation Reputational damage for the COVAX Facility and Gavi	• Inability to meet supply promises • Large-scale wastage or idle doses in-country • (Perception of) inequitable allocation and distribution • (Geo)political tensions and conflicts of interest					

Risk description

The COVAX Facility is a high-profile project with global participation and high expectations, and is operating in a dynamic, competitive and often politicised external environment – with many factors required for success being outside of its direct control. This makes the Facility and therefore also Gavi vulnerable to reputational backlashes, e.g., in case of failures in execution and meeting (supply) promises to participants, (perceived) inequitable or sub-optimal allocation of vaccines, delivery issues such as large-scale wastage of vaccines in-country or deliberate misuse of vaccine or cash support, serious adverse events following immunisation, (geo)political tensions (e.g. around IP or perceived vaccine diplomacy regarding dose sharing), anti-vaccine attacks and disinformation being spread about COVAX, or generally mismanagement of or a lack of transparency about challenges and risks. Reputational damage would affect the COVAX Facility's and Gavi's ability to deliver on its mission, leverage effective relationships and count on continued donor, participant and public support.

Existing mitigation

To manage this risk, a proactive media and communications strategy has been implemented that does not downplay the challenge of ending the pandemic or overstate the role of vaccines but supports the achievements of COVAX. There is strong global media monitoring as well as participation in internal discussion to ensure emerging risks can be assessed quickly and effectively. Newly recruited champions tell the COVAX story and country stories are developed for digital media to capture the progress COVAX is making away from the public eye. Multiple media briefings were held in September and the new round of communications and advocacy has been more transparent on challenges outside of COVAX's control that prevent it from being successful, with calls to action on donations, manufacturer transparency, manufacturer queue slot-swapping and ending of export bans to ease supplies. Communications with participants has also been enhanced with the establishment of a country communications team for more effective and timely country communications, and a country communications liaison group with WHO, PAHO, UNICEF, and CEPI for better coordination across partners on aligned communications and briefings. Systems are in place to facilitate information sharing and there is active engagement by focal points with governments on concerns, as well as monthly briefings on delivery and supply communications. There is extensive work with CSO focal points to include them in as many new workstreams as possible and establish open communication channels. There is also a tailored governance mechanism with regular, formal participant meetings as well as informal consultations and briefings, and active engagement with Shareholders Council and AMC Engagement Group Co-chairs. Regarding dose-sharing, there are guardrails on earmarking of shared doses with only broad earmarking being encouraged and a scorecard to evaluate incoming offers including political risks and transaction costs. To combat the perception of dose-dumping, real-time sharing of doses that donors already use and donations of a variety of vaccines are being encouraged. Furthermore, adjustments to the allocation framework design are

being explored to take into account criteria that could include total population coverage data, absorptive capacity and epidemiological considerations. Finally, since COVAX supply and delivery risks are the main underlying contributors to reputational risk currently, mitigation strategies to address those will contribute primarily to reduce the derived reputational impact of those risks materialising.

Current risk exposure

Current exposure to this risk is very high, due to varying interests of many stakeholders, a high need for information sharing, and frustration at the current slow pace of shipments. There was however positive feedback from the last round of communications and advocacy that was more transparent on challenges outside of COVAX's control that prevent it from being successful, with calls to action on donations, manufacturer transparency, manufacturer queue slot-swapping and ending of export bans to ease supplies. There was also strong political support at the UNGA. While the current reputational risks are mostly grounded in the supply challenges experienced by COVAX, going forward the risk may shift to be driven by delivery-related issues. Poor absorption, earmarked dose-sharing or the perception of dose-dumping of lesser vaccines by HICs may result in (the perception of) an uneven roll-out across countries, and wastage of vaccines in country could affect the COVAX Facility's and Gavi's reputation with donors, participants and the public.

Risk appetite and planned further mitigation

Since Gavi's reputation is critical to its ability to deliver on the mission, the Alliance has a in general a low appetite for risks affecting its image and confidence of its stakeholders, including its governance bodies, but is also accepting that in administrating the COVAX Facility it needs to assume new levels of reputational risk. Current exposure is deemed just within risk appetite and requires ongoing attention. The COVAX Facility continues to actively monitor and anticipate reputational risks and is balancing maintaining stakeholder relationships with the need to call out issues transparently where this is needed to protect its reputation and unlock barriers for its continued success.

e) COVAX Facility

Inability to adequately operationalise the COVAX Facility

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
COVAX Facility Inability to adequately operationalise the COVAX Facility	- Overstretched people, processes, systems - Ineffective coordination, project management, governance - Inadequate financial risk and liquidity management	VH		JUST WITHIN		

Risk description

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. Being the biggest multilateral effort since the Paris climate agreement – with global participation representing over 90% of the world's population, consisting of both Self-Financing Participants ("SFP") and 92 COVAX AMC-eligible economies ("AMC92") – it is a large, unique and structurally complex undertaking which requires new processes, capacities and capabilities, and involves increased volumes of activities and transactions compared to Gavi's regular business. This naturally comes with operational risks associated with overstretched people, systems and processes (which could also affect broader Secretariat capacity and distract from Gavi's core mission). 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 did not yet have established relationships. Furthermore, since Gavi is the legal entity administering the Facility, Gavi will ultimately be assuming the financial risk exposure of the Facility. Gavi needs to protect its balance sheet and minimise risks to Gavi core resources and programmes, such as SFP countries defaulting (being unable to pay) or breaching contractual

commitments (being unwilling to pay) while Gavi has outstanding commitments with manufacturers. Without a successfully operationalised 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.

Existing mitigation

To manage this risk, the Office of the COVAX Facility has developed a full end-to-end operations plan and continues to document priority processes in SOPs. It also continues to hire additional and dedicated resources supported by onboarding programmes and mapping of roles and responsibilities, regular meetings to facilitate coordination across teams, co-creation of processes, problem-solving, work planning and sharing of information. IT systems have been developed to ensure reliable, accessible data for staff and participants including the COVAX Collaboration Portal, intranet and shared drive. A tailored Governance structure, a Pillar level Strategic Coordination Office and a dedicated Country Communications team ensure multi-stakeholder coordination, communication, and decision-making. 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). Financial risk mitigation has been implemented actively with the help of financial advisors, including a decision-making framework and dashboard to optimise the choice of sovereign credit risk cover vis-à-vis particular participant country exposures, and actual insurance coverage with insurance providers for 32 countries. Furthermore, a comprehensive operational cash flow model has been developed to understand liquidity needs, and the need for liquidity buffers and providers. Treasury operations, accounting and banking services have also been reviewed and recommendations to enhance workflows, automate processes and optimise resources are being implemented.

Current risk exposure

Current exposure to this risk has decreased due to progress in mitigating operational and financial risks, but it remains high. The COVAX Facility is no longer in start-up mode and has effectively shifted its focus on operationalisation, with formalised processes, increased resourcing and a dedicated organisational structure. It however continues to operate in a dynamic, competitive and challenging external environment, continues to develop new initiatives such as dose-sharing, cost-sharing and the humanitarian buffer, and awaits a large scale-up of activities and transactions going forward after the smaller first wave of vaccine allocations and shipments (given the expectation of more supply availability going forward and in the context of contributing to high global coverage target of 70% in 2022). The new country participation model ("SFP 2.0") as part of the 2022 strategy will also considerably reduce inherent financial risks with revised SFP terms and conditions relying more on upfront payments. Finally, the ongoing development of a clear 2022 strategy may also bring new risks.

Risk appetite and planned further mitigation

The Alliance acknowledges that the administration of the COVAX Facility requires navigating uncharted territory at unprecedented speed and scale. It is understood that the risks that come with that are worth taking in an effort to end the acute phase of the pandemic, as inaction would leave lower income countries behind and the global economy and Gavi's core mission would continue to be disrupted by the pandemic. The Alliance therefore seeks to find the right balance between successfully delivering on the promise of the Facility and minimising risks to Gavi core resources and programmes. The Alliance has overall a lower appetite for operational risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners. It also in general has a low appetite for risks affecting its finances and seeks to maintain low levels of accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk. Current exposure is now deemed just within risk appetite due to progress on mitigation and with better clarity on the size of risks and possibilities to mitigate them. It still requires ongoing attention and to bring it more fully within appetite, the COVAX Facility continues

to surge capacity, implement robust project and risk management and fill critical skills and capacity gaps. The Facility is currently transitioning to the 'delivery at scale' mode, enhancing and formalising the design to support the expected ramp-up in supply. Looking ahead to 2023 and beyond, attention is likely to turn to integration of COVAX strategy and operations into Gavi's routine immunisation programmes.

f) 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
Sustainable transition Some countries may fail to sustain progress of their immunisation programmes after transition	• Lack of (subnational) ability/capacity/fiscal space • Poor preparation for transition by Alliance • Insufficient prioritisation of health and immunisation • Overreliance on external support • Lack of access to global markets and expertise • External programme disruption (economic, outbreaks)					

Risk description

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.

Existing mitigation

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. 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. In exceptional cases where countries were not on track for a successful transition, the accelerated transition phase has been tailored, allowing those countries for more time and tailored support to enhance country readiness for transition. Nigeria and PNG were identified as countries at high risk for transition and implementation of approved tailored support is underway, albeit with some delays, partially due to COVID-19. During the pandemic, Gavi and its Alliance partners, in particular the World Bank, have also been engaging with countries to mitigate the impact of the pandemic on domestic financing and protect the significant gains achieved in strengthening the financial sustainability of immunisation programmes. Furthermore, the Alliance provides time-limited, catalytic post-transition support in already transitioned countries to mitigate residual post-transition risks.

Current risk exposure

Current exposure to this risk remains high despite the positive trend of successful transitions, post-transition support having been rolled-out and an increased focus on programmatic sustainability under Gavi 5.0. The number of countries that have transitioned to self-financing remained stable in 2021 as a result of the eligibility freeze that has been approved by the Gavi Alliance Board in response to the pandemic. Penta3 coverage has dropped in Honduras and Bolivia, and the pandemic may further affect transitioned countries' programmatic

performance. 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 domestic financing and risks of backsliding in already transitioned countries. Part of the success in preventing backsliding in transitioned countries has been achieved through an expansionary fiscal policy that has seen Governments taking on public debt to support their economies, increase health expenditure per Capita, and off-set reduced revenues due to COVID-19. Despite access to emergency financing, policy responses in low-income countries have been hindered by a lack of fiscal space and little room for monetary policy. While 90% of advanced economies are expected to regain their pre-pandemic per capita income levels by 2022, only one-third of emerging markets and developing economies are expected to do so. 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.

Risk appetite and planned further mitigation

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, despite 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 Alliance continues to engage after transition, but recognises that it will have less ability to fully mitigate performance stagnating or declining once it stops fully financing a country's programme. 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, together with the planned expanded focus on programmatic sustainability. To further mitigate this risk, Gavi is developing a "transition continuum framework" to prepare countries along their transition process with a set of minimum requirements and suitable interventions for each critical immunisation system component, adapted to each of these maturity levels with the aim of monitoring and supporting progress towards a healthy transition. Support to prevent and mitigate the risk of backsliding will continue to be part of the Middle-Income Countries (MICs) approach that has been approved by the Gavi Alliance Board in December 2020 and is now being operationalised in several identified priority countries, although it has experienced some delays due to the COVID-19 pandemic and vaccine roll-out.

g) 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
9	Insufficient demand Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation	- Lack of knowledge / information about immunisation - Hesitancy due to mistrust/fear - Anti-vax sentiment, politicization, false vaccines - Logistical and gender barriers, lack of prioritisation - Poor quality services / experience - Weak government systems for generating demand			JUST WITHIN		

Risk description

High levels of community demand are critical to successfully reach every child and community with vaccines and achieve high levels of vaccine uptake. Demand can be affected by 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 gender-related barriers, lack of convenient access to health facilities, or households becoming accustomed to services being delivered at their doorstep with immunisation campaigns 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.

Existing mitigation

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, the Alliance continues to intensify its efforts to actively generate demand for vaccines. Under the Country Delivery Support Early Action Window for COVID-19 vaccine introduction, 56 countries have applied to receive funding for demand generation and Gavi is supporting another 20 priority countries with low vaccine uptake to provide expert technical assistance through UNICEF. This targeted investment is designed to rapidly generate learnings, best practices, tools and approaches to be scaled up swiftly across all countries. New survey tools have been developed under the Demand Hub to assess the behavioural and social drivers for vaccination (BeSD), both for childhood vaccination and COVID-19 vaccines. They have been systematically validated in six Gavi countries – Nigeria, Ethiopia, Pakistan, Angola, India and DRC and are being reviewed by WHO SAGE. Gavi has started using the BeSD tools to collect real time data on vaccine confidence and uptake in 9 countries (8 in Africa and one in Asia) with a data innovations partner, using an innovative low-cost methodology to collect data remotely to track important demand trends over time. Remote data collection can be used as an early warning system to identify demand side concerns and to prioritise efforts to swiftly design – and redesign interventions. Gavi also continues to work closely with WHO, UNICEF and civil society organizations to develop a globally coordinated approach to Social Listening and Engagement, leveraging growing relationships with social media companies and content developers to undertake sentiment analysis as well as scaling up efforts to systematically collect behaviourally focused demand-side data in country-level and multi-country surveys. Gavi is also working with WHO to scale up WHO EARS (A Platform for artificial intelligence-Supported Real-Time Online Social Listening of COVID-19 Conversations) to 15 more countries with a special focus on those with low vaccine uptake due to misinformation to track and counter.

Current risk exposure

Current exposure to this risk continues to be high due to COVID-19 restrictions and vaccine hesitancy given mis- and disinformation about vaccines (with COVID-19 rumours and conspiracy theories potentially spilling over into demand for routine vaccines). Real time data collection on vaccine confidence and uptake registered an increase in COVID-19 related vaccine hesitancy as vaccines were introduced in countries, and triangulation with social listening data suggested increased rumours started to circulate. Analysis of the BeSD data shows that there are more “doubters” than “resistors” suggesting there is an opportunity to rapidly increase demand by targeting those who are unsure and hence, potentially willing to shift preferences. Currently, despite efforts,

demand remains stagnant, suggesting an urgent need to review strategies and implementation. 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.

Risk appetite and planned further mitigation

The Alliance has a low appetite for the risk of a significant drop or insufficient increase in demand and public confidence in vaccines in implementing countries, including due to vaccine hesitancy and gender-related barriers, as this is critical for achieving the equity agenda and reaching missed communities. Current exposure is therefore just within risk appetite and requires ongoing attention. As COVID-19 vaccine introduction accelerates we need to understand the impact on demand and uptake for routine immunisation particularly where capacity is stretched and where there is disruption on the operation of routine services. Increased availability of social data will make it possible to understand trends, and to identify and address emerging issues as soon they emerge in countries.

h) 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
h) VPD outbreaks Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries	• Low population immunity, vaccine hesitancy • Climate change, urbanisation, deforestation, globalisation, migration and human displacement, population growth • Lack of capacity/tools to detect, prevent and respond • External programme disruption (conflict, disasters)			JUST WITHIN		

Risk description

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 mosquitoes 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 immunisation coverage may exacerbate the effects of outbreaks, which, if uncontained in a timely manner, risk spreading to neighbouring countries and beyond. Timeliness of the outbreak response could be compromised by underperforming surveillance systems along with supply, logistic and human resources restrictions in the context of the COVID-19 pandemic response.

Existing mitigation

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 emergency 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 the availability of globally stockpiled vaccines. 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. Outbreak signals are being monitored for timely outbreak response vaccination to emerging outbreaks. Gavi furthermore supports vaccine stockpiles and provides operational funding to implement outbreak response (cholera, yellow fever, meningitis and Ebola stockpiles are managed by the International

Coordination Group (ICG) and an outbreak response fund for measles is managed by the Measles and Rubella Initiative (MRI)), including the undertaking of outbreak root cause analysis to inform remedial measures through strengthened RI planning and delivery. 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 strengthening immunization systems. The Fragility, Emergencies and Refugees policy provides flexibilities to conduct preventive immunisation for refugees. The Alliance is also 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 resources so that children missed before, during and after the pandemic are vaccinated, primarily through routine immunisation services.

Current risk exposure

Current exposure to this risk remains high, due to the disruption to routine vaccination services resulting in missed children (early lockdowns at the beginning of the pandemic appear to have led to a 37% reduction in Penta3 doses administered, which has been restored in later months but inconsistent reporting across countries makes it difficult to assess portfolio-level impacts). Another risk factor is the easing of transmission limiting COVID-19 restrictions such as international travel, hygiene promotion and mask wearing. Disease surveillance systems have also been disrupted, which is likely to impact the ability of countries to quickly detect and respond to outbreaks. While the number of outbreaks requiring vaccination responses since the start of the COVID-19 pandemic is relatively low, cholera outbreaks have been recently notified in Nigeria, Niger and Bangladesh and three vaccine requests for more than 10 million Oral Cholera Vaccine (OCV) doses have been received in the last weeks. These large requests have momentarily depleted the global OCV stockpile. Moreover, substantial pressure on OCV supply is anticipated to remain during the foreseeable future, partly due to capacity diversion to COVID-19 related activities. Additionally, 16 countries are experiencing a resurgence of measles, with Cameroon, DRC and Yemen preparing or having already submitted measles outbreak response support.

Risk appetite and planned further mitigation

The Alliance aims to reduce the risk of vaccine-preventable disease outbreaks through enhanced routine vaccine support for outbreak-prone diseases, funding of global stockpiles for outbreak response and investments in disease surveillance. It however accepts that disease outbreaks will continue to occur since fully addressing the significant gaps in health systems and preparedness and response capacities require engagement beyond its current mission and resources. It furthermore acknowledges that reducing reliance on frequent and disruptive planned campaigns (see risk of "sub-optimally planned campaigns") may require a higher acceptance of the risk of outbreaks in the short-term. Current exposure is therefore just within risk appetite and requires ongoing attention. The Alliance accepts that there is significant risk that VPD outbreaks will continue to occur, and will continue to ensure that at-risk countries introduce Gavi-supported vaccines, and timely outbreak response interventions are implemented. A revised TCA grant to support timely ICG applications is being developed and a full proposal on enhanced diagnostic support for disease surveillance is going to be submitted for the Board approval in December.

i) Misuse by countries

Deliberate misuse of Gavi support in many Gavi-supported countries

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	• Culture of gifts/corruption • Opportunity for personal gain • Weak monitoring/deterrence • Weak institutions and systems			JUST WITHIN		

Risk description

Gavi uses country systems (supply chains for vaccines and financial management systems for cash 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 developing countries, many have weak systems, low capacity, weak program design, poor governance and management, and / or prevailing corruption, and this exposes the Alliance to the risk of its support being misused, undocumented or inadequately accounted for (deliberately as well as by mistake). The inherent risk is particularly high for cash programmes (especially for campaigns), which account for about 20% of Gavi's programmatic expenditure – the remainder being vaccines procured through UNICEF and PAHO, which in general are less prone to theft and diversion (COVID-19 vaccine may be an exception during an initial period of supply constraints), due to a lack of secondary markets, short shelf life 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). Furthermore, the Alliance's ambition on reaching zero-dose children and missed communities will require working with new partners and civil society organisations which in some cases may have lower financial management capacity. Misuse has a cost to Gavi and countries as it reduces the programmatic impact of its investments. It can result in the suspension of cash support to countries, requiring reimbursement from an already tight budget (reverse aid), 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 failure, usually due to weak, compromised or inadequate systems and processes, and poorly designed programs, which may impede countries' ability to effectively manage their programmes, and ultimately potentially compromising a country's successful transition away from Gavi support.

Existing mitigation

To manage this risk, the Secretariat has strengthened grant oversight by Senior Country Managers and support by a specialist Programme Financial Management team engaging with countries to resolve fiduciary risk challenges and improve budgeting, accounting, reporting and oversight. As of today, all 53 countries have benefited from a Programme Capacity Assessment (PCA) intended to 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. A new assessment is done when the funding modality changes. The GMRs are monitored throughout the lifecycle of the grant and where necessary disbursements are conditional to the fulfilment of certain key Grant Management Requirements for the specific country. Other fiduciary safeguards include annual independent external audits by private firms and/or the Supreme Audit Institutions. Occasionally, where necessary, Programme Management Units (PMUs) working in conjunction with governmental agencies are used, as well as embedded Fiduciary Agents and independent Monitoring Agents (often with a capacity-building role as well). Many of these 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 leveraged UNICEF's services given its aptitude in this area, in particular in the supply of cold chain equipment. For countries that lack basic capacity or in challenging operating environments due to conflict, Gavi – in consultation with the country – also channels 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. PCA and audit findings are furthermore informing grant inputs such as stronger human resources, removal of riskier activities and stricter budget discipline. Gavi has also strengthened – through Leadership, Management & Coordination (LMC) and other technical assistance – the ability of countries to provide adequate funds through a robust Immunisation Coordinating Committee.

Programme Audits by Gavi 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). 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. The Secretariat has set aside an envelope of funding to provide assurance over a wider spread of risks, including supply chain, programmatic and fiduciary risk in COVAX AMC-eligible economies through increased use of monitoring agents in high-risk countries.

Current risk exposure

Current exposure to this risk remains high during these times of crisis, economic uncertainty, low morale and financial pressures. This provides more opportunities to commit and rationalise fraud due to a weakened internal control environment and possibilities to take advantage of people's fear and distraction. Equally countries are under pressure during a health emergency to spend faster, and to set aside their usual processes for emergency procurements. At the same time, travel restrictions continue to impair grant oversight and assurance in Gavi-supported countries. Gavi also provided increased funding to help countries respond to the pandemic and maintain, restore and strengthen immunisation programmes, using a fast-tracked application and review process. Furthermore, to move quickly in response to COVAX delivery risks Gavi is making funds available with less up-front due diligence (however mitigated by post facto assurance mechanisms). 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 the existence of secondary markets (although they still require a cold chain). They could also be diverted to non-target groups within countries or be used in exploitative transactions.

Risk appetite and planned further mitigation

The Alliance has in general 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 pandemic context and the ability to mitigate and obtain assurance is constrained. The Alliance therefore acknowledges that, during the duration of the crisis, risks may increasingly materialise despite best efforts to mitigate them. The Alliance is also willing to take risk where this is needed to respond flexibly and quickly to evolving needs, recognising that Gavi support to maintain, restore and strengthen immunisation services is needed more than ever due to the impact of the pandemic on routine immunisation programmes. Risks furthermore need to be balanced when reaching zero-dose children requires working more sub-nationally and in challenging operating environments with very weak financial management capacity; and when building sustainable country capacity and ownership requires channelling support through government systems. Accepting to be exposed to fiduciary risk does not mean actual occurrence is desirable or it should be tolerated should it occur. In case of actual misuse, Gavi will always require reimbursement as a condition of continued support. Current exposure is therefore just within risk appetite and requires ongoing attention. Following the June Board's approval of the Gavi 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, additional support will be provided to help countries develop better systems. This Board decision also provided a ring-fenced source of funding for continued development of other risk mitigation and assurance options, institutionalising the approach to fiduciary risk assurance and financial management capacity-building introduced in Gavi 4.0. Other planned initiatives include deepening working relationships with other non-traditional partners to improve capacities, e.g. Supreme Audit Institutions (SAIs), Country Internal Audit Departments and the International Federation of Accountants (IFAC).

j) 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
Cyber-attack Large cyber-attack significantly compromising critical information systems or data	• Increase in phishing, malware and ransomware • Work-from-home vulnerabilities • Increased target for cybercrime, activism and espionage			JUST WITHIN		

Risk description

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.

Existing mitigation

To manage this risk, the Secretariat has implemented several measures which include single sign-on with multi-factor authentication, regular patching, local file encryption, and annual security scans. The Secretariat also implemented a Security Operations Centre and security incident and alerts monitoring (SIEM) on the Gavi network in collaboration with the Global Fund. Gavi's cloud-based systems provide a level of redundancy and back-up across key systems, and allow reliance on the security resilience of large cloud providers. There is furthermore a formal framework for data classification and tools and controls for information protection. User awareness on security risks (including phishing and sharing of documents and data) continues to be enhanced (e.g. through training and fake phishing campaigns) with a specific focus on high profile users, IT staff with elevated privileges and COVAX Facility users. Business continuity and IT disaster recovery plans have been created based on a business impact analysis of IT systems' unavailability on Gavi's operations. Processes have been put in place for early detection of malware and account compromise and to ensure a swift response and recovery to security related attacks. There is also a focus on enhanced threat intelligence (including an ongoing security forum with WHO, UNICEF and CEPI) and regular assessments and vulnerability testing. 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. An internal audit and an ISO 27001 gap analysis are currently ongoing to gauge the effectiveness of these mitigations and identify any further steps to improve.

Current risk exposure

Current exposure to this risk has increased 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 COVID-19. Phishing and other human-facing social engineering tactics remain the primary vectors of potentially successful attacks, but credential guessing leading to account compromise, malware and ransomware is also increasing. 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 a substantial increase in financial resources 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. 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.

Risk appetite and planned further mitigation

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. Additional security enhancements continue to be delivered as part of the Cybersecurity programme, overseen by a Cybersecurity Steering Committee. This includes continued enhancements to e-mail, mobile phone and cloud security; a security drill exercise; and further audit findings remediations and actions based on an ongoing ISO 27001 gap analysis.

k) Data on zero-dose

Poor or lacking data may affect the ability of the Alliance to identify and reach 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
k Data on zero-dose Poor or lacking data may affect the ability of the Alliance to identify and reach zero-dose children, implement effective interventions, understand progress and demonstrate impact	• More precise data is not available • Existing data is not shared • Data is not timely • Data is not used effectively to identify children • Poor data culture, capacity and systems			JUST WITHIN		

Risk description

Reaching missed communities and zero-dose children requires more granular (e.g. subnational) and different types of data (e.g. operational data, qualitative and effectiveness studies) to provide greater visibility into who, where, how many and why they have been missed and to implement interventions to effectively reach them and bring them into the immunisation system. Existing data and systems provide information on the distribution and concentration of zero-dose but insufficient information on the root causes for missed immunization including the access to or quality of health services or are structurally or politically marginalised as they may not be officially registered or recognised. Where these data do exist, they are infrequently brought together to effectively identify, advocate for and reach zero-dose children and missed communities, track progress along the way and to learn to scale best practices.

Existing mitigation

To manage this risk, Gavi continues to work with countries and Alliance partners to strengthen the availability and use of quality data for immunisation, to ensure the systems are fit-for-purpose to identify, understand and design the right interventions to reach zero-dose children and missed communities. Building on the work of the Data Strategic Focus Area in Gavi 4.0, there is increasing experience and alignment on how to identify missed communities and engagement with partners on sub-national data, use of data to support advocacy, and data sharing across systems and programmes (e.g. with GPEI). Zero-dose is the focus of the Digital Health Information activities to support timely use of information and to strengthen country capacity to triangulate existing subnational data (both within immunisation and other sectors such as nutrition and education) from multiple sources (e.g. in health management information systems, logistic information systems, surveys, and geospatial mapping) to generate quality evidence to inform management of country EPI programmes. A request for proposals was recently launched to for technical assistance (TA) providers to help countries identify zero-dose children and missed communities and prepare robust equity plans as well as a global learning partner to help identify and disseminate key learning. A cross-Alliance community of practice was established, which includes an online platform to facilitate sharing of knowledge and experience across

partners and countries, including for data. Gavi is also designing Learning Hubs in a few countries to be able to better measure progress, support cross-country synthesis and identify and share best practices. 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/religion/ethnicity, geographical concentration of zero-dose children within a country, distribution by Equity Reference Group (ERG) setting and the overlap between zero-dose children and other primary health care (PHC) services. The Alliance is also leveraging campaigns to include specific activities to identify and incorporate zero-dose children in campaign and routine immunisation planning.

Current risk exposure

Current exposure to this risk is decreasing due to progress in mitigation. It however remains 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, geospatial and qualitative 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 as lack of clustering sub-nationally would make it harder to intervene. Delays in implementation of Gavi levers such as HSS and the new EAF at country level due to the COVID-19 situation may slow down the scale-up of these data activities.

Risk appetite and planned further mitigation

The Alliance is willing to face 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 acknowledges that improving data availability, quality and use in-country is not fully within Gavi's control and would likely remain a challenge for a long time. It however has a lower appetite for risks to 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. The Alliance continues to improve measurement including through targeted sub-national surveys and assessments and building country capacity and tools for generating insights from monitoring dashboards and analytics (including provision of global analytics of local data to inform country conversations). This includes, for example, scaling up District Health Information Software 2 (DHIS-2) dashboards for district-level immunisation monitoring and increased use of DHIS-2 campaign monitoring module where post-campaign surveys cannot be completed. It is also strengthening data triangulation to utilize "imperfect" data and introducing real-time campaign monitoring. Gavi is also strengthening global level data, including a revision of WUENIC and refining the electronic Joint Reporting Form. 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. To better measure progress, support cross-country synthesis, inform key strategy and policy questions, and help identify best practices to share across countries, the Secretariat is planning to create a number of learning hubs, which will supplement routine monitoring with deeper measurement, analysis and understanding of factors influencing the performance of approaches to reach zero-dose children and missed communities.

I) Polio disrupting immunisation

Polio ramp-down or resurgence may adversely affect routine immunisation

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
Polio disrupting immunisation Polio ramp-down or resurgence may adversely affect routine immunisation	• Eradication challenges / Vaccine-derived outbreaks • Reliance on GPEI staff/assets, weak national systems • Delayed transition plans, incomplete polio asset mapping • GPEI funding cuts / uncertain fund-raising for new strategy			JUST WITHIN		

Risk description

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. However, the ramp-down of GPEI financial support for activities and human resources in countries that have eliminated wild poliovirus has now begun, principally in Africa but also in other countries considered at lower risk. 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 ongoing efforts to control COVID-19 as well as improve coverage and equity and conduct high-quality supplemental immunisation activities.

However, the eradication effort could also experience further setbacks, e.g. with a resurgence of wild poliovirus transmission, such as was the case in Pakistan and Afghanistan pre-COVID-19. In addition, in countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2 (and some type 1) outbreaks could increase 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 (mOPV2) vaccine risk themselves to cause further vaccine-derived poliovirus cases in under-immunised populations (especially in areas with poor sanitation and hygiene), as a new, more genetically stable vaccine (novel oral poliovirus vaccine type 2, nOPV2) is still being rolled out. 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) in case of failure to deliver the promise of a world free of polio.

Existing mitigation

To manage this risk, GPEI has been 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). Furthermore, leveraging Gavi's engagement in the Endemic country Hub, coordinated planning and communication between National EOCs, polio partners and Gavi has steadily improved. Through targeted HSIS and PEF TCA funding, Gavi and GPEI are supporting immunisation strengthening and coverage and equity improvement of polio and routine EPI vaccines.

Current risk exposure

Current exposure to this risk remains high as the COVID-19 related programme pauses and disruptions of preventive and outbreak response campaigns have likely resulted in lower population immunity with potential for increased transmission. While the earlier setbacks in the eradication effort in Pakistan and Afghanistan

have been followed by a significant downturn in transmission since beginning of this year (possibly due to the lockdowns, school closures, and attention to hygiene/hand-washing – but disease surveillance may also have missed low-lying chains of transmission), the political upheaval and population movement in Afghanistan risk a resurgence. In countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2 remain a large risk with widespread transmission in west Africa (with ongoing outbreaks in northern Nigeria) as well as cases detected in Tajikistan and now emergent in Ukraine. Outbreak response activities continue in a number of countries, primarily in Africa with Emergency Use Listed (EUL) novel OPV2, a more genetically stable vaccine, being increasingly used. While the impact of nOPV2 is still being assessed, data thus far indicate a high degree of genetic stability that would signal less potential seeding of vaccine-derived virus to type-2 immune naïve populations. However, as supply of nOPV2 is currently limited, countries will need to respond to outbreaks with monovalent oral polio type 2 vaccine (mOPV2), which risks causing further vaccine-derived poliovirus cases, or wait and risk further transmission and paralysis of children.

Risk appetite and planned further mitigation

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. 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. As a core GPEI partner, Gavi continues to shape the Integrated Service Delivery workstream for both endemic and outbreak countries in line with 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).

m) Secretariat disruption

Significant disruption of Secretariat operations

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
m. Secretariat disruption Significant disruption of Secretariat operations	• Stretched capacity and increased complexity of work • Pandemic impact on mental health and staff engagement • Leadership succession issues • Departures of key staff with critical knowledge • Incident or loss of life in the workplace or during travel			JUST WITHIN		

Risk description

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.

Existing mitigation

To manage this risk, there are 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 (while currently still embargoed until the end of the year, with

very few exceptions requiring high levels of due diligence and contingency plans) 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. Employees have also followed respectful workplace training to protect a culture of tolerance and respect, including training on ethical behaviour on Gavi missions. The Secretariat has furthermore rolled out the new organisational structure recommended through the organisational review that includes reinforcement of executive leadership and progress in recruitment is starting to alleviate Secretariat capacity constraints. The HR, Communications and Operations teams continue to engage staff and focus on wellbeing, finding ways to keep them connected. A Health and Wellness Committee has been launched with prominent participation from staff. Communication with staff has increased with exchange of regular information. 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. Throughout the remote working period Gavi has been collaborating and aligning safety measures with the other GHC partner organisations, with the joint goal to keep all employees as safe as possible at the Global Health Campus. A similar approach has been adopted in the Washington office. A Ways of Working project has redefined the role of the office once staff can return and physical adjustments to the Gavi offices have been made to enable hybrid working. A Crisis Management team remains deployed against the current crisis.

Current risk exposure

This risk is increasing due to the ongoing impact of the pandemic on the Secretariat by increasing complexity to the work on its core mission, adding COVAX and the delivery of COVID-19 vaccines to its priorities and changing its ways of working due to virtual and hybrid working and travel restrictions. While mitigation of the current disruption is taking effect, further disruption could still occur if the pandemic continues or worsens, with increased workload due to COVID-19 delivery scaling up, and with continued organisational changes due to optimisation and integration of COVAX and Gavi core processes. 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 stress 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 substantially reduced given the travel restrictions. Furthermore, being part of a COVID-19 vaccine roll-out is attracting 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 also remains critical (reflected in the medium risk of *Secretariat capacity*) with a heightened workload across the Secretariat to respond to the COVID-19 impact on immunisation, to operationalise the COVAX Facility at record speed, and to support the delivery of 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 and virtual working. 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. Finally, with the current Chief Executive completing his term of appointment in 2023 and the Deputy CEO due to retire in the same year, the Secretariat may be exposed to disruption if the transition to new leadership does not go smoothly (as reflected in the medium risk of *Leadership succession*).

Risk appetite and planned further mitigation

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 and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. In preparation for business travel to resume, staff security training will be made mandatory and additional processes are being developed for managing travel in a COVID and post COVID world. Additional Secretariat resources approved by the Gavi Alliance Board in December 2020 and a rigorous focus on staff wellbeing are expected to improve conditions. The Secretariat is furthermore developing a new Incident Response Policy and procedures based on learnings from dealing with the current crisis. In addition, all Business Continuity and Incident Response plans will be revisited to fill any gaps by the end of the year.

n) 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
n. Partner capacity Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries.	• Lack of alignment and coordination • Lack of capacity / expertise • Lack of availability • Lack of accountability / performance			JUST WITHIN		

Risk description

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 engaging more local partners. Support also needs to be truly country-owned and well coordinated across partners. While WHO and UNICEF will remain the primary partners of the Alliance, it will be necessary to continue to diversify provision of Targeted Country Assistance (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.

Existing mitigation

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 50 expanded partners (including 14 local 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 25 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" to ensure sustainability of TA. 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. 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. The Partnerships Team oversees TA delivery with continued attention to lessons learned based on independent reviews. Furthermore, the Alliance is actively mitigating the risk that COVAX could further divert partner's attention away from Gavi's core mission, through increased resources to manage COVAX in each partner organisation, a revised partnership model and increased COVAX resources for

partners through COVID-19 Delivery Support (CDS). Gavi is funding more than 450 additional staff positions at WHO and UNICEF to provide technical assistance for COVAX on top of existing PEF-funded TA.

Current risk exposure

Current exposure to this risk remains high 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 COVID-19 vaccines may divert attention and resources away from routine immunisation. As an indication, partner performance in countries remained below pre-pandemic levels with 69% of milestones achieved (a slight improvement from mid-2020, but still below 2019). 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. With PEF Targeted Country Assistance (TCA) design shifting its focus towards zero-dose children and missed communities, the ability to develop local partnerships to better serve these missed communities has been raised as a key challenge. Furthermore, currently only 6% of programmed TCA activities specifically mention zero-dose children, and especially fragile countries are seeing poor utilisation of TCA funds. While local partner engagement is improving overall, this is limited by local partners not being empowered to participate in government level discussions and planning of immunisation services, and insufficient capacity building and strengthening of local partners on the ground to ensure there is a wider pool of partners with local expertise to access TCA funds.

Risk appetite and planned further mitigation

The Alliance has overall a lower appetite for risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners. It seeks to reduce risks related to the capacity and performance of Alliance partners. As such, it is aiming to engage with a wider set of partners, including local organisations and CSOs, and to collaborate with other health actors to strengthen primary health care and multisectoral approaches. This broader engagement requires a constant trade-off with the increased complexity of managing many partners at country level. The Alliance also has a low appetite for risks which could undermine accountability and transparency within and between the Secretariat, Alliance partners and implementing countries. The Alliance has a high appetite for risks associated with working with new partners, including local organisations and CSOs, which have critical context-specific expertise and the ability to reach zero-dose children in humanitarian and conflict areas outside government reach. The current risk exposure is therefore just within risk appetite and requires ongoing attention. Ensuring that 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, new partnerships (including increased engagement of local institutions and Civil Society Organisations) and sustainability. Another key shift in Gavi 5.0 is the way Partner performance will be monitored. Milestone reporting (used to monitor Partner performance in Gavi 4.0) will become more results-focused and more strongly aligned with Gavi's overarching monitoring framework and 5.0 key performance indicators. A global Expression of Interest and prequalification process is underway to further engage local institutions and global partners with a comparative advantage for subnational work. US\$ 100 million of the EAF will be allocated to new multi-country partnerships to reach zero-dose children and missed communities in fragile, conflict and cross-border settings outside government reach. A call for proposals to find appropriate partners was launched in September 2021, with the selection of providers expected to conclude before the end of the year. In order to build momentum and cohesion across the Alliance, a cross-Alliance Community of Practice (COP) on the zero-dose agenda is being established.

o) Forecasting variability

Gavi forecasting variability drives inappropriate decision-making

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
0 Forecasting variability Gavi forecasting variability drives inappropriate decision-making	• Uncertainty over vaccine demand • Financial uncertainties (e.g., prices, FX) • Complexity of process • Sub-optimal systems			JUST WITHIN		

Risk description

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.

Existing mitigation

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. There is also better integration of systems and processes within the Secretariat among key teams 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. The vaccine forecasting process has 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. 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. Areas of uncertainty are discussed within the forecasting group and during management reviews prior to deciding on the point estimate that is used to inform key forecasts to manage expectations on the level of precision that is possible and sensitize audiences to the substantial degree of uncertainty in the forecasts. 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, which can be declined or deferred in the light of resource availability as foreseen at that time.

Current risk exposure

Current exposure to this risk remains high with the ongoing uncertainty in the context of COVID-19 creating a higher risk of variability as compared to previously, with the exact trajectory of disease and its ultimate impact on immunisation programmes and vaccine introductions in Gavi supported countries difficult to predict. There is also a high level of dependency on procurement partners for vaccine purchases (around 50% of disbursements) and there is not yet sufficient clarity on their long-term forecasting and underlying arrangements with manufacturers. The successful and timely execution of Gavi programmes depends on appropriate capacity in the Secretariat, Alliance partners, Ministries of Health (MOH) and other in-country partners. It is also anticipated that additional donor contributions will be received over and above the pledges reflected in the forecast, particularly from donors that have not made multi-year pledges for the entire strategic period. While there is evolving information about suppliers adjusting to incorporate the impact of COVID-19, it is too early to reflect a major shift in supply capacity or price in the forecast with certainty. The forecast does furthermore incorporate the short-term economic impact of the pandemic on country eligibility and transition, but the long-term co-financing is based on a highly uncertain GNI projection outlook.

Risk appetite and planned further mitigation

Current exposure is just within risk appetite and therefore requires ongoing attention. More frequent updates to the forecast continue to capture fast evolving assumptions, including greater integration of the forecast with various additional short-term data (e.g. shipments, disbursements, COVID-19 trackers). Forecasting and planning processes need to continue to be strengthened and better integrated. 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.

p) Sub-optimally planned campaigns

Multiple large disease focused 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
p Sub-optimally planned campaigns Multiple large disease focused vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services	- Periodic very large cash inflows for campaigns - Front line workers diverted to implement campaigns - Management capacity diverted to manage campaigns - Infrastructure (e.g., supply chain, transport) repurposed for campaigns - Poor planning and management undermine quality of the campaign, resulting in low coverage			JUST WITHIN		

Risk description

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 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.

Existing mitigation

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 and under-immunised communities and children. An analysis of specific reasons for sub-optimal coverage in campaigns identified that delayed disbursement of funds from global to national level and from national to subnational level, along with 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 to plan and implement the campaign including carrying out monitoring activities to guide mop up vaccination, if necessary, along with the required independent post-campaign coverage surveys to evaluate overall performance. However, ensuring completion and timely submission of technical reports and post-campaign coverage survey reports by countries remains a challenge. 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. Countries are encouraged to use campaign operational support to differentiate delivery strategies, targeting measles campaigns to high transmission counties, while using multi-antigen intensified routine services to close measles and other vaccine preventable diseases (VPD) immunity gaps in lower risk areas. 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 quality of measles campaign planning has improved over recent application rounds, with better use of data, including innovations like use of geospatial tools, to improve targeting of activities to zero-dose communities. There is however further room to improve measles campaign applications, in particular the use of quality survey data, increased coherence between campaign plans of action and related budgets, and translation of gender and equity analysis into targeted strategies to reach zero-dose children. 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 risk exposure

Current exposure to this risk remains high. As a result of COVID-19, the majority of planned campaigns had 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. Many delayed campaigns have now been targeted for 2021 to clear the backlog created by the pandemic. As more campaigns resume, 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. COVID-19 may therefore impact the ability to implement high quality campaigns, and pressure to implement quickly may result in insufficient consideration of effective integration and focus on zero-dose communities. 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.

Risk appetite and planned further mitigation

The Alliance has in general a low appetite for the risk of preventive immunisation campaigns undermining the capacity to manage and deliver long-term sustainable routine health and immunisation services and bring zero-dose children into the routine health system. It also has in general a low appetite for the risk of such supplementary campaigns being of low quality due to sub-optimal planning and implementation. However, the Alliance may need to assume a higher level of risk in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term, and in emergency situations where immunity gaps need to be closed rapidly to prevent imminent disease outbreaks. 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. The Secretariat is strengthening its screening of campaign applications and piloting differentiated operational costs for M/MR campaigns. The Alliance is reimagining how to support countries to plan comprehensive immunisation services with appropriate delivery strategies and build back better with a focus on zero dose children and reaching them with all antigens as well as other essential health services.

q) 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
Global supply shortages Shortages in the global vaccine supply affect Gavi-supported countries	- Manufacturing capacity inadequate to meet demand - Unable to meet country presentation preference - Lack of supply security - External disruption (epidemiological, political, technical)			JUST WITHIN		

Risk description

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.

Existing mitigation

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 risk exposure

Current exposure to this risk remains high, with six vaccine markets assessed to be of low health (Measles, MR, MenA, JE, HPV, OCV). Three markets (Measles, MenA, JE) were scored as such because of low supplier diversity but are considered within acceptable risk levels due to sufficient capacity and a strong track record of the dominant supplier. Global demand for HPV continues to outpace available supply, as well as the manufacturing capacity expansion efforts of a major supplier to Gavi, but overall HPV supply is expected to increase in Gavi 5.0. Rotavirus vaccine experienced an unexpected reduction in the volume outlook from the primary supplier (not pandemic related), resulting in a ~10 million annual dose gap versus future demand. The Secretariat and Alliance partners are working with six countries to provide planning and technical support to facilitate switches to alternative rotavirus vaccines starting in 2022. The risk to supply of Gavi-supported vaccines posed by Covid-19 may be receding, but still exists. The impact of a 2020 PCV disruption was successfully managed with partners into 2021, although the risk has not materialised beyond this so far. Some repurposing of primary and secondary production lines for Covid-19 vaccines is inevitable, but this has not resulted in any material trade-off with non-Covid-19 vaccine processes. Additionally, Gavi is also monitoring Covid-19's impact on development timelines of pipeline vaccines in Gavi-supported categories; some delays have been reported by manufacturers, which in two cases resulted in revisions to Roadmap assumptions. At present there are no pipeline delays considered to be critical to long-term market health outcomes.

Risk appetite and planned further mitigation

The Alliance takes a balanced approach to the risk of supply shortages and aims to ensure sufficient and uninterrupted supply of vaccines, especially if this may impact existing programmes. It however also acknowledges that demand and supply are inherently volatile and 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. Furthermore, mitigation is constrained by limitations in the degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges.

Current risk exposure is therefore just within appetite and requires ongoing attention. Alliance partners are closely monitoring the Covid-19 situation, with regular engagement of manufacturers, and with the COVAX Manufacturing Task Force making progress in the CEPI-led effort to de-risk the environment for raw materials and consumables such as adjuvants, tubing, glass vials, filters, single-use bags, etc. This effort is initially focused on Covid-19 supply chains, but its applicability will be broader and is expected to be formally extended to non-Covid-19 vaccines in early 2022.

r) 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
Health systems strengthening HSS investments do not materially improve programmatic outcomes.	• Key bottlenecks not addressable by HSS • HSS grants not designed to target key bottlenecks • HSS grants duplicative with other donor funding • HSS grants not large enough to have significant impact • HSS not disbursed in timely fashion • Programmes funded by HSS not well-managed • Misuse of HSS resources			BROADLY WITHIN		

Risk description

Health systems and immunisation strengthening grants to implementing countries 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. During Gavi 5.0, the Alliance is projected to invest ~US\$ 2 billion in health system strengthening (HSS), equity accelerator funding to reach zero-dose communities (EAF) and cold chain equipment and optimisation platforms (CCEOP) and TCA. Nonetheless, Gavi's cash 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, major gaps in health workforce). Even when HSS grants are well-used, many factors impact the performance of immunisation programmes, so Gavi can contribute but not fully attribute outcomes and impact to its investments. 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.

Existing mitigation

To manage this risk, the approach to programming, planning and monitoring of grants has been 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. Secretariat support has been reprioritised to high impact and fragile countries with increased resources through the organisational review. Operationally, the funding is programmed through the new portfolio management processes with an integrated theory of change and budget across all Gavi support windows. Full Portfolio Planning (FPP) processes help countries holistically programme Health Systems Strengthening (HSS), EAF, PEF Targeted Country Assistance (TCA) and other funding envelopes on reaching zero-dose children, supported by a new, integrated application kit. There is also a workplan to plan and track activities and a redesigned monitoring and evaluation plan to better track progress. All HSS grants have performance frameworks with intermediate indicators measuring direct outputs as well as outcomes, and there is a core set of indicators across all countries to analyse progress at portfolio level. A unit cost and

benchmarking database ensures economy in HSS grants. The Secretariat is revising its programme funding guidelines, including new guidelines on programming to reach zero-dose children and missed communities, and there is an increasing focus on key systems areas which have historically been less of a focus but are critical to the zero-dose agenda (e.g., demand, gender, CSO engagement). There are also new approaches and partners for key settings (e.g. urban and conflict). A portion of HSS funding has been allocated to EAF which has much more targeted requirement for access based on robust identification and plans to reach zero-dose children, and \$200M of it is also being invested in new partnerships for multi-country approaches to accelerate progress on zero-dose in Horn of Africa and Sahel. This also enables countries to accelerate implementation of grants in countries that have experienced challenges in absorbing HSS funding. Furthermore, learning hubs have been established in key countries to enable deeper understanding of progress and challenges on HSS grants.

Current risk exposure

Current exposure to this risk remains high. The Secretariat 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. Progress continues to be at risk as current and future waves of COVID-19 infections and the anticipated surge of COVID-19 vaccine delivery will likely limit countries' bandwidth to conduct further FPP processes and will divert core health systems resources to the COVID response. In 2020, only 3 of 16 countries due to complete their FPP were able to do so and further delays in countries anticipated to undertake FPP are expected. The US\$500 million Equity Accelerator Fund (EAF), approved by the Board in December 2020, has been operationalised and countries can now apply for dedicated, additional funding to reach zero-dose children. Up to 20 country applications are expected by mid-2022, although this number remains uncertain as the pandemic continues to stretch the capacity of Ministries of Health.

Risk appetite and planned further mitigation

The Alliance has in general a high appetite for risks required to strengthen health systems and increase equity in immunisation by extending immunisation services to regularly reach under-immunised and zero-dose children, since this is essential for achieving the mission of leaving no-one behind with immunisation. It recognises that improving equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations. It therefore acknowledges that health systems and immunisation investments may not always improve outcomes as long as there is robust design, implementation and oversight of grants. The current risk exposure is therefore broadly within risk appetite. The Secretariat continues to pursue a more deliberate approach to learning and portfolio analysis and explores the potential for more directive guidance in application kit.

s) Donor support

Significant reduction in donor support to Gavi

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
Donor support Significant reduction in donor support to Gavi	- Reduction in development budgets - Competing priorities in development - Competing priorities within health - Loss of donor confidence in Gavi / COVAX Facility			BROADLY WITHIN		

Risk description

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 potential hit to Gavi's reputation (including that of the COVAX Facility), e.g. due to mismanagement or underperformance, may also lead to reduced donor support. 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. Reduced donor support and immediate and early access to cash financing for the COVAX AMC would undermine accelerated and expanded vaccination in lower income countries, which is essential to beat the pandemic globally and assure recovery.

Existing mitigation

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 COVAX AMC fundraising strategy 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. Several mechanisms and initiatives have helped mobilise additional sources of funding and supply: dose sharing (16 donors have committed to donate a total of 660 million doses), cost sharing (146 million doses have been purchased by countries through their own resources, including supported by MDBs, and options for a further 150 million doses have been secured), EIB and IFFIm frontloading of donor pledges and country cost sharing financing, and private sector funding and delivery support.

Current risk exposure

The overall risk of a significant reduction in donor support remains a high risk despite a strong track record in raising funds so far. Gavi's successful replenishment at the Global Vaccine Summit in June 2020 exceeding the target represented a huge vote of confidence in Gavi, Alliance partners and the collective mission. However, given the ongoing economic uncertainty 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, the commitments to COVAX represent an unprecedented mobilisation of support (to date, US\$ 9.8 billion has been pledged to the Gavi COVAX AMC, of which US\$ 6.6 billion has so far been received by Gavi). These financial pledges have been complemented by increased dose sharing commitments of 660 million doses following a strong call to action at the G7 Summit in June 2021. Overall, the COVAX AMC has benefitted from funding from more than 40 governments and 47 private sector partners, complemented by additional doses sharing and cost sharing support. However, given intense competition for doses and the daunting challenges of scaling up supply, moving forward, reducing the gap between pledges and receipt of

funds will be vital to allow the COVAX Facility to lock in doses as fast as possible. Early receipt of funds is therefore vital to help countries control the pandemic. Furthermore, the COVAX Facility continues to aspire to support countries in achieving the coverage goals they set in the context of the WHO Global Vaccination Strategic Vision aiming to cover 70% of the population with COVID-19 vaccines. Based on the diverse portfolio built by the COVAX Facility and a price point reflecting a higher proportion of mRNA vaccines, coverage scenarios of 60-70% are estimated to cost US\$ 6.8-12.8 billion on top of the existing COVAX AMC resources. Furthermore, with Gavi being a prominent player in the global response to the COVID-19 pandemic, most notably as the administrator of the COVAX Facility, 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.

Risk appetite and planned further mitigation

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. It is however willing to take risk where this is required for attracting new donors to broaden its donor base. The current risk exposure is therefore broadly within risk appetite, but strong advocacy efforts continue to be required to secure donor pledges into cash contributions and to raise additional funding for the COVAX AMC in a constrained resource environment.