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Gavi
The Vaccine Alliance

December 2022

Risk & Assurance Report 2022

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1. Introduction

1.1. Purpose of this report

The world continues to be uncertain and faces unexpected shock after shock: first the pandemic with health impacts and supply chain disruptions, then the Russia-Ukraine crisis with food and energy shortages, and now increasing inflation and rising interest rates, as well as increasingly visible impacts of climate change. Many organisations are adapting their focus from efficiency and "just in time" towards resiliency and "just in case". Gavi is pursuing an ambitious strategy in this risky world, and it can 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 Gavi's Risk Appetite Statement. 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 changed with seven top risks increasing and three top risks decreasing. One risk exposure is deemed to be outside of Gavi's updated risk appetite with intensive mitigation 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. It is working with the Finance team to review its Finance Risk and Control Matrix, which defines key internal controls in finance operations, and is a member of the standing Treasury risk committee. Through the Cybersecurity steering committee, it engages regularly on IT risks. With the Legal team it is engaged on vetting risks of new initiatives, e.g., related to the operationalisation of new innovative financing mechanisms, including potential operational and compliance risks. With the Operations team it is working on crisis management and business continuity, updating incident response plans and conducting a simulation exercise of a ransomware attack. The Risk function worked with the Secretariat's Health & Wellbeing Committee on clarifying people risk drivers and mitigation actions. It also continues to engage through regular meetings with the Global Fund, WHO and UNITAID on safeguarding risk, including through periodic public health collaboration workshops and a joint three-day safeguarding training.

The Risk function furthermore has been part of the Situation Response Team set up in the Secretariat following the Russia-Ukraine crisis, and prepared a cross-cutting review of associated impacts and risks to Gavi's programmes, supply, positioning, donor support, cyber security and staff. This was discussed in-depth in the Secretariat's Risk Committee (chaired by the CEO with senior leadership from across the organisation). The Risk Committee also had a meeting on Data Protection and Privacy risks, to better understand Gavi's current data landscape and associated risks such as data breaches and loss of confidential or sensitive/personal data. It also had a meeting on vaccine supply risk and geographical diversification in the context of geopolitical developments.

The Risk function is routinely participating in COVAX Facility Leadership and Delivery Leadership Team meetings to highlight risk aspects of discussion items, and to provide monthly reviews of the dynamically evolving COVAX risk profile. It gave input on risk management learnings into the COVAX evaluation and continues to be engaged in discussions on a potential pandemic preparedness and response mechanism, drawing on learnings from the COVAX Facility from a risk management and a risk sharing perspective.

The Risk function has also been working with the Policy team to inform the risk and risk appetite aspects of the Fragility, Emergencies and Displaced populations (FED) policy and has started discussions on operationalising Gavi's higher risk appetite as per its Board-approved Risk Appetite Statement in fragile and conflict settings. It has furthermore been engaging on an end-to-end review of the COVID-19 Delivery Support (CDS) application-to-disbursement process to more explicitly frame key risks in the process, and redesign proportionate controls and checks that are truly risk-based and in line with Gavi's risk appetite in order to improve disbursement speed. The Risk function has also participated in EVOLVE workshops to inform the risk and risk appetite aspects of simpler and integrated country programme portfolio management processes and to embed enhanced programmatic risk management across the grant cycle. It also worked with the Secretariat's Monitoring and Performance Management (MPM) Task Force on defining common country programme risks and inclusion of risk indicators into a new programmatic monitoring tool.

Finally, the Risk function's capacity has been stretched this year by a vacant temporary position on the COVAX budget (pending rehiring of a new team member) and is in general struggling to respond to increased demands from the business and to audit findings recommending more operational and programmatic risk management. There is also an ongoing need to be on top of new initiatives to analyse the associated risks, and the organisational growth, reorganisations and management changes require more touch points to re-educate people on risk, redefine roles and responsibilities for risk, identify new risks early-on, and operationalise and align on risk appetite. As increased uncertainty, complexity, funding and change in Gavi require increasingly robust risk management, the Secretariat is exploring options to establish a more future-proof and resilient Risk team.

2. Alliance-wide risk exposure

2.1. Macro trends affecting Gavi's risk profile

The Alliance continues to operate in a volatile global environment and is exposed to continuously changing exogenous factors which could affect Gavi's risk profile. The Secretariat reviews various independent reports[1] 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 has dramatically impacted economies across the world. Since March 2020, over 6.4 million people globally have died of COVID-19 and while over 12.4 billion vaccine doses have been administered, there continues to be great disparities in vaccination coverage between countries and regions. As the epidemiology has now changed to the milder Omicron variant, there is a reduced sense of urgency for vaccine uptake due to a change in disease risk perception, and this has led to a global COVID-19 vaccine oversupply situation. However, there is still a risk that a next virus variant or a new wave (e.g., due to waning immunity) reverses the current situation and would bring procurement and supply risks back to the fore.

The COVID-19 crisis has also had extensive collateral health impacts, partly because other diseases were deprioritised. The latest WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) results confirm a continued disruption of Routine Immunisation services (which was less acute but more prolonged than the severe disruption in Q2 2020), with 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). The pandemic also led to an additional 53 million cases of major depression globally and mental health has deteriorated significantly. The incidence of noncommunicable diseases has also worsened due to treatment delays and antimicrobial resistance has increased (particularly for malaria and tuberculosis) because of the inappropriate use of antibiotics to treat COVID-19. The pandemic and its collateral health impacts may continue to put pressure on health systems across the globe, widen health inequalities between and within countries, create social frictions and weigh down long-term economic growth potential.

The Russia-Ukraine crisis is further exacerbating economic risks through rising food and energy prices, and poses additional regulatory (sanctions), reputational (geopolitical), supply, donor support and cyber risks. The crisis may also affect immunisation programmes in (former) Gavi-supported countries due to the refugee flows and potential resulting disease outbreaks, potential food insecurity, as well as distracted focus and capacity of countries and partners. Due to the surge in energy and food prices, along with the supply and trade disruptions and the necessary interest rate normalisation now underway, global economic growth is expected to slump. Several years of above-average inflation and below-average growth ("stagflation") are now likely, with potentially destabilising consequences for low- and middle-income economies. Further steep interest rate increases to control inflation could trigger a global recession, along with a string of debt crises in developing economies. External public debt in developing economies is at record levels today and most of it is owed to private creditors with variable interest rates that could spike suddenly. As global financing conditions tighten and currencies depreciate against the US dollar, debt distress can spread from low-income economies to middle-income countries. For Gavi, this may also affect the priorities and budgets of its donors. Financial market volatility may furthermore affect the Secretariat's finances, bank counterparties, foreign exchange hedging, investments and forecasting. Moreover, the outlook is subject to various downside risks, including

[1] Amongst others World Economic Forum Global Risks Report 2022; IMF World Economic Outlook 2022; World Bank Global Economic Prospects 2022; Eurasia Group Top Risks 2022; Uppsala Conflict Data Program

intensifying geopolitical tensions, rising financial instability, continuing supply strains, and worsening food insecurity.

Before the Ukraine war, fatalities stemming from organised violence in the world had already increased significantly in 2021 with a 46% increase in deaths largely driven by escalating conflicts in Afghanistan, Ethiopia and Yemen. Despite the increase in fatalities, the number of active state-based conflicts decreased with violence concentrated to fewer but bloodier conflicts. Africa remained the region with the most state-based conflicts. For Gavi this could lead to a further disruption of immunisation programmes and challenges to reaching zero-dose communities. Over the last decade, the number of international migrants has grown consistently, from 221 million people in 2010 to 281 million in 2020. Economic hardship, climate change, conflict and political instability are forcing millions more people to leave their homes. Geopolitical tensions and rivalry have increased substantially, even involving nuclear threats. The global divergence that risks resulting from ruptures within the world economy, stronger competition for geopolitical advantage and domestic pressures to prioritise national and regional objectives will create complex challenges for global cooperation and multilateralism over the next years. It may complicate stronger global governance and more effective international risk mitigation efforts needed to address the global, interconnected challenges that cannot be solved by national governments alone.

Climate change is now manifesting clearly and rapidly in the form of droughts (e.g., in the Horn of Africa), floods (e.g., in Pakistan recently), fires and heatwaves (e.g., in Europe this summer), which increasingly may disrupt immunisation programmes. The economic overhang of the COVID-19 and Russia-Ukraine crisis and weakened social cohesion may further limit the financial and political capital available for stronger climate action, raising the risk of disease outbreaks and future pandemics as 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).

Growing dependency on digital systems, intensified by COVID-19, has altered societies. Industries have undergone rapid digitalisation, workers have shifted to remote working where possible, and platforms and devices facilitating this change have proliferated. At the same time cybersecurity, ransomware and misinformation threats are growing, outpacing societies' ability to effectively prevent or respond to them. Work-from-home also appears to have had a profound impact on attitudes about work-life balance among various parts of the labour force. A growing number of employees have been leaving their jobs voluntarily (dubbed "The Great Resignation"), which may have long-term effects on the workforce. In an increasingly tight labour market, risks related to the ability to attract, retain and develop top talent have become more prominent.

2.2. Changes to the Alliance-wide top risks in 2022

Last year's report[2] prioritised 19 top risks in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility, with most top risks continuing to be elevated. This year's report prioritises 18 top risks, and shows that Gavi's overall risk profile has changed, with seven top risks increasing and three top risks decreasing (as illustrated by the arrows next to each top risk below). One risk exposure is deemed to be outside of Gavi's risk appetite with intensive mitigation still ongoing (see section 2.3 for more detail on risk appetite). 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 top risk information).

The 3 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) **Sustainable transition** ▲
Some countries fail to successfully transition out of Gavi support or see their immunisation programmes backslide after transition

c) **Insufficient demand** ▲
Significant drop or insufficient increase in vaccine demand due to hesitancy, gender inequity or other socioeconomic or cultural barriers, or lack of prioritisation

The 15 top risks rated as ***high*** are:

d) **VPD outbreaks** ▲
Sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries

e) **COVAX delivery** ▼
Significant COVID-19 delivery issues and impact on routine immunisation

f) **COVAX supply** ▼
Significantly reduced and unpredictable COVID-19 vaccine supply

g) **Misuse by countries**
Deliberate misuse of Gavi support in many Gavi-supported countries

h) **Secretariat capacity**[3] ▲
Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy

i) **Secretariat disruption**[4] ▲
Significant disruption of Secretariat operations

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 immunisation**
Polio resurgence or a ramp-down after eradication adversely affecting routine immunisation

m) **Partner capacity**
Sum of comparative advantages of Alliance partners may be inadequate to effectively deliver required technical support to countries

n) **Donor support** ▲
Significant reduction in donor support to Gavi

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 and

[2] See for the 2021 Risk & Assurance Report: https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2021

[3] Up from being a medium risk previously

[4] Now including previous top risks *COVAX Facility* and *COVAX reputation*

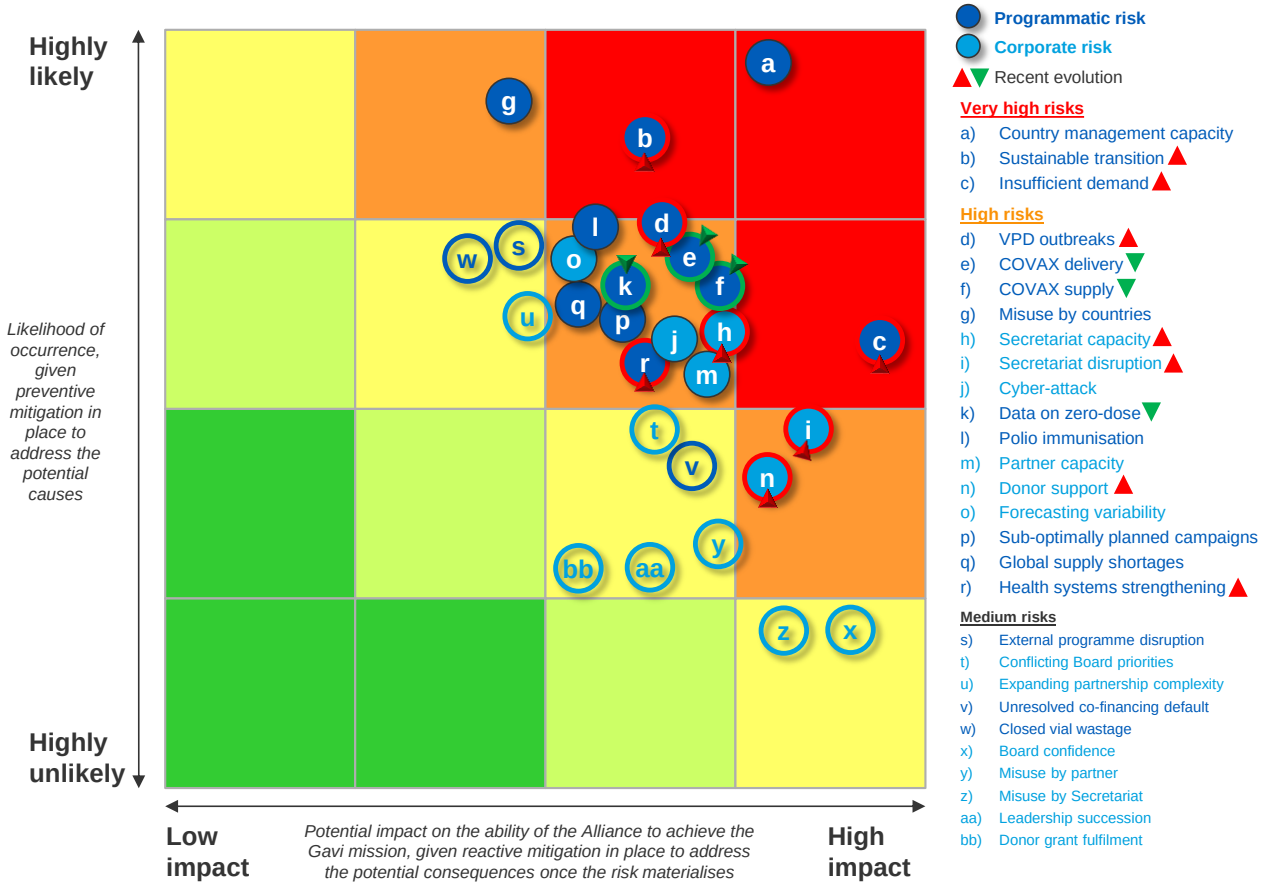
implemented may undermine capacity to manage and deliver routine health and immunisation services

q) **Global supply shortages**
Significant shortages in the global vaccine supply

r) **Health systems strengthening**
HSS investments may not materially improve programmatic outcomes

Alliance top risks ranked against likelihood and impact

2022 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2022 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 next segment of risks in the yellow zone are medium[5] risks (depicted with hollow circles), shown for comparison purposes only and not designated as top risks. The Secretariat also maintains a register containing

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

Alliance-wide top risks summary

	Alliance–wide top risks		Risk assessment			Risk evolution	
	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a	**Country management capacity** Many countries may lack or have insufficiently resilient 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	**Sustainable transition** Some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide 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	↑	⟷
c	**Insufficient demand** Significant drop or insufficient increase in vaccine demand due to hesitancy, gender inequity or other socioeconomic or cultural barriers, or 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	VH		JUST WITHIN	↑	⟷
d	**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	↑	↑
e	**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	H		JUST WITHIN	↓	↓
f	**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	H		JUST WITHIN	↓	↓
g	**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	⟷	⟷
h	**Secretariat capacity** Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy	• Increased volume and complexity of work • Lean operating model no longer fit for evolved mandate • Insufficient people, headcount ceiling • Insufficient/inadequate skills and competencies • Inability to adapt processes, systems and culture	H		JUST WITHIN	↑	↓
i	**Secretariat disruption** Significant disruption of Secretariat operations	• Catastrophic event impacting facilities and operations • Mental health issues, burn-out and staff disengagement due to pandemic and stretched Secretariat capacity • Misconduct or reputational attack/backlash • Leadership transition and succession issues • Departures of key staff with critical knowledge • Incident or loss of life in the workplace or during travel	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 immunisation** Polio resurgence or a ramp-down after eradication adversely affecting 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	**Partner capacity** Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	• Right partners unavailable / unable to access Gavi funding • Lack of capacity / relevant expertise for new strategy • Lack of alignment and coordination across partners • Inability to manage accountability and performance	H		JUST WITHIN	⟷	↓
n	**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	↑	↑
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 and implemented 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		JUST WITHIN	↑	↓

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, risk appetite and further planned mitigation. 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) Sustainable transition ▲ – The risk that some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide after transition has increased 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 impact of COVID-19, now combined with high inflation, interest rate rises combined with high debt levels, a rising US dollar, and economic uncertainty related to the Russia-Ukraine crisis, has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' fiscal space for domestic financing, their transition trajectories, and backsliding in already transitioned countries. Whilst all Gavi countries have recorded an increase in debt levels compared to pre-COVID-19, countries in the initial self-financing phase have recorded a ten-percentage point increase in debt to GDP ratio in only two years from 62% in 2019 to 72% in 2021 due to the economic impact of the pandemic. The risk of co-financing defaults is high with payments for 49% of Gavi-supported countries fully outstanding at the end of August, compared to 35% at the same time in 2019. Of particular concern is the fragile and conflict segment where 8 of 12 countries have yet to meet their co-financing obligations. Countries entering or currently in Accelerated Transition (AT) are facing some unprecedented challenges and transition risks. Their GNI per capita is about a third lower than the 16 countries that have previously transitioned from Gavi support. Moreover, their immunisation coverage rates are lower as well, with some facing backsliding due to the pandemic. Finally, their transition occurs in a period of considerable economic uncertainty, while countries that have already transitioned did so during an economic boom. Risks of backsliding in already transitioned countries are also high. Of the 17 countries that had transitioned as of 2021, seven were able to sustain DTP3 coverage above 90% from 2019 to 2021. Among the remaining ten countries, declines in DTP3 coverage ranged from 2 to 18 pp. To further mitigate this risk, the Gavi Board agreed that it will be essential to continue to strongly advocate to protect domestic financing for health and immunisation, as well as to ensure global health agencies collaborate further to unlock efficiencies in health spending at country level. Gavi proactively engages in a dialogue with countries to assess the risk of countries not paying their co-financing, supports engagement with Ministries of Finance and partners, and advocates for alternative sources of funding through close collaboration with the World Bank (and is further exploring similar engagement with the IMF). Building on the co-financing flexibilities approved by the Board in June 2022 for countries facing humanitarian crisis or severe fiscal distress, waivers have been requested for Somalia and North-West Syria. Intensive follow-up with governments and development partners is ongoing in the other fragile countries. A specific co-financing approach for the high-cost malaria vaccine has also been designed with financial implications assessed to facilitate uptake. Furthermore, the Funding Policy Review (FPR) will recommend an extension of Accelerated Transition from 5 to 8 years to allow for a more gradual acceleration of co-financing to support countries in addressing financial sustainability challenges due to the impacts of the pandemic, ongoing war in Ukraine, and increasing debt. The Alliance also prioritised support to mitigate the risk of backsliding in four already transitioned countries through the Middle-Income Countries (MICs) Approach. While implementation was slow initially, proposals have now been approved or are in development for all four countries, and the Secretariat continues to actively monitor the situation in other former-Gavi eligible countries to identify where there may be additional need for support.

c) Insufficient demand ▲ – The risk of a significant drop or insufficient increase in vaccine demand due to hesitancy, gender inequity or other socioeconomic or cultural barriers, or lack of prioritisation has increased to very high, especially for COVID-19 vaccines as community demand in-country is affected by a changed risk perception due to the milder Omicron variant and vaccine hesitancy in some cases (with currently a downward

vaccination trend in many AMC participants), which could lead to in-country vaccine expiries and wastage. Mis- and disinformation about COVID-19 vaccines and vaccination fatigue could potentially also spill over into demand for routine vaccines. The risk also remains 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. To further mitigate this risk, COVID-19 demand will remain a high focus for the COVID-19 Delivery Partnership, including by increasing the engagement of more expanded and local partners to build trust and generate demand.

d) VPD outbreaks ▲ – The risk of sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries has increased, with the overall number of vaccine preventable disease outbreaks prompting internationally supported outbreak response vaccination campaigns in 2022 already exceeding the 2021 numbers, driven primarily by measles and cholera outbreaks. The unprecedented emergency environment of the COVID-19 pandemic has posed a challenge to many countries, leaving Ministry of Health, healthcare workers, communities and partners stretched at central and subnational levels. Countries and Alliance partners dealt with competing health priorities and limited programmatic capacity leading to delays and making microplanning and implementation a challenge, in terms of social mobilisation, supervision, monitoring and follow-up, in particular regarding carrying out Post Campaign Coverage Surveys and reporting. The pandemic has led to declines in routine immunisation coverage in some countries, as well as an increase in malnutrition, which weakens the immune system and particularly exposes children to measles infection and complications. Since January 2022, WHO has identified 24 large, disruptive measles outbreaks in Gavi-supported countries, often compounded by malnutrition and increased risk of measles-related mortality. To date, eight countries have requested support to the Measles Rubella Initiative for outbreak response campaign (compared to 18 outbreaks and four requests in the whole of 2021). Cholera outbreaks are also on the rise, with 12 requests from seven countries in Asia and Africa submitted so far in 2022 to the ICG for oral cholera vaccine campaigns in response to outbreaks (compared to 10 requests from six countries in 2021) translating to over 18 million doses of OCV shipped in response to outbreaks so far in 2022 (compared to 17 million in all of 2021). The risk of cholera outbreaks is expected to persist in 2023-2025, considering known transmission dynamics from previous pandemic waves and climate-related events such as the floods in Pakistan or the droughts in the Horn of Africa. Furthermore, six yellow fever requests have been submitted in 2022 (compared to 3 in 2021), to support reactive campaigns in Ghana, Chad, Central African Republic, Cameroon and Kenya targeting over 3 million individuals in the first half of 2022. To further mitigate this risk, close monitoring will continue to be needed as well as an assessment of the link between an outbreak occurrence and gaps in routine immunisation to better develop recovery plans that strengthen routine immunisation services and prevent future outbreaks. In addition, a revised PEF TCA grant to support timely ICG applications has been signed with WHO and root-cause analyses are being encouraged, especially when immunisation gaps are likely at the source of outbreaks. Potential further areas for improvement involve the confirmation and reporting of outbreaks, the shipping and clearing of vaccines, and the implementation of vaccination activities once vaccines arrive in countries. Addressing these issues will require stronger collaboration and follow-up across the Alliance and enhanced technical support at country level.

e) COVAX delivery ▼ **–** The risk of significant COVID-19 delivery issues and impact on routine immunisation has decreased as AMC countries continue to make good progress with overall population coverage levels increasing, especially amongst lowest coverage countries. As of Sept 2022, 57% of people in all AMC countries have received at least one dose and 50% have completed primary series. Primary series coverage of highest- and high-risk individuals has continued to gradually improve, reaching 63% coverage of older adults and 75% coverage of healthcare workers. However, inequities persist, and coverage is reaching a plateau partly due to the decreasing risk perception in many countries (see top risk *Insufficient demand*), external headwinds and competing priorities. There remain 9 countries below 10% overall population coverage due to fragility and conflict, bureaucratic and logistical constraints, and/or limited health systems capacity to sustain concentrated COVID-19 vaccination efforts. Many of these countries face ongoing humanitarian, conflict, and other crisis

situations that severely constrain their ability to prioritise and dedicate resources to COVID-19 vaccination. Across AMC participants, there remain at least 115 million highest-risk individuals that have yet to receive complete primary series vaccinations and there is a need to improve reporting on coverage with booster doses across these population groups. There are also emerging risks with in-country absorption and utilisation of COVID-19 Delivery Support (CDS) funding along the ambitious target timelines originally outlined. CDS Early Access Window funding disbursed in the second half of 2021 remains less than 80% utilised at country-level, with some countries remaining below 50% utilisation. This is mainly due to competing health and other political priorities during the pandemic, overburdened planning and financial management capacities, health workforce constraints, and other external factors. However, as countries will continue to integrate COVID-19 vaccination with their existing immunisation programmes and primary healthcare systems (shifting away from COVID-19 specific campaign-style delivery approaches), many will continue to require concerted support to achieve this integration. To further mitigate this risk, the COVAX Facility and the COVID-19 Vaccine Delivery Partnership (CoVDP) will continue to actively monitor and mitigate delivery risks, with a continued focus on reaching the highest-risk populations and through specific programmes targeted at fragility, emergencies, and displaced populations. While accelerating its delivery support until the end of the year, CoVDP is also preparing a transition plan to completely phase out by the end of Q2 2023 as it will set the floor for a full integration of COVID-19 into routine immunisation and primary healthcare.

f) COVAX supply ▼ – The risk of significantly reduced and unpredictable COVID-19 supply has decreased substantially given that most vaccines have been granted regulatory approval, most manufacturers have successfully scaled-up production, export restrictions have eased, and demand for vaccines in HICs has waned. Together with lower-than-expected vaccine candidate attrition and evolved demand due to the Omicron variant, this has led to a current global oversupply situation. Negotiations with manufacturers and donors to rephase and reduce incoming supply has helped to reduce the risk of vaccine expiries, while ensuring that COVAX maintains sufficient volumes (although it may result in a more concentrated vaccine portfolio). While the exact composition of 2023 supply remains subject to change based on several uncertainties, it is anticipated that under WHO's base case scenario COVAX supply volumes will be broadly sufficient to satisfy most demand in 2023. In general, uncertainties persist around future demand (e.g., potential new waves and variants; evolving coverage targets; and policy recommendations on boosters and paediatric doses) as well as future supply (e.g. level of non-COVAX supply and new dose donations; the effect of domestic manufacturing efforts; vaccine market developments and changes in manufacturer confidence; and access to next generation and new variant-adapted vaccines). Specifically, five key uncertainties continue to influence COVAX's 2023 supply portfolio: (i) remaining 2022 demand above existing allocations which will affect remaining COVAX supply available at the beginning of 2023; (ii) outcomes of renegotiations which are seeking to reduce and rephase existing supply; (iii) availability of, and access to, variant-containing vaccines (VCVs) through APAs and donations in the event they are recommended by SAGE and approved by WHO; (iv) whether and when VCVs could be indicated for primary series use which will affect the need to maintain other vaccines suitable for this use; and (v) risks to demand for prototype vaccines in the current portfolio in the event that countries decide to wait for access to VCVs. As manufacturers now transition production from prototype vaccines to VCVs, the COVAX Facility currently has very little supply of mRNA prototype vaccines for use in 2023. It is expected that VCVs will initially be approved for booster use only and the COVAX Facility likely will initially fulfil primary series demand in 2023 through its supply of non-mRNA vaccines. It is also important to underline that the supply risk can quickly increase again in case of a resurgence of the pandemic (e.g., due to waning immunity) or the emergence of a new virus variant requiring COVAX to compete again for places in the queue with manufacturers. The current low demand may also have implications on the ability to secure volumes (through contracts and donations) and have implications on AMC funding. Furthermore, the current economic environment may limit availability of funds going forward, in particular to acquire variant adapted vaccines. However, there is donor commitment to share doses early when needed, renegotiations with manufacturers may release funds, and the Facility may draw on the Pandemic Vaccine Pool for contingent funding in case of a shock. To further mitigate this risk, the COVAX Facility continues to closely monitor the

scientific developments and the supply and demand landscape. It remains important to maintain a diversified portfolio, but when the supply situation remains healthy 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. Despite high levels of uncertainty persisting across multiple dimensions including disease trajectory, optimal vaccination strategies, vaccine effectiveness, and demand, COVAX is planning for a 2023 strategy based on WHO's base case scenario. This scenario foresees that periodic boosting for high priority populations may be required, resulting in an ongoing need for vaccines although most likely on a smaller scale than in the first two years of the pandemic. Therefore, COVAX aims to continue supporting AMC participants to meet their ambitions with a particular emphasis on expanding protection for higher risk populations including with boosters and in line with the evolving product landscape. In preparation for 2024 and a more routine COVID-19 programme, pending Board approval, COVAX will also continue to transition towards established Alliance structures while retaining capacity to respond to the WHO worst-case scenario through the Pandemic Vaccine Pool and enhancing preparedness for future pandemics (as part of the transition to Gavi 5.1). If variant-containing vaccines (VCVs) are approved by WHO and are recommended by SAGE for use, COVAX will seek to provide them in line with country demand. If there are initial supply constraints COVAX would first provide VCVs to the highest priority user group to have the greatest impact against severe disease and death. As more data emerges about VCVs, COVAX will continue to assess their role in an optimal vaccination strategy. In this context, the Pandemic Vaccine Pool (PVP) provides the financial flexibility to procure additional VCVs if needed, including in case of a resurgence of COVID-19.

h) Secretariat capacity ▲ – The risk that Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy is increasing with a heightened workload across the Secretariat to respond to the COVID-19 impact on routine immunisation, to accelerate the zero-dose agenda, and to continue to support the delivery of COVID-19 vaccines and integration of the COVAX Facility into Gavi core. A proper root cause analysis of what is driving workload and a method for prioritisation is however lacking. The employee pulse survey showed that wellbeing is the lowest scoring category (see also top risk *Secretariat disruption* for risks of staff disengagement and low morale) with 67% of respondents saying that staff is insufficient for the workload. Training budgets remain also underutilised. While the current pandemic evolution justifies resizing and integration of the COVAX Facility into Gavi core, multiple challenges remain for the COVAX Facility with still high transaction costs (e.g., resizing/rephasing negotiations, SFP and cost share close outs, 2023 planning, integration, COVID-19 Delivery Support, and audits and evaluations) and the design and strategy of the Facility needs to continue to adapt to the evolving pandemic and global strategy to remain fit for purpose. There are also new ideas and initiatives being explored with potentially significant operational implications for the Secretariat such as supporting regional manufacturing and pandemic preparedness and ongoing innovative financing mechanisms that need to be serviced and operationalised by support teams in the Secretariat. Gavi's current systems have become complex with laboursome processes and approvals combined with multiple funding levers and funding buckets and not always clear roles and responsibilities. Existing pressure on keeping resourcing within a headcount ceiling as well as trying to reduce the number of consultants has led to resourcing decisions that are not necessarily informed by a strategic approach to workforce planning aimed at ensuring quality of services, fit for the organisation and sustainability. The rapid growth of the Secretariat did also not allow its processes and operational support functions to evolve with it and siloes and ineffective practices have crept into the work. To further mitigate this risk, the Secretariat will work on its processes and policies, to ensure faster, simpler and more flexible funding by operationalising FED flexibilities for fragile countries and making improvements in Gavi's end-to-end processes with the multi-year EVOLVE programme and a continuous improvement approach for SAP optimisation. The Chief Operating Officer (COO) is exploring costs, benefits and timelines of an approach to Operational Excellence (OE) structured around 5I's: Innovate (e.g., with EVOLVE), Integrate (e.g., COVAX integration), Improve (simplification focused on efficiency and effectiveness), Invigorate (the Gavi culture), and Inform (change management and communication). An Enterprise Project Management Office (EPMO) will support OE across the organisation with clear governance and accountability and will set up a balanced scorecard. It will also be

fundamental to get a common understanding of current and required resourcing levels, covering permanent headcount, long-term consultants, surge/project consultants and COVAX temporary staff and consultants.

i) Secretariat disruption ▲ – The risk of significant disruption of Secretariat operations is increasing with staff mental health and staff engagement under continued pressure due to ongoing uncertainty in the external environment (with threats of an escalating war, a cost-of-living crisis and a global recession) as well as a high rate of internal change due to process optimisation and integration of COVAX Facility and Gavi core processes and multiple leadership transitions (with the current Chief Executive Officer completing his term of appointment in 2023, the Deputy CEO having retired, a new Chief Operating Officer having joined, and a Chief Programme Strategy Officer appointed). Staff also still suffers from the after-effects of the pandemic but continues to face a heightened workload across the Secretariat due to resourcing constraints (reflected in the top risk *Secretariat capacity*). The employee pulse survey showed that wellbeing is the lowest scoring category. There are high levels of unpaid leave requests and sick leave has also been increasing. While overall turnover still appears to be reasonable, there are staff retention risks going forward, especially given the current tight labour market and the fact that there is high reliance on key persons in various areas without succession planning. The current uncertainty around the future of the pandemic and related vaccination requirements also poses risks to COVAX Facility staff morale, recruitment and retention of high-performing staff, and succession and knowledge management. Internal disruption, including both turnover and intra-organisational movements remain a concern within the COVAX Facility. With COVAX Facility staff on short-term contracts (to retain necessary flexibility in the Secretariat), key personnel have already been leaving due to the lack of security and finding a permanent job elsewhere, with implications on Secretariat capacity to deliver and staff workloads. Further disruption could also still occur if the virus would resurge, and capacity cannot catch up again soon enough. Finally, with travel now resuming, travel to high-risk countries has increased fourfold, especially as Gavi is using more (local) partners in fragile and conflict areas. To further mitigate this risk, the Secretariat's Crisis Management team continues to monitor the evolution of the pandemic as well as potential new developments related to the Ukraine-Russia conflict and the energy crisis and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. Furthermore, there is strong global media monitoring as well as participation in internal discussion to ensure emerging reputational risks can be assessed quickly and effectively. This has helped mainstream and de-sensationalise an otherwise potentially key reputational risk related to COVID-19 vaccine expiries by transparently managing expectations that supply-demand mismatches and expiries will happen and that this is a risk that was accepted as necessary to take in order to fight the pandemic (which required upfront procurement at risk while demand was still unknown and continued to evolve with the pandemic). The new Chief Operating Officer's (COO) number one focus will be on people and invigorating Gavi's culture, focused on an engaged and motivated workforce based on Gavi values, leadership competencies, Diversity, Equity and Inclusion, and the Code of Conduct. Additional Secretariat resources requested from the Gavi Alliance Board and a rigorous focus on staff wellbeing would also improve conditions. Gavi is also working on making enhancements to the recruitment process with stronger checks in place to ensure that Gavi does not recruit individuals with a proven history of misconduct or inappropriate behaviour and is putting together a plan to regularly remind the workforce of being vigilant about their own behaviour as well as intervening when required when they witness inappropriate behaviour. Furthermore, HR is developing a new employee performance appraisal process with a clear development focus. The onboarding process for new hires is also being reviewed and more training will be available for managers to manage as a coach.

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 mitigation actions with zero-dose identification efforts happening at scale across countries. The hypothesis that zero-dose children are clustered in pockets and can be targeted sub-nationally has also now been tested by quantifying the degree of concentration for each country. It is estimated that around 43% of zero-dose children live in conflict, remote rural or conflict settings, and an estimate exists for each country,

confirming that they are concentrated to some extent. However, it remains an important risk fundamental to the Gavi mission. Analysis of data needs required in Gavi 5.0 had identified significant gaps in the data required for identification of missed communities and current efforts still need to be proven to be adequate. Diverted EPI and Alliance capacity due to COVID-19 have slowed down work on zero-dose implementation of HSS and the new EAF at country level. The shift from using data to measure coverage post-facto in Gavi 4.0 to needing to use (different types of) data ex-ante to target interventions in Gavi 5.0 requires more granular, sub-national, geospatial and qualitative data, including on information on the root causes for missed immunisation. It also requires timely data, which can be a challenge if data collection is lagged. To further mitigate this risk, 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, data triangulation 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 with complementary support to countries to triangulate their data and improve their reported official coverage estimates through the Measurement & Learning Strategic Focus Area.

m) Donor support ▲ – The risk of significant reduction in donor support to Gavi is increasing despite a strong track record in raising funds so far and having been able to secure sufficient pledges for the COVAX AMC. The pandemic clearly highlighted routine immunisation and pandemic preparedness and response as global priorities and significant donor support represented a huge vote of confidence in Gavi, Alliance partners and the collective mission. However, the ongoing geopolitical developments and the conflict in Ukraine risk drawing donor attention and funding away from global health and development due to competing priorities. Furthermore, significant financial and economic uncertainty in many donor countries, with inflation and rising interest rates potentially resulting in a cost-of-living crisis and a global recession, may constrain donor country budgets going forward, and popular discontent can contribute to a further rise in political parties opposing development aid winning elections. It is therefore needed to remain vigilant and continue to transform pledges into full financial contributions, hedged against a rising US dollar. For Gavi core, 72% of pledged amounts (volume) are signed, 23% are signed on an annual basis and 5% remain to be signed. For COVAX AMC, 84% of the pledges (in volume of US$) are signed. It also remains important to further solidify and broaden donor support for Gavi, with opportunities to showcase Gavi’s achievements and successes through the ongoing COVAX evaluations and the upcoming Mid-Term Review (MTR) and donor assessments such as MOPAN. Gavi donors have doubled compared to the past, adding to the challenge of servicing them and ensuring that they are briefed, brought to the table, and understand progress and achievements. Relationships with existing donors have also shifted, with immunisation and health security now being high priorities for important donors, who are now both more keen and more impatient at seeing results.

r) Health Systems Strengthening ▲ – The risk that HSS investments do not materially improve programmatic outcomes has increased due to the pandemic switching the focus in many countries away from routine immunisation and towards COVID-19. Both country teams and partner capacity have been significantly diverted to the COVID response and COVID vaccine scale-up. There have also been major other sources of disruption in several larger Gavi-supported countries (e.g., massive flooding in Pakistan, internal conflict in Afghanistan, Ethiopia and Myanmar). This has resulted in significant delays in programming of new Gavi support for health systems (e.g., very few full portfolio planning processes were completed in 2020 and 2021) as well as slowed down implementation of existing grants. Therefore, while the Alliance has laid strong foundations for pivoting its support for health systems in line with Gavi 5.0, there have been significant delays in this translating into active programmes while roll out of the new Monitoring & Learning plans is also delayed. The COVID-19 pandemic has also resulted in backsliding of immunisation coverage in many countries, which

means that they will need to catch-up those children missed during the pandemic as well as working to reach zero-dose children within their available resource envelopes. This will be a particular challenge in countries which saw their HSS ceilings fall in Gavi 5.0 (e.g., due to having increased coverage or GNI per capita in Gavi 4.0). To further mitigate this risk, the Secretariat and Alliance will continue to make concerted efforts to work with countries to accelerate FPP, EAF and TCA planning processes, ensuring that new grants which align to the Alliance's 5.0 goals are approved and begin implementation as soon as possible.

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 considering 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 Statement[6], 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 riskier 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.

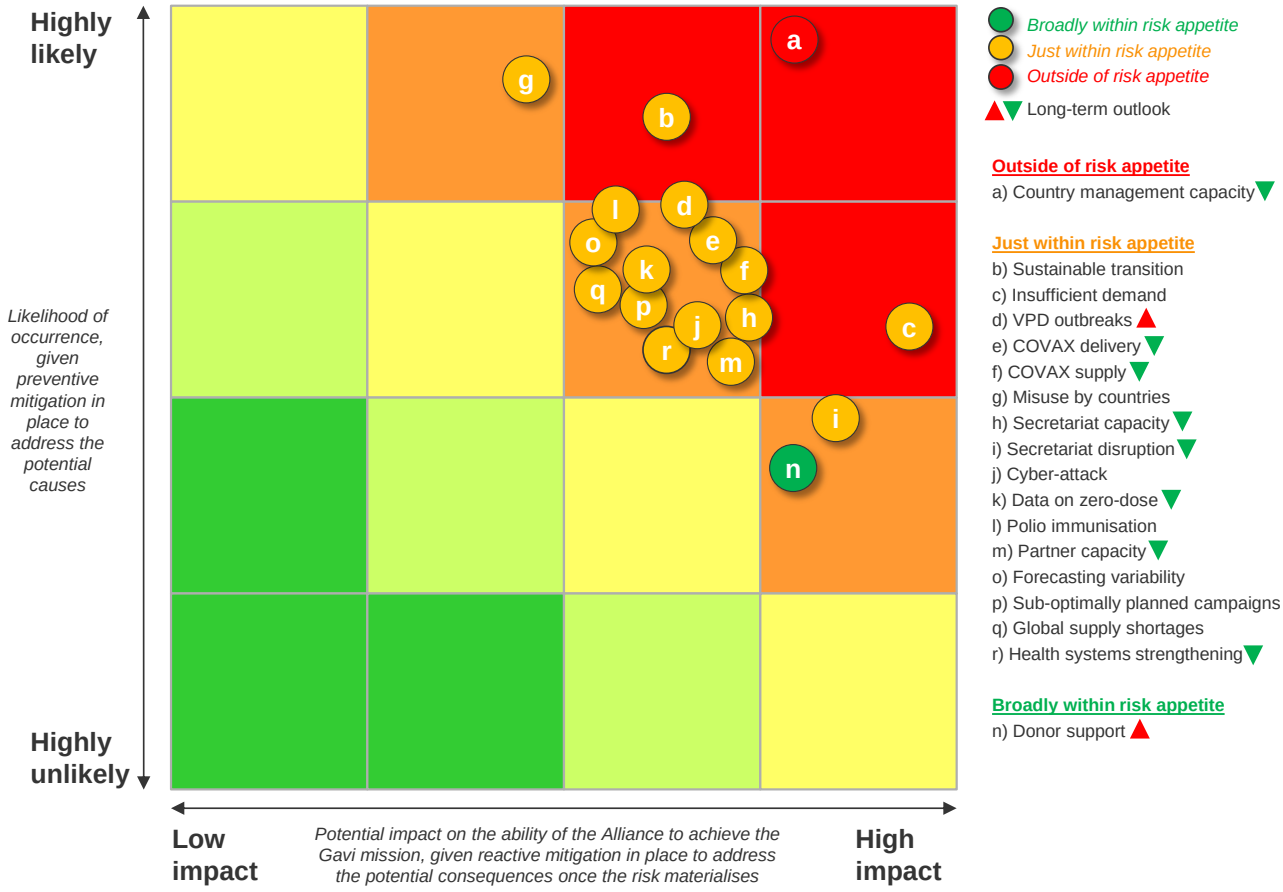
For each of the Alliance's top risk exposures (as presented in the previous section), the Secretariat has interpreted how the high-level statement translates into an appetite for each of the Alliance's top risks as described below (and in more detail in Annex IV). As depicted in the risk appetite heat map below, 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). 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.

[6] 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

Willingness to accept current top risk exposures

Actual exposures reviewed against a recalibrated risk appetite



Top risks outside of risk appetite – requiring intensive mitigation efforts

a) Country management capacity – The risk that many countries may lack or have insufficiently resilient 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, countries continue to have difficulties managing competing priorities. The latest WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) results confirm a continued disruption of Routine Immunisation services (which was less acute but more prolonged than the severe disruption in Q2 2020) due to varying drivers, including health worker strikes, political unrest and conflict, continued measures to control the pandemic and COVID-19 vaccine scale up. The recent institutional capacity survey also suggested a drop in EPI capacity across all Gavi country segments during the pandemic, hindering implementation of activities as well as slowing down country applications to HSS and EAF. There have also been delays in Full Portfolio Planning (FPP) and fewer countries than initially expected have received IRC approval to date. Capacity may continue to be constrained as the delivery of COVID-19 vaccines, climate change-related disasters, and economic and social turmoil continue. Furthermore, most countries do not have contingency plans for natural disasters, outbreaks or other disruptions to immunisation programmes and would need help to plan for possible disruptions, especially in countries that are more prone to such risks. Moreover, increased capacity may be needed to plan and coordinate many catch-up campaigns to restore coverage levels after vaccine introductions and campaigns were suspended during lockdowns, while immunisation is also becoming more complex with additional needs of routinising COVID-19 vaccines, rebooting HPV, and potentially introducing malaria. 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. To bring this risk within appetite, the Secretariat is actively streamlining processes and adapting funding policies to facilitate access to funding considering limited country bandwidth. The recently concluded "Full Portfolio Planning (FPP) step-back exercise" led to a series of simplifications in application requirements that aim to reduce the average length of the FPP process from nine to 22 months to not more than six months. There will be an intense focus on FPP towards the end of the year with up to 22 countries applying. To achieve more radical improvements in the medium term, the EVOLVE project was launched with an aim to restructure and simplify the grant management process. COVAX TA is used to provide surge capacity – including additional Leadership, Management & Coordination (LMC) capacity – dedicated to COVID-19 vaccine rollout and thereby limiting the disruption on routine work. There is also continued engagement of Ministries of Health to ensure sustained prioritisation of routine immunisation (RI). Country dialogues and advocacy efforts focus on integrated planning for COVID-19 and RI (micro plans, budget, and delivery strategies). Gavi is also operationalising the Fragility, Emergencies and Displaced populations (FED) policy which enables a time-limited fast response to acute emergencies that have a direct impact on a country's immunisation programme, and pose risks to Gavi's gains, finances, and investments. The devastating floods in Pakistan triggered the emergency component of the FED policy, calling on all teams involved in the grant management cycle to expedite, waive some of the normal review policies and exercise a greater risk appetite. For countries in chronic fragility, bespoke flexibilities are being extended to reduce requirements to apply for Gavi support, extend thresholds for HR costs due to dire economic situations, sensitise review bodies on what is "good enough" and simplify Gavi's processes.

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

Exposure for **b) Sustainable transition**, **c) Insufficient demand**, **d) VPD outbreaks**, **e) COVAX delivery**, **f) COVAX supply**, **g) Misuse by countries**, **h) Secretariat capacity**, **i) Secretariat disruption**, **j) Cyber-attack**, **k) Data on zero-dose**, **l) Polio immunisation**, **m) Partner capacity**, **o) Forecasting variability**, **p) Sub-optimally planned campaigns**, **q) Global supply shortages**, and **r) Health systems strengthening** falls just within risk appetite. More information on these risks and further mitigation to bring them more fully within risk appetite can be found in Annex IV. It should be noted, however, that the long-term outlook for **d) VPD outbreaks** is expected to increase, and it is important to continue to monitor whether the risk will move more outside of risk appetite at some point.

Top risks broadly within risk appetite – to be monitored

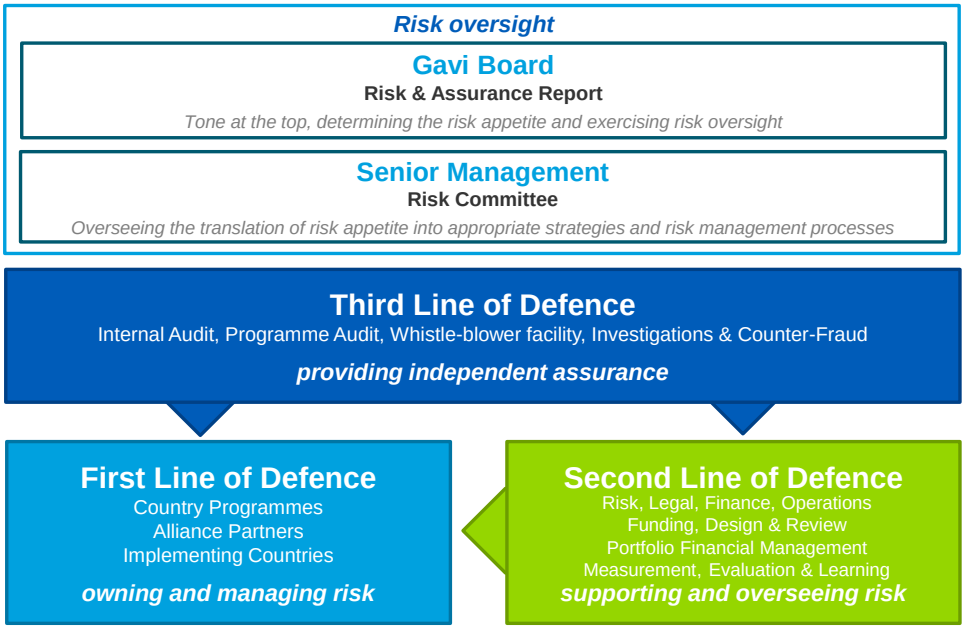
Exposure for **s) Donor support** falls broadly within risk appetite. More information on this risk can be found in Annex IV. It should be noted, however, that the long-term outlook for this risk is expected to increase and it is important to continue to monitor this risk.

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

Strategic Goals

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

1 INTRODUCE AND SCALE UP VACCINES

High appetite
- 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 appetite
- Vaccine introduction decisions exacerbating inequities or affecting sustainability
- Campaigns undermining routine immunisation or being of low quality

2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION

High appetite
- 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 appetite
- Fraudulent misuse of Gavi support
- Drop or insufficient increase in vaccine demand and confidence
- Weak systems jeopardising vaccine and immunisation safety

3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES

Balanced
- Countries transitioning without sufficient financial and programmatic capacity
- Significant reduction in performance post-transition

Low appetite
- Drop in political will and social commitment for immunisation
- Countries defaulting on co-financing obligations

4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS

High appetite
- 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

OPERATIONAL RISK

Low appetite
- 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

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 appetite
- Risks undermining accountability and transparency

REPUTIONAL, FUNDING AND FINANCIAL RISK

High appetite
- Risks required for attracting new donors

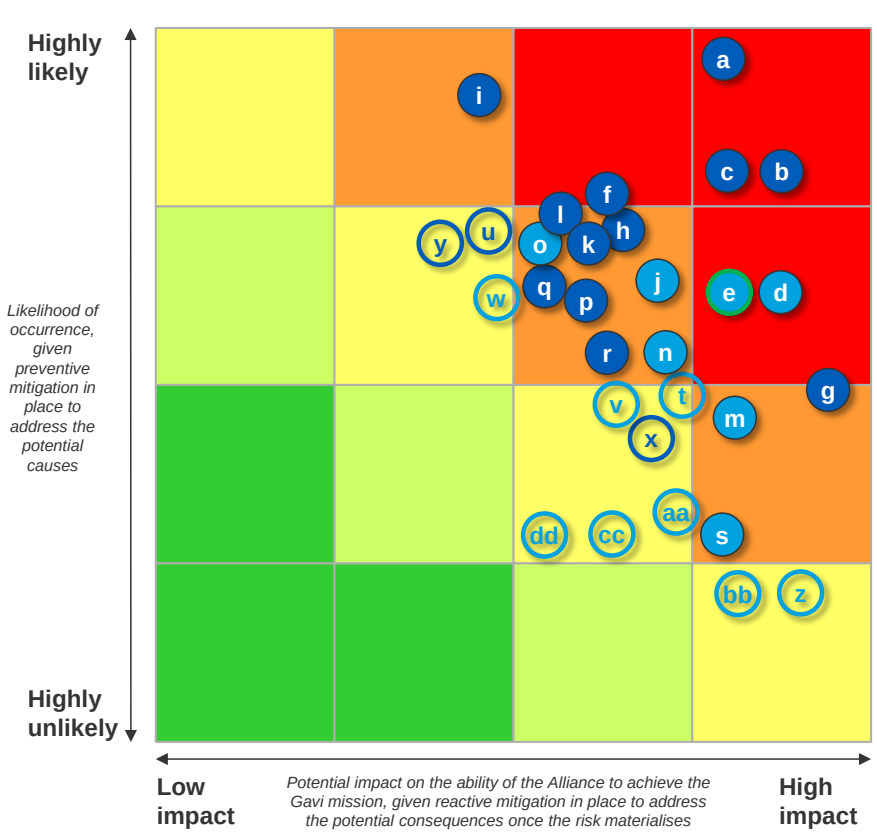
Balanced
- Risks affecting Gavi's image and confidence of its stakeholders

Low appetite
- 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

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

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

2021 residual risk exposure, taking into account existing mitigation



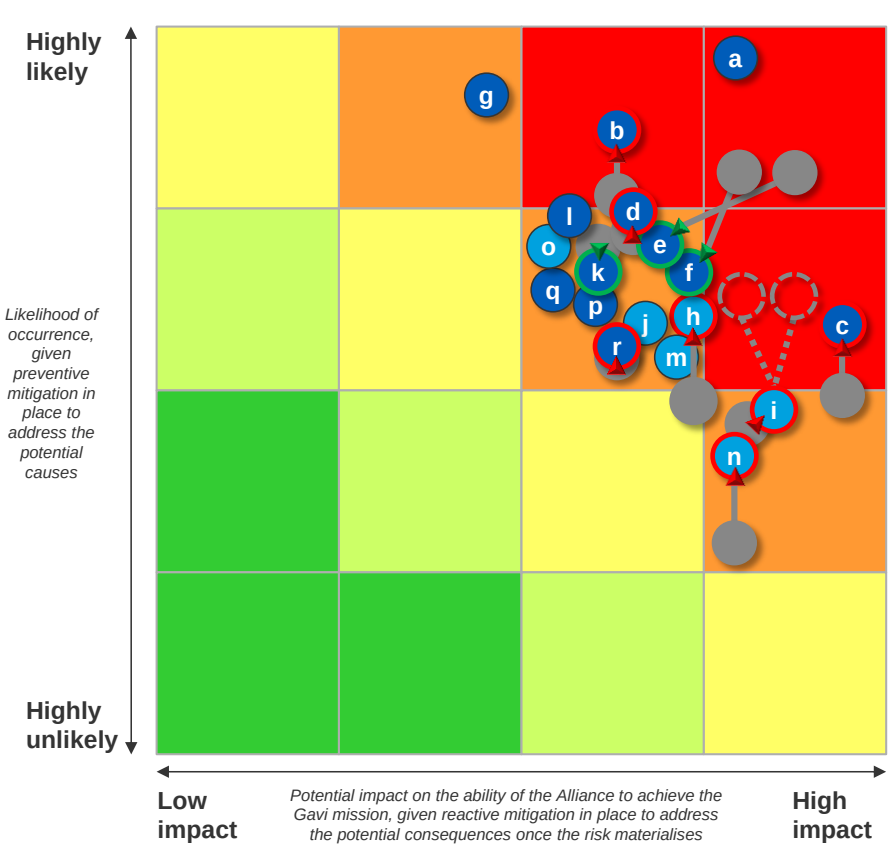
Programmatic risk
Corporate risk

Very high risks
a) Country management capacity
b) COVAX delivery
c) COVAX supply
d) COVAX reputation
e) COVAX Facility
f) Sustainable transition

High risks
g) Insufficient demand
h) VPD outbreaks
i) Misuse by countries
j) Cyber-attack
k) Data on zero-dose
l) Polio disrupting immunisation
m) Secretariat disruption
n) Partner capacity
o) Forecasting variability
p) Sub-optimally planned campaigns
q) Global supply shortages
r) Health systems strengthening
s) Donor support

Medium risks
t) Secretariat capacity
u) External programme disruption
v) Conflicting Board priorities
w) Expanding partnership complexity
x) Unresolved co-financing default
y) Closed vial wastage
z) Board confidence
aa) Misuse by partner
bb) Misuse by Secretariat
cc) Leadership succession
dd) Donor grant fulfilment

Trajectory of the evolved top risks since last year



Programmatic risk
Corporate risk
▲▼ Recent evolution

Very high risks
a) Country management capacity
b) Sustainable transition ▲
c) Insufficient demand ▲

High risks
d) VPD outbreaks ▲
e) COVAX delivery ▼
f) COVAX supply ▼
g) Misuse by countries
h) Secretariat capacity ▲
i) Secretariat disruption ▲
j) Cyber-attack
k) Data on zero-dose ▼
l) Polio immunisation
m) Partner capacity
n) Donor support ▲
o) Forecasting variability
p) Sub-optimally planned campaigns
q) Global supply shortages
r) Health systems strengthening ▲

Annex IV – Individual top risk descriptions

a) Country management capacity

Many countries may lack or have insufficiently resilient 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
a	**Country management capacity** Many countries may lack or have insufficiently resilient 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	⇔	↓

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 or diverted due to instability, shocks or political change (such as devolution), retention challenges and more recently – the COVID-19 pandemic and the roll-out of COVID-19 vaccines. Natural disasters due to climate change are also becoming more frequent with most countries having weak management capacity to respond to emergencies. Furthermore, due to population growth in Africa, increasingly more capacity will be needed to maintain coverage levels in the context of increasing birth cohorts. 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 were impacted during the pandemic, such as country visits and joint appraisals. Nevertheless, country management capacity gaps continued 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, embedded management support, and building effective teams through management training programmes. 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 Health Systems Strengthening (HSS), Equity Accelerator Funding (EAF) and Partners' Engagement Framework (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, countries continue to

have difficulties managing competing priorities. The latest WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) results confirm a continued disruption of Routine Immunisation services (which was less acute but more prolonged than the severe disruption in Q2 2020) due to varying drivers, including health worker strikes, political unrest and conflict, continued measures to control the pandemic and COVID-19 vaccine scale up. The recent institutional capacity survey also suggested a drop in EPI capacity across all Gavi country segments during the pandemic, hindering implementation of activities as well as slowing down country applications to HSS and EAF. There have also been delays in Full Portfolio Planning (FPP) and fewer countries than initially expected have received IRC approval to date. Capacity may continue to be constrained as the delivery of COVID-19 vaccines, climate change-related disasters, and economic and social turmoil continue. Furthermore, most countries do not have contingency plans for natural disasters, outbreaks or other disruptions to immunisation programmes and would need help to plan for possible disruptions, especially in countries that are more prone to such risks. Moreover, increased capacity may be needed to plan and coordinate many catch-up campaigns to restore coverage levels after vaccine introductions and campaigns were suspended during lockdowns, while immunisation is also becoming more complex with additional needs of routinising COVID-19 vaccines, rebooting HPV, and potentially introducing malaria.

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 outside of risk appetite as long as intensive mitigation is still ongoing. To bring this risk within appetite, the Secretariat is actively streamlining processes and adapting funding policies to facilitate access to funding considering limited country bandwidth. The recently concluded "Full Portfolio Planning (FPP) step-back exercise" led to a series of simplifications in application requirements that aim to reduce the average length of the FPP process from nine to 22 months to not more than six months. There will be an intense focus on FPP towards the end of the year with up to 22 countries applying. To achieve more radical improvements in the medium term, the EVOLVE project was launched with an aim to restructure and simplify the grant management process. COVAX TA is used to provide surge capacity – including additional Leadership, Management & Coordination (LMC) capacity – dedicated to COVID-19 vaccine rollout and thereby limiting the disruption on routine work. There is also continued engagement of Ministries of Health to ensure sustained prioritisation of routine immunisation (RI). Country dialogues and advocacy efforts focus on integrated planning for COVID-19 and RI (micro plans, budget, and delivery strategies). Gavi is also operationalising the Fragility, Emergencies and Displaced populations (FED) policy which enables a time-limited fast response to acute emergencies that have a direct impact on a country's immunisation programme, and pose risks to Gavi's gains, finances, and investments. The devastating floods in Pakistan triggered the emergency component of the FED policy, calling on all teams involved in the grant management cycle to expedite, waive some of the normal review policies and exercise a greater risk appetite. For countries in chronic fragility, bespoke flexibilities are being extended to reduce requirements to apply for Gavi support, extend thresholds for HR costs due to dire economic situations, sensitise review bodies on what is "good enough" and simplify Gavi's processes.

b) Sustainable transition

Some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide after transition

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
b	**Sustainable transition** Some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide 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		

Risk description

Gavi support is intended to be time-limited and catalytic. Countries are therefore expected to co-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 backsliding 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. Gavi proactively engages in a dialogue with countries and advocates for timely payment of co-financing, including with partners engagement. 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 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. 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. Countries at greatest risk of backsliding after transition have been identified and the first phase of implementing the Middle-Income Country's (MICs) Approach has started with a focus on mitigating backsliding in former-Gavi countries with a defined theory of change and learning agenda.

Current risk exposure

Current exposure to this risk has increased 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 impact of COVID-19, now combined with high inflation, interest rate rises combined with high debt levels, a rising US dollar, and economic uncertainty related to the Russia-Ukraine crisis, has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' fiscal space for domestic financing, their transition trajectories, and backsliding in already transitioned countries. Whilst all Gavi countries have recorded an increase in debt levels compared to pre-COVID-19, countries in the initial

self-financing phase have recorded a ten-percentage point increase in debt to GDP ratio in only two years from 62% in 2019 to 72% in 2021 due to the economic impact of the pandemic. The risk of co-financing defaults is high with payments for 49% of Gavi-supported countries fully outstanding at the end of August, compared to 35% at the same time in 2019. Of particular concern is the fragile and conflict segment where 8 of 12 countries have yet to meet their co-financing obligations. Countries entering or currently in Accelerated Transition (AT) are facing some unprecedented challenges and transition risks. Their GNI per capita is about a third lower than the 16 countries that have previously transitioned from Gavi support. Moreover, their immunisation coverage rates are lower as well, with some facing backsliding due to the pandemic. Finally, their transition occurs in a period of considerable economic uncertainty, while countries that have already transitioned did so during an economic boom. Risks of backsliding in already transitioned countries are also high. Of the 17 countries that had transitioned as of 2021, seven were able to sustain DTP3 coverage above 90% from 2019 to 2021. Among the remaining ten countries, declines in DTP3 coverage ranged from 2 to 18 pp.

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 very 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. To further mitigate this risk, the Gavi Board agreed that it will be essential to continue to strongly advocate to protect domestic financing for health and immunisation, as well as to ensure global health agencies collaborate further to unlock efficiencies in health spending at country level. Gavi proactively engages in a dialogue with countries to assess the risk of countries not paying their co-financing, supports engagement with Ministries of Finance and partners, and advocates for alternative sources of funding through close collaboration with the World Bank (and is further exploring similar engagement with the IMF). Building on the co-financing flexibilities approved by the Board in June 2022 for countries facing humanitarian crisis or severe fiscal distress, waivers have been requested for Somalia and North-West Syria. Intensive follow-up with governments and development partners is ongoing in the other fragile countries. A specific co-financing approach for the high-cost malaria vaccine has also been designed with financial implications assessed to facilitate uptake. Furthermore, the Funding Policy Review (FPR) will recommend an extension of Accelerated Transition from 5 to 8 years to allow for a more gradual acceleration of co-financing to support countries in addressing financial sustainability challenges due to the impacts of the pandemic, ongoing war in Ukraine, and increasing debt. The Alliance also prioritised support to mitigate the risk of backsliding in four already transitioned countries through the Middle-Income Countries (MICs) Approach. While implementation was slow initially, proposals have now been approved or are in development for all four countries, and the Secretariat continues to actively monitor the situation in other former-Gavi eligible countries to identify where there may be additional need for support.

c) Insufficient demand

Significant drop or insufficient increase in vaccine demand due to hesitancy, gender inequity or other socioeconomic or cultural barriers, or lack of prioritisation

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
c	**Insufficient demand** Significant drop or insufficient increase in vaccine demand due to hesitancy, gender inequity or other socioeconomic or cultural barriers, or 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	VH		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 (e.g., lack of autonomy, access to funds, inability for mothers to engage with male health workers and sexual harassment and gender-based violence against health workers, caregivers and adolescents), other socioeconomic or cultural barriers (e.g., religious norms), lack of awareness or knowledge about immunisation, 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, rude and low-skilled health-workers, 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, demand generation became a priority under Gavi 5.0 given its centrality to reach zero-dose children and missed communities. The Alliance's demand generation framework includes building vaccine confidence and trust as a central component. Recognising the previous lack of standardised and regular data on demand trends in the context of COVID-19, the Alliance is systematically tracking the demand situation with SCMs and Partners and coordinates partner support, including contracting of new CSO partners for trust building and community engagement. A further $16m was provided to UNICEF for intensified support in ~20 countries. have developed survey tools to assess the behavioural and social drivers for vaccination (BeSD), both for childhood vaccination and COVID-19 vaccines, and are working with countries to routinely collect this data. 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. In a number of countries undergoing HSS, TCA and EAF planning, bottom-up programme design is focused on strengthening health systems comprehensively addressing specific barriers which caregivers and communities face, enhancing parents' and communities' service experience, systematically building a cadre of country demand experts at scale, and regular collection of standardised demand data. PEF Strategic Focus Area (SFA) investments are focused on fast tracking country uptake of effective interventions to address gender-related barriers and implementing a learning agenda. Furthermore, a new capacity building initiative has been undertaken in partnership with the Global Women's Institute with two training courses on addressing gender related barriers in immunisation programmes including modules on Sexual Exploitation, Abuse and Sexual Harassment (SEAH). To date 75 staff from the Secretariat and Alliance partners have been trained and the target is to train 150 staff by December 2022. In the context of COVID-19, the Alliance is systematically tracking the demand situation with SCMs and Partners and coordinates partner support, including contracting of new CSO partners for trust building and community engagement. A further $16m was provided to UNICEF for intensified support in ~20 countries.

Current risk exposure

Current exposure to this risk has increased to very high, especially for COVID-19 vaccines as community demand in-country is affected by a changed risk perception due to the milder Omicron variant and vaccine hesitancy in some cases (with currently a downward vaccination trend in many AMC participants), which could lead to in-country vaccine expiries and wastage. Mis- and disinformation about COVID-19 vaccines and vaccination fatigue could potentially also spill over into demand for routine vaccines. The risk also remains 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.

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. To further mitigate this risk, COVID-19 demand will remain a high focus for the COVID-19 Delivery Partnership, including by increasing the engagement of more expanded and local partners to build trust and generate demand.

d) 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
d	**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	↑	↑

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 increasing impacts of malnutrition and conflict, deforestation and urbanisation increasing human exposure to zoonotic disease reservoirs and urbanisation, globalisation, travel and population movement allowing for diseases to circulate

quicker. Climate change may cause mosquitos who transmit diseases to change their geographical footprint and an increase in natural disasters from climate change may create the right conditions for outbreaks more frequently. Furthermore, weak country capacity for surveillance and disease diagnosis, and low routine 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 preventive 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, and facilitates improvement in country diagnostic testing capacity. As part of this, the WHO Eliminating Yellow Fever Epidemics Laboratory Technical Working Group has recently validated two first-line yellow fever antibody tests, which are both faster and less logistically challenging than the current ones. In 2022, such testing provided Kenya with an early warning of yellow fever in an area previously considered to be low risk, allowing rapid containment efforts. More generally, Gavi and the Foundation for Innovative New Diagnostics (FIND) have established a collaborative agreement to improve availability and use of diagnostic tests for diseases with targeted vaccination. Furthermore, outbreak signals are being monitored for timely outbreak response with data on outbreaks incorporated into RI-C19 and country dashboards. Building on experience from measles, draft Standard Operating Procedures (SOPs) have also been developed to flag outbreaks as signals of immunisation gaps. 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 to strengthen immunisation systems. The Fragility, Emergencies and Displaced populations policy provides flexibilities to conduct preventive immunisation for refugees. Among 2021 outbreaks with internationally supported response vaccination campaigns, 27.6% were detected and responded to in a timely manner, a moderate improvement on the 2018-2020 baseline of 25%. However, the proportion of those responses with timely outbreak detection and response varied considerably, from 100% for Ebola to 0% for measles. Consolidated data on timeliness of outbreak response in 2022 are not yet available; however, preliminary data from the first two quarters indicates that countries are experiencing delays in applying for outbreak response support and in implementing the approved campaigns across programmes.

Current risk exposure

Current exposure to this risk has increased, with the overall number of vaccine preventable disease outbreaks prompting internationally supported outbreak response vaccination campaigns in 2022 already exceeding the 2021 numbers, driven primarily by measles and cholera outbreaks. The unprecedented emergency environment of the COVID-19 pandemic has posed a challenge to many countries, leaving Ministry of Health, healthcare workers, communities and partners stretched at central and subnational levels. Countries and Alliance partners dealt with competing health priorities and limited programmatic capacity leading to delays and making microplanning and implementation a challenge, in terms of social mobilisation, supervision, monitoring and follow-up, in particular regarding carrying out Post Campaign Coverage Surveys and reporting. The pandemic has led to declines in routine immunisation coverage in some countries, as well as an increase

in malnutrition, which weakens the immune system and particularly exposes children to measles infection and complications. Since January 2022, WHO has identified 24 large, disruptive measles outbreaks in Gavi-supported countries, often compounded by malnutrition and increased risk of measles-related mortality. To date, eight countries have requested support to the Measles Rubella Initiative for outbreak response campaign (compared to 18 outbreaks and four requests in the whole of 2021). Cholera outbreaks are also on the rise, with 12 requests from seven countries in Asia and Africa submitted so far in 2022 to the ICG for oral cholera vaccine campaigns in response to outbreaks (compared to 10 requests from six countries in 2021) translating to over 18 million doses of OCV shipped in response to outbreaks so far in 2022 (compared to 17 million in all of 2021). The risk of cholera outbreaks is expected to persist in 2023-2025, considering known transmission dynamics from previous pandemic waves and climate-related events such as the floods in Pakistan or the droughts in the Horn of Africa. Furthermore, six yellow fever requests have been submitted in 2022 (compared to 3 in 2021), to support reactive campaigns in Ghana, Chad, Central African Republic, Cameroon and Kenya targeting over 3 million individuals in the first half of 2022.

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. To further mitigate this risk, close monitoring will continue to be needed as well as an assessment of the link between an outbreak occurrence and gaps in routine immunisation to better develop recovery plans that strengthen routine immunisation services and prevent future outbreaks. In addition, a revised PEF TCA grant to support timely ICG applications has been signed with WHO and root-cause analyses are being encouraged, especially when immunisation gaps are likely at the source of outbreaks. Potential further areas for improvement involve the confirmation and reporting of outbreaks, the shipping and clearing of vaccines, and the implementation of vaccination activities once vaccines arrive in countries. Addressing these issues will require stronger collaboration and follow-up across the Alliance and enhanced technical support at country level.

e) 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
e	**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	H		JUST WITHIN		

Risk description

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 country readiness issues, 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 (see top risk *Insufficient demand*). Insufficient absorption can result in idle doses in-country, which represent an opportunity cost globally and

could lead to wastage if these expire (especially in case of short shelf lives). 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, the COVID-19 Vaccine Delivery Partnership (CoVDP) helps to increase vaccination coverage by flagging lagging countries for deep dives to identify and resolve bottlenecks, by enhanced country level intelligence (especially needed to track coverage in high-risk populations and vaccine expiries and wastage), by supporting and monitoring country specific action plans with actionable next steps, owners and timelines, and by coordinating in country and across Alliance partners and other COVAX stakeholders (especially important to reduce transaction costs for countries). Furthermore, insights from monthly reports from Monitoring Agents are being used for course correction. In order to further mitigate the impact on routine immunisation (RI), countries are being supported to do integrated planning of COVID-19 and RI. Countries seem to achieve the most success accelerating their programmes through a combination of political commitment at the highest level, access to timely funding, and activation of national and sub-national partners, including civil society, to drive concentrated COVID-19 vaccination efforts. To further accelerate uptake of COVID-19 vaccines towards reaching national coverage targets and with a renewed focus on high-risk populations, COVID-19 Delivery Support (CDS) funding requests have been approved, funds have been disbursed in a timely manner, and activities are being implemented. After initial early-access and needs-based funding tranches, a third application window of US$ 600 million was launched in July focussing on reaching high-risk populations, achieving country coverage targets and integrating COVID-19 with routine immunisation (RI) and Primary Healthcare (PHC). All partners are supporting COVAX AMC 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 has decreased as AMC countries continue to make good progress with overall population coverage levels increasing, especially amongst lowest coverage countries. As of Sept 2022, 57% of people in all AMC countries have received at least one dose and 50% have completed primary series. Primary series coverage of highest- and high-risk individuals has continued to gradually improve, reaching 63% coverage of older adults and 75% coverage of healthcare workers. However, inequities persist, and coverage is reaching a plateau partly due to the decreasing risk perception in many countries (see top risk *Insufficient demand*), external headwinds and competing priorities. There remain 9 countries below 10% overall population coverage due to fragility and conflict, bureaucratic and logistical constraints, and/or limited health systems capacity to sustain concentrated COVID-19 vaccination efforts. Many of these countries face ongoing humanitarian, conflict, and other crisis situations that severely constrain their ability to prioritise and dedicate resources to COVID-19 vaccination. Across AMC participants, there remain at least 115 million highest-risk individuals that have yet to receive complete primary series vaccinations and there is a need to improve reporting on coverage with booster doses across these population groups. There are also emerging risks with in-country absorption and utilisation of COVID-19 Delivery Support (CDS) funding along the ambitious target timelines originally outlined. CDS Early Access Window funding disbursed in the second half of 2021 remains less than 80% utilised at country-level, with some countries remaining below 50% utilisation. This is mainly due to competing health and other political priorities during the pandemic, overburdened planning and financial management capacities, health workforce constraints, and other external factors. However, as countries will continue to integrate COVID-19 vaccination with their existing immunisation

programmes and primary healthcare systems (shifting away from COVID-19 specific campaign-style delivery approaches), many will continue to require concerted support to achieve this integration.

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 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. Current exposure is therefore just within risk appetite and requires ongoing attention. To further mitigate this risk, the COVAX Facility and the COVID-19 Vaccine Delivery Partnership (CoVDP) will continue to actively monitor and mitigate delivery risks, with a continued focus on reaching the highest-risk populations and through specific programmes targeted at fragility, emergencies, and displaced populations. While accelerating its delivery support until the end of the year, CoVDP is also preparing a transition plan to completely phase out by the end of Q2 2023 as it will set the floor for a full integration of COVID-19 into routine immunisation and primary healthcare.

f) COVAX supply

Significantly reduced and unpredictable COVID-19 supply

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
f	**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	H		JUST WITHIN		

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 can happen 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 continues to work with manufacturers and donors to align the volume and timing of supply to evolving country demand, including for 2023. Substantial progress has been made in negotiations with manufacturers and donors to rephase and reduce incoming supply and the Facility is on track to achieve reductions in its APA supply within the target range of 400-600 million doses. Management of the vaccine portfolio is being undertaken against the backdrop of broader market shifts (e.g., the transition of the main mRNA manufacturers away from production of prototype vaccines and towards variant-containing vaccines (VCVs)) and an increasingly complex demand picture (e.g., primary vs. booster doses, paediatric vs. adult doses, prototype vs. variant-containing vaccines). The COVAX Facility is working with manufacturers and donors to ensure it has access to VCVs if they are approved, recommended, and there is demand from countries. While mRNA variant containing vaccines from Moderna and Pfizer/BioNTech are likely to be first-

to-market, COVAX is in discussions with other manufacturers working on VCVs including those using different technology platforms.

Current risk exposure

Current exposure to this risk has decreased substantially given that most vaccines have been granted regulatory approval, most manufacturers have successfully scaled-up production, export restrictions have eased, and demand for vaccines in HICs has waned. Together with lower-than-expected vaccine candidate attrition and evolved demand due to the Omicron variant, this has led to a current global oversupply situation. Negotiations with manufacturers and donors to rephase and reduce incoming supply has helped to reduce the risk of vaccine expiries, while ensuring that COVAX maintains sufficient volumes (although it may result in a more concentrated vaccine portfolio). While the exact composition of 2023 supply remains subject to change based on several uncertainties, it is anticipated that under WHO's base case scenario COVAX supply volumes will be broadly sufficient to satisfy most demand in 2023. In general, uncertainties persist around future demand (e.g., potential new waves and variants; evolving coverage targets; and policy recommendations on boosters and paediatric doses) as well as future supply (e.g., level of non-COVAX supply and new dose donations; the effect of domestic manufacturing efforts; vaccine market developments and changes in manufacturer confidence; and access to next generation and new variant-adapted vaccines). Specifically, five key uncertainties continue to influence COVAX's 2023 supply portfolio: (i) remaining 2022 demand above existing allocations which will affect remaining COVAX supply available at the beginning of 2023; (ii) outcomes of renegotiations which are seeking to reduce and rephase existing supply; (iii) availability of, and access to, variant-containing vaccines (VCVs) through APAs and donations in the event they are recommended by SAGE and approved by WHO; (iv) whether and when VCVs could be indicated for primary series use which will affect the need to maintain other vaccines suitable for this use; and (v) risks to demand for prototype vaccines in the current portfolio in the event that countries decide to wait for access to VCVs. As manufacturers now transition production from prototype vaccines to VCVs, the COVAX Facility currently has very little supply of mRNA prototype vaccines for use in 2023. It is expected that VCVs will initially be approved for booster use only and the COVAX Facility likely will initially fulfil primary series demand in 2023 through its supply of non-mRNA vaccines. It is also important to underline that the supply risk can quickly increase again in case of a resurgence of the pandemic (e.g., due to waning immunity) or the emergence of a new virus variant requiring COVAX to compete again for places in the queue with manufacturers. The current low demand may also have implications on the ability to secure volumes (through contracts and donations) and have implications on AMC funding. Furthermore, the current economic environment may limit availability of funds going forward, in particular to acquire variant adapted vaccines. However, there is donor commitment to share doses early when needed, renegotiations with manufacturers may release funds, and the Facility may draw on the Pandemic Vaccine Pool for contingent funding in case of a shock.

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 just within risk appetite and requires ongoing attention. To further mitigate this risk, the COVAX Facility continues to closely monitor the scientific developments and the supply and demand landscape. It remains important to maintain a diversified portfolio, but when the supply situation remains healthy 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. Despite high levels of uncertainty persisting across multiple dimensions including disease trajectory, optimal vaccination strategies, vaccine effectiveness, and demand, COVAX is planning for a 2023 strategy

based on WHO's base case scenario. This scenario foresees that periodic boosting for high priority populations may be required, resulting in an ongoing need for vaccines although most likely on a smaller scale than in the first two years of the pandemic. Therefore, COVAX aims to continue supporting AMC participants to meet their ambitions with a particular emphasis on expanding protection for higher risk populations including with boosters and in line with the evolving product landscape. In preparation for 2024 and a more routine COVID-19 programme, pending Board approval, COVAX will also continue to transition towards established Alliance structures while retaining capacity to respond to the WHO worst-case scenario through the Pandemic Vaccine Pool and enhancing preparedness for future pandemics (as part of the transition to Gavi 5.1). If variant-containing vaccines (VCVs) are approved by WHO and are recommended by SAGE for use, COVAX will seek to provide them in line with country demand. If there are initial supply constraints COVAX would first provide VCVs to the highest priority user group to have the greatest impact against severe disease and death. As more data emerges about VCVs, COVAX will continue to assess their role in an optimal vaccination strategy. In this context, the Pandemic Vaccine Pool (PVP) provides the financial flexibility to procure additional VCVs if needed, including in case of a resurgence of COVID-19.

g) 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
g	**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		

Risk description

Gavi, in line with the Paris declaration on aid effectiveness, 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 programme design, poor governance and management, and / or prevailing corruption, and this exposes the Alliance to the risk of its support being misappropriated or inadequately accounted for with unsupported or ineligible expenditures (deliberately as well as by mistake). This is compounded by the fact that it is hard for countries to deal with a significant influx of fragmented donor funds that often come with differing and complex requirements, as well as with a lack of predictability not necessarily aligned with country budget cycles. 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, 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 where zero-dose children are. 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 by the state (even if monies have been misused by individuals) from an already tight budget ("reverse aid"), undermining their programmes, and creating significant transaction costs to manage that support and address fiduciary risks going forward. 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 with weak

oversight, 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 differentiated grant oversight by Senior Country Managers with strengthened oversight in country segments at higher risk of misuse, and with support by a specialist Portfolio Financial Management (PFM) team engaging with countries to resolve fiduciary risk challenges and improve budgeting, accounting, reporting and oversight. Country cash usage is monitored and cash balances in-country are reviewed when making disbursement decisions, and disbursements are made against budgets for the following period. Budgets are being reviewed against guidelines that distinguish between eligible and ineligible costs. There is an annual compliance review on country reporting and SCMs are following up with non-compliant countries. Countries have also benefited from a Programme Capacity Assessment (PCA) intended to assess a country's capacity to manage support which, together with other information (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. PCA and audit findings furthermore inform 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 Inter-Agency Coordinating Committee. 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. Following the Board's guidance to accelerate movement of funds back to government systems while at the same time keeping fiduciary risk at an acceptable level, additional financial management capacity building has been provided and assurance measures rolled out to manage fiduciary risks. With an aim to achieve an average of 55% through hybrid and government systems by the end of Gavi 5.0 (with the rest channelled through partners), currently 37% of funds are being channelled through government systems, well on track to achieve the target. Programme Audits by Gavi are conducted periodically with higher risk programmes being covered more frequently. As second time audits are now being undertaken in a number of programmes, it has been observed (from the small number of second-time audits conducted so far) that some enhancements can be seen to have been made in some instances whilst elsewhere little progress has been made. This underlines the need for more robust follow-up on the remediation of issues arising from Programme Audits. Gavi also has an anonymous and confidential whistle-blower hotline to which anyone can report suspected wrongdoings and has a fraud investigator to follow up on suspected cases. In case of actual identified misuse, Gavi will always require reimbursement as a condition of continued support (to date close to 93% payments have been received against scheduled reimbursement for misuse found by Programme Audits). Counter-fraud activity has continued through ongoing engagement with industry and others in the international sector on diverted and counterfeit vaccines, and participation in the multi-agency working group on medical product security which is exploring a global track-and trace facility for COVID-19 and other vaccines/medical products. In addition, a counter-fraud framework has been developed and issued and is being used to form the basis of a fraud risk assessment methodology to be trialled in-country. During

the COVID-19 crisis, Gavi-funded assurance providers have been adapting their procedures through remote working options and virtual solutions. Furthermore, some de-risking of programmes has been taking place by curtailing risky activities or moving them to lower risk implementers. The Secretariat has also invested in obtaining assurance over a wide spread of risks, including supply chain, programmatic and fiduciary risk in COVAX AMC-eligible economies through increased use of monitoring agents (MAs) in high-risk COVAX AMC countries. 27 higher risk countries are now covered by 11 different MA firms, which covers roughly half of the COVAX vaccine investment by dosage.

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. Countries have been under pressure during a health emergency to spend faster, and to set aside their usual processes for emergency procurements, while at the same time, travel restrictions impaired 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, and at the explicit request of the Board to provide funds on a 'no-regrets' basis, Gavi is making funds available with less up-front due diligence (however mitigated by post facto assurance mechanisms).

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 and economic context and the ability to mitigate and obtain assurance has been 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 identified misuse, Gavi will always require reimbursement as a condition of continued support. Current exposure is therefore just within risk appetite and requires ongoing attention. To further mitigate this risk, working relationships with other non-traditional partners are deepened to improve capacities, e.g., Supreme Audit Institutions (SAIs), INTOSAI Development Initiative, Ministries of Health Internal Audit Departments and the International Federation of Accountants (IFAC). The PFM team will also review all disbursements >$1m, including with reference to cash in country, and review the general norms for operational costs for campaigns and make sure to have exceptional flexibilities for some settings while checking country by country for justifications. Gavi will continue to ensure that all risk assurance actors, particularly those funded by Gavi directly, are fully able to perform their tasks, including through an extension of scope to new funding streams and potentially higher risks, and will strengthen oversight by a programme of quality assurance. The results of specific COVAX Monitoring Agents will be closely monitored and reported on throughout the year. The model will be evaluated to assess the potential for application of this approach to Gavi's broader assurance model. Audit and Investigations will continue to conduct misuse investigations where warranted and deliver country fraud risk assessments.

h) Secretariat capacity

Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
h	**Secretariat capacity** Secretariat capacity, capabilities and processes may be inadequate to deliver on the new strategy	• Increased volume and complexity of work • Lean operating model no longer fit for evolved mandate • Insufficient people, headcount ceiling • Insufficient/inadequate skills and competencies • Inability to adapt processes, systems and culture	H		JUST WITHIN		

Risk description

Gavi has a lean and distributed operating model, being an Alliance with a small Secretariat without in-country presence and depending on many partners for technical assistance and implementing countries to own delivery and sustainability of immunisation programmes. Secretariat efforts and the funding it provides is aimed to be catalytic and by design relies on others to complement and adopt activities and objectives. Since the inception of Gavi in 2000, this model of a lean Secretariat has been very efficient to foster the spirit of partner reliance and to allow for quick decision-making. It has also been effective at a time when Gavi's business was still relatively simple focussing on pooling demand and introducing new vaccines, and leveraging the proven competencies of existing Alliance partners in these areas. Over the years however, Gavi's programmes have grown substantially, increasing the complexity of grant management and Secretariat operations. Furthermore, donors increasingly realised that an overly "light-touch" model may not provide sufficient assurance and accountability and have gradually tasked the Secretariat with more oversight responsibilities, requiring greater involvement in and understanding of in-country programmes and partner performance. Moreover, Gavi's strategy has shifted from national vaccine introductions to more complex sustainable coverage and equity objectives and more recently to reaching zero-dose children and missed communities in hard-to-reach areas. The work of the COVAX Facility (and its integration into Gavi core) adds another significant level of complexity, with unique activities around securing supply and matching it with still uncertain demand and an aim to get vaccines in arms quickly rather than the traditional Gavi longer-term focus on sustainable development. There is therefore a risk that Gavi's current operating model (designed to fit its original more simple business activities with high reliance on Alliance partners), including competencies, processes and resourcing across the Alliance, will not be fit for delivering on its new strategy, as this requires more differentiated and tailored approaches at the subnational level, strengthened accountability of Alliance partners as well as direct contracting and more hands-on management of many new unproven partners, greater country capacity-building, more coordination and collaboration with other health actors as part of integrated delivery and multisectoral approaches, the ability to respond quickly in fragile environments and emergencies, and potentially continued COVID-19 vaccine procurement and delivery and pandemic preparedness. These all have the potential to significantly increase transaction costs and workload and may require different competencies and expertise.

Existing mitigation

To manage this risk, the Secretariat has partly rolled out a new organisational structure recommended through the organisational review, however this was based on a pre-pandemic assessment and did not take some functions and consultants into account and may therefore not alleviate capacity constraints sufficiently. A Chief Operating Officer (COO) has been appointed, which is a new role aimed at enhancing Gavi's operational excellence and it will play a central role in the optimisation of organisational design, structure, culture, business processes, and operational effectiveness. Furthermore, a multi-year EVOLVE programme has been launched to engineer simpler and integrated country programme portfolio management processes and improve grant application, approval, and disbursement processes, programmatic and financial performance reporting and monitoring, data quality for decision-making and collaborative technology systems between secretariat, countries, and partners. Project teams and dedicated Business Transformation Senior Managers have been appointed and a Steerco has been established to review scope and milestones, communication and the change strategy for the programme. The team has started mapping out the grant management process as it

is currently to have a clear view of each step and identify the pain points. Furthermore, a Programme Support Team (PST) has been established within the Country Programmes department to strengthen and support grant management and contracting processes to promote efficiency and end-to-end coordination within the Secretariat.

Current risk exposure

Current exposure to this risk is increasing with a heightened workload across the Secretariat to respond to the COVID-19 impact on routine immunisation, to accelerate the zero-dose agenda, and to continue to support the delivery of COVID-19 vaccines and integration of the COVAX Facility into Gavi core. A proper root cause analysis of what is driving workload and a method for prioritisation is however lacking. The employee pulse survey showed that wellbeing is the lowest scoring category (see also top risk *Secretariat disruption* for risks of staff disengagement and low morale) with 67% of respondents saying that staff is insufficient for the workload. Training budgets remain also underutilised. While the current pandemic evolution justifies resizing and integration of the COVAX Facility into Gavi core, multiple challenges remain for the COVAX Facility with still high transaction costs (e.g., resizing/rephasing negotiations, SFP and cost share close outs, 2023 planning, integration, COVID-19 Delivery Support, and audits and evaluations) and the design and strategy of the Facility needs to continue to adapt to the evolving pandemic and global strategy to remain fit for purpose. There are also new ideas and initiatives being explored with potentially significant operational implications for the Secretariat such as supporting regional manufacturing and pandemic preparedness and ongoing innovative financing mechanisms that need to be serviced and operationalised by support teams in the Secretariat. Gavi's current systems have become complex with laboursome processes and approvals combined with multiple funding levers and funding buckets and not always clear roles and responsibilities. Existing pressure on keeping resourcing within a headcount ceiling as well as trying to reduce the number of consultants has led to resourcing decisions that are not necessarily informed by a strategic approach to workforce planning aimed at ensuring quality of services, fit for the organisation and sustainability. The rapid growth of the Secretariat did also not allow its processes and operational support functions to evolve with it and siloes and ineffective practices have crept into the work.

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. Current exposure is therefore just within risk appetite and requires ongoing attention. To further mitigate this risk, the Secretariat will work on its processes and policies, to ensure faster, simpler and more flexible funding by operationalising FED flexibilities for fragile countries and making improvements in Gavi's end-to-end processes with the multi-year EVOLVE programme and a continuous improvement approach for SAP optimisation. The Chief Operating Officer (COO) is exploring costs, benefits and timelines of an approach to Operational Excellence (OE) structured around 5I's: Innovate (e.g., with EVOLVE), Integrate (e.g., COVAX integration), Improve (simplification focused on efficiency and effectiveness), Invigorate (the Gavi culture), and Inform (change management and communication). An Enterprise Project Management Office (EPMO) will support OE across the organisation with clear governance and accountability and will set up a balanced scorecard. It will also be fundamental to get a common understanding of current and required resourcing levels, covering permanent headcount, long-term consultants, surge/project consultants and COVAX temporary staff and consultants.

i) Secretariat disruption

Significant disruption of Secretariat operations

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
i	**Secretariat disruption** Significant disruption of Secretariat operations	• Catastrophic event impacting facilities and operations • Mental health issues, burn-out and staff disengagement due to pandemic and stretched Secretariat capacity • Misconduct or reputational attack/backlash • Leadership transition and succession issues • Departures of key staff with critical knowledge • Incident or loss of life in the workplace or during travel	H		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, the departure or disengagement of a large number of key staff, major misconduct by staff, or a reputational backlash. The Secretariat is located in a place with limited exposure to natural disasters and terrorism, however staff are 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 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 training based on the Respectful Behaviour Policy to protect a culture of tolerance and respect, including training on ethical behaviour on Gavi missions. The HR, Communications and Operations teams continue to engage staff on wellbeing. The Health & Wellbeing Committee is planning to roll out initiatives to better understand root causes (by engaging an external expert), to provide additional support to staff, and to prevent issues (i.e., burn-out, increasing stress levels) with a focus on reducing stigma, health promotion, respectful behaviour and onboarding; however, there is currently no dedicated staffing for this committee. Health insurance coverage for mental health costs has been increased considerably. HR also continues to support Team Health discussions as part of Team Performance management conversations. To retain high-performing staff, long-term roles are offered to temporary COVAX Facility staff when possible and internal movement is promoted. 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, and radio breakfast shows. A Ways of Working project has redefined the role of the office now 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 and a new Incident Response Policy and preparedness plans are being developed based on learnings from 2020 and the 2021 internal audit on crisis management. Furthermore, a proactive media and communications strategy has been implemented that supports the achievements of COVAX and its legacy. There is strong global media monitoring as well as participation in internal discussion to ensure emerging reputational risks can be assessed quickly and effectively. This has helped mainstream and de-sensationalise an otherwise potentially key reputational risk related to COVID-19 vaccine expiries by transparently managing expectations that supply-demand mismatches and expiries will happen and that this is a risk that was accepted as necessary to take in order to

fight the pandemic (which required upfront procurement at risk while demand was still unknown and continued to evolve with the pandemic).

Current risk exposure

Current exposure to this risk is increasing with staff mental health and staff engagement under continued pressure due to ongoing uncertainty in the external environment (with threats of an escalating war, a cost-of-living crisis and a global recession) as well as a high rate of internal change due to process optimisation and integration of COVAX Facility and Gavi core processes and multiple leadership transitions (with the current Chief Executive Officer completing his term of appointment in 2023, the Deputy CEO having retired, a new Chief Operating Officer having joined, and a Chief Programme Strategy Officer appointed). Staff also still suffers from the after-effects of the pandemic but continues to face a heightened workload across the Secretariat due to resourcing constraints (reflected in the top risk *Secretariat capacity*). The employee pulse survey showed that wellbeing is the lowest scoring category. There are high levels of unpaid leave requests and sick leave has also been increasing. While overall turnover still appears to be reasonable, there are staff retention risks going forward, especially given the current tight labour market and the fact that there is high reliance on key persons in various areas without succession planning. The current uncertainty around the future of the pandemic and related vaccination requirements also poses risks to COVAX Facility staff morale, recruitment and retention of high-performing staff, and succession and knowledge management. Internal disruption, including both turnover and intra-organisational movements remain a concern within the COVAX Facility. With COVAX Facility staff on short-term contracts (to retain necessary flexibility in the Secretariat), key personnel have already been leaving due to the lack of security and finding a permanent job elsewhere, with implications on Secretariat capacity to deliver and staff workloads. Further disruption could also still occur if the virus would resurge, and capacity cannot catch up again soon enough. Finally, with travel now resuming, travel to high-risk countries has increased fourfold, especially as Gavi is using more (local) partners in fragile and conflict areas.

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. Gavi's reputation is also critical to its ability to deliver on the mission, and the Alliance has a in general a low appetite for risks affecting its image and confidence of its stakeholders, including its governance bodies. Current exposure is therefore just within risk appetite and requires ongoing attention. To further mitigate this risk, the Secretariat's Crisis Management team continues to monitor the evolution of the pandemic as well as potential new developments related to the Ukraine-Russia conflict and the energy crisis and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. The new Chief Operating Officer's (COO) number one focus will be on people and invigorating Gavi's culture, focused on an engaged and motivated workforce based on Gavi values, leadership competencies, Diversity, Equity and Inclusion, and the Code of Conduct. Additional Secretariat resources requested from the Gavi Alliance Board and a rigorous focus on staff wellbeing would also improve conditions. Gavi is also working on making enhancements to the recruitment process with stronger checks in place to ensure that Gavi does not recruit individuals with a proven history of misconduct or inappropriate behaviour and is putting together a plan to regularly remind the workforce of being vigilant about their own behaviour as well as intervening when required when they witness inappropriate behaviour. Furthermore, HR is developing a new employee performance appraisal process with a clear development focus. The onboarding process for new hires is also being reviewed and more training will be available for managers to manage as a coach.

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
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		

Risk description

The Secretariat increasingly makes use of IT systems, software applications 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 or confidential 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. A risk analysis has started with main suppliers to review their security controls and create a business continuity plan for their services. 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. 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. Business continuity and IT disaster recovery plans have been created based on a business impact analysis of IT systems' unavailability on Gavi's operations. Incident response documents have been developed to cover various scenarios, integrated with Gavi crisis management, and a CSIRT team has been formed with clear roles and responsibilities, formalising Cyber Incident Response with internal and external stakeholders. Processes have been put in place for early detection of malware and account compromise, e-mail quarantine, 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.

Current risk exposure

Current exposure to this risk remains high. 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. The Russia-Ukraine conflict has also identified new exploits and threat vectors. 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. Furthermore, although a mandatory training completed in Q4 2021 included a module on phishing, the May 2022 phishing campaign resulted in 31% of users failing to spot a phish, up from 14% prior campaigns, requiring reinforcement of user awareness activities. Mandatory phishing training has been re-assigned to all staff followed by a second phishing campaign in August 2022 resulting in a 5% click rate. Significant improvements have been observed in user capabilities to report phishing (from 8% in May to 25% by August).

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 Secretariat seeks to maintain robust processes and management, and reliable and secure systems, to prevent interruption of core systems and business-critical operations. The current exposure is therefore just within appetite and requires ongoing attention. To further mitigate this risk, additional security enhancements continue to be delivered as part of the Cybersecurity programme, overseen by a Cybersecurity Steering Committee. This includes an ISO27001 ISMS implementation, a zero-trust architecture implementation, audit finding remediation, security drills and penetration tests, a user awareness programme, harmonisation of cybersecurity tools and threat intelligence. Incident response preparedness will be assessed through a Ransomware simulation exercise planned in October 2022. To reinforce user awareness, two security awareness training refresher courses are being assigned to users who have fallen into the phishing lure. With already many Internal Audit findings closed, the remaining 32 Cyber security internal audit findings are on track to be closed by the end of Q4 2022.

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	H		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 some information on the distribution and concentration of zero-dose children, but insufficient information on the root causes for missed immunisation 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. Standardised zero-dose geospatial analyses have now been provided to country teams for all countries with further analyses for priority countries. Pro-equity mapping has been completed with results presented to key stakeholders. Technical Assistance (TA) support has been deployed in ~25 countries to date with another 15 in the pipeline to identify zero-dose children and missed communities and prepare robust equity plans. Robust zero-dose identification was also a requirement for access to Equity Accelerator Funding (EAF). A global learning partner helps identifying and disseminating 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. A partner has been contracted for zero-dose case studies and inception phase underway. 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 mitigation actions with zero-dose identification efforts happening at scale across countries. The hypothesis that zero-dose children are clustered in pockets and can be targeted sub-nationally has also now been tested by quantifying the degree of concentration for each country. It is estimated that around 43% of zero-dose children live in conflict, remote rural or conflict settings, and an estimate exists for each country, confirming that they are concentrated to some extent. However, it remains an important risk fundamental to the Gavi mission. Analysis of data needs required in Gavi 5.0 had identified significant gaps in the data required for identification of missed communities and current efforts still need to be proven to be adequate. Diverted EPI and Alliance capacity due to COVID-19 have slowed down work on zero-dose implementation of HSS and the new EAF at country level. The shift from using data to measure coverage post-facto in Gavi 4.0 to needing to use (different types of) data ex-ante to target interventions in Gavi 5.0 requires more granular, sub-national, geospatial and qualitative data, including on information on the root causes for missed immunisation. It also requires timely data, which can be a challenge if data collection is lagged.

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. To further mitigate this risk, 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, data triangulation 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 with complementary support to countries to triangulate their data and improve their reported official coverage estimates through the Measurement & Learning Strategic Focus Area. 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 immunisation

Polio resurgence or a ramp-down after eradication adversely affecting routine immunisation

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
I	**Polio immunisation** Polio resurgence or a ramp-down after eradication adversely affecting 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	⟺	⟺

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 sometimes 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 the ongoing circulation in Pakistan and Afghanistan and recent importation from Pakistan to South-eastern Africa in end of 2021. 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 routine IPV coverage leading to reduced immunity especially against type 2 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) and the reduction in preventive campaigns. 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 as a member of GPEI) 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, coordination between GPEI and Gavi at the country level is happening on how to support improved integration of polio and routine immunisation including through the Full Portfolio Planning (FPP) process. This helps to ensure alignment on near-term immunisation strengthening activities and longer-term Gavi investments as a way to help pave the way towards a successful transition. However, coordinated planning and communication between National EOCs, polio partners and Gavi should be further improved. Through targeted HSIS and PEF TCA funding, Gavi and GPEI are supporting immunisation strengthening and coverage and equity improvements of polio and routine EPI vaccines including in polio consequential geographies.

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. Following a significant reduction in WPV1 cases in Pakistan and Afghanistan in 2020-2021, an intense outbreak of WPV1 is ongoing in southern Khyber Pakhtunkhwa, Pakistan and has been detected in the traditional reservoir of Karachi. Additionally, an importation of WPV1 from Pakistan to Malawi was detected in February 2022, the first case of wild poliovirus since the region was certified polio-free. A multi-country regional response to this outbreak has been effective so far with no additional cases detected. However, the threat remains that the virus may be circulating elsewhere undetected. In addition to WPV circulation, more than 500 cases of circulating vaccine-derived poliovirus have been detected in the past 12 months across 17 African countries, Afghanistan, Pakistan, Ukraine, Yemen, Israel, UK and USA. In June 2022, the WHO concluded that the risk of international spread of poliovirus continues to be a public health emergency of international concern (PHEIC), and its eradication would create a global public good. 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, given the co-circulation of cVDPV1, 2 and WPV1, the choice of which vaccine to use remains a challenge for the programme and for polio outbreak response.

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. To further mitigate this risk, 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. 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). Gavi and the Global Polio Eradication Initiative (GPEI) are working closely together in priority countries to ensure that resources and interventions to address these outbreaks are leveraged to also identify and reach zero-dose children and communities with multiple interventions through integrated immunisation activities.

m) 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
m	**Partner capacity** Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	• Right partners unavailable / unable to access Gavi funding • Lack of capacity / relevant expertise for new strategy • Lack of alignment and coordination across partners • Inability to manage accountability and performance	H		JUST WITHIN	⟺	↓

Risk description

Alliance core and expanded partners, including civil society organisations (CSOs), 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, providing technical and capacity-building support to countries, complement on-the-ground activities, and advocate for financial sustainability and domestic funding. Partners' collective capacity to provide the full range of support which countries require is therefore critical. The ambitious goals of the current strategy to reach zero-dose children and missed communities 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 and support 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 Health Systems Strengthening (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. At country-level, the new Civil Society and Community Engagement (CSCE) approach aims to commit at least 10% of Gavi funding across all funding levers to civil society partners. This broader engagement will however also come with increased complexity of programmes and of contracting and managing new, untested partners at country level. If not well managed by the Secretariat, this could undermine accountability and transparency within and between the Secretariat, Alliance partners and implementing countries, and affect relationships and Gavi's reputation.

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) and has brought on board ~70 expanded partners since 2016 (including CSOs and local partners), bringing new areas of comparative advantage. It has focussed on delivering more partner capacity directly to countries (including technical support provided at subnational level), and further enhanced the effectiveness, efficiency and transparency of collaboration with core partners. MoUs have been signed in 2021 with seven humanitarian organisations which now start to translate into country-level collaboration. For example, Gavi is now working with the International Organisation for Migration (IOM) in various countries to reach mobile populations. US$ 100 million of Equity Accelerator Funding (EAF) has been allocated to new multi-country partnerships to reach zero-dose children and missed communities in

fragile, conflict and cross-border settings outside government reach. This Zero-Dose Immunization Programme (ZIP) initiative is managed by two consortia under the leadership of World Vision in the Sahel and the International Rescue Committee (IRC) in the Horn of Africa to find and serve missed communities. An MoU is currently being negotiated with the African Union and the African CDC that includes areas such as country engagement, advance Zero Dose policies, operationalising on vaccine manufacturing and regulatory aspects. Legal agreements have been developed and negotiated with World Vision and IRC and template agreements are finalised with IoM, UNICEF and expanded partners. In order to build momentum and cohesion across the Alliance, a cross-Alliance Community of Practice (COP) on the zero-dose agenda has been established. There is also proactive engagement with countries to work with a diversified set of context-appropriate partnerships in line with the aim of up to 30% of TCA to be used to engage and build capacity of local partners with a focus on the zero-dose agenda. Partnerships with PMNCH, the CORE group, IVAC and AMREF are being implemented and partnership work with IPU is advancing. Humanitarian partners, IA2030 network, and SDG3 GAP agencies are leveraged to position Gavi's vaccine equity agenda. Priorities and deliverables of the Gavi CSO Steering Committee have been developed for 2022/2023. Furthermore, 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. The new Partnerships Team (PT) was set up in 2021 as an evolution of the PEF Management Team, providing oversight of PEF at country, regional and global levels. It provides strategic guidance on how to best leverage partners in support of Gavi 5.0 priorities, makes recommendations on allocation of funding within Board-approved PEF envelopes for Foundational Support (FS), SFA (Special Focus Areas) and the TCA reserve and reviews Partner performance to ensure investments are on track to deliver intended impact. To support the PT in conducting their performance management function, a results framework has been developed for FS and SFA to compliment the TCA milestone reporting. These will be assessed as per the performance management approach for Gavi 5.0, for FS and SFA, approved earlier this year. Furthermore, the Alliance has actively been mitigating the risk that COVAX could 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 as Gavi is still developing the tools in collaboration with the CSO constituency to find the right local partners, and CSOs and local partners may not always be able to access Gavi funding as existing processes and systems for accessing funding and reporting are complex and developed for a different set of partners (EAF applications were impacted by delays in the selection and contracting of expanded partners). Existing partner organisations may also still be disrupted by the pandemic and focused on delivery of COVID-19 vaccines, with potential risks around changing their traditional technical assistance (TA) approaches in line with the strategic shift to reach zero-dose children. New local partners may also not always be empowered to participate in government level discussions and planning of immunisation services, including in Full Portfolio Planning (FPP) processes. When selecting new untested partners, there may also be risks related to quality of services, financial viability, conflicts of interest, money laundering and terrorist financing, and longer-term sustainability of the impact of activities in-country. Furthermore, accountability and performance, coordination and measurability of cross-cutting TA priorities like equity are more complex to manage in a broader partnership 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. It also comes with increased transaction costs to design programmes (including deliverables, milestones, reporting obligations and payment schedules) and to contract and manage multiple new partners, identifying and incorporating partners into activities and budgets at country level, and in many

cases reshaping internal processes to accommodate local institutions. Political, relationship and reputational risks may also intensify as the partnership evolves, with varying potentially conflicting interests from different types of partners positioning themselves or asserting new demands on Gavi, which could affect the strength of the Alliance and strain intra-Alliance relationships.

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 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 however 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. To further mitigate this risk, Gavi continues to ensure that the right partners work at the right level with the right capacity and performance. 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. The Secretariat will also continue to implement the CSCE approach through targeted efforts to ensure and track inclusion of CSOs and local partners in country dialogues and planning processes preceding submission of funding applications; strengthened and adapted mechanisms to select and engage CSOs and local partners; strengthened tracking of funding reaching CSOs and local partners; and establishment of a cross-departmental taskforce, which will dedicate internal resources to focus on Local Partner/CSO engagement in a holistic way. With the help of the catalytic CSCE Strategic Initiative funding, Gavi is aiming to tailor Gavi processes to the needs of CSOs and local partners and strengthen impact at the local and community level.

n) Donor support

Significant reduction in donor support to Gavi

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
n	**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		

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 international cooperation and aid (such as the war in Ukraine, food crisis, declining interest for the global health agenda and Covid-19) 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 limit Gavi's capacity to maintain reactive capacities in case of a resurgence of the pandemic. It could also prevent the Board from opening support windows for new initiatives and vaccines. Reduced donor support would likely also increase the effort and cost of mobilising resources and servicing donors.

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 drew 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 (donors have committed to donate a doses), cost sharing (doses have been purchased by countries through their own resources, including supported by MDBs), EIB and IFFIm frontloading of donor pledges and country cost sharing financing, and private sector funding and delivery support.

Current risk exposure

Current exposure to this risk is increasing despite a strong track record in raising funds so far and having been able to secure sufficient pledges for the COVAX AMC. The pandemic clearly highlighted routine immunisation and pandemic preparedness and response as global priorities and significant donor support represented a huge vote of confidence in Gavi, Alliance partners and the collective mission. However, the ongoing geopolitical developments and the conflict in Ukraine risk drawing donor attention and funding away from global health and development due to competing priorities. Furthermore, significant financial and economic uncertainty in many donor countries, with inflation and rising interest rates potentially resulting in a cost-of-living crisis and a global recession, may constrain donor country budgets going forward, and popular discontent can contribute to a further rise in political parties opposing development aid winning elections. It is therefore needed to remain vigilant and continue to transform pledges into full financial contributions, hedged against a rising US dollar. For Gavi core, 72% of pledged amounts (volume) are signed, 23% are signed on an annual basis and 5% remain to be signed. For COVAX AMC, 84% of the pledges (in volume of US$) are signed. It also remains important to further solidify and broaden donor support for Gavi, with opportunities to showcase Gavi's achievements and successes through the ongoing COVAX evaluations and the upcoming Mid-Term Review (MTR) and donor assessments such as MOPAN. Gavi donors have doubled compared to the past, adding to the challenge of servicing them and ensuring that they are briefed, brought to the table, and understand progress and achievements. Relationships with existing donors have also shifted, with immunisation and health security now being high priorities for important donors, who are now both more keen and more impatient at seeing results.

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 showcase Gavi's results and relevance.

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
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	⟺	⟺

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 loss of stakeholder confidence and 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 SAP, and additional steps are being taken to improve processes and reporting solutions externally with partners and countries. The annual renewals 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 with key business stakeholders before Senior Management endorsement, 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 sensitise audiences to the substantial degree of uncertainty in the forecasts. HSS and Cold Chain Equipment (CCE) forecasting has also been strengthened with country level forecasts proposed by Senior Country Managers and reviewed and challenged by Country Support Segment Directors and Portfolio Financial Management before endorsement by Senior Management. 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. Gavi's expenditure is principally in US dollars and to provide predictability of funding available for Gavi's 5.0 strategic period, Gavi applies currency hedging to provide certainty of funding and reduce the volatility in the US dollar value of future net cash inflows due to exchange rate fluctuations. 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, the Russia-Ukraine crisis and increasing inflation and interest rates creating a higher risk of variability as compared to previously. Programmatic delays could occur given ambitious plans in uncertain times, or resilience and pandemic-recovery could turn out stronger than anticipated – both possibilities potentially affecting forecasted disbursement levels and the phasing of the financial forecast. The Russia-Ukraine conflict can continue to impact supply availability, vaccine prices and raw materials (although a substantial portion of the strategic period pricing is already covered by tender agreements). Moreover, as a result of the uncertain global financial and economic environment, price variability due to inflation (in particular input prices such as energy), investment returns and large exchange rate fluctuations (including a rising US dollar in combination with any remaining unhedged non-US dollar denominated pledges) may also affect the forecasted available resources and expenditure levels. In addition, given the extent of the current crisis, there is a risk that donors divert pledges from Gavi (although since Gavi's inception, approximately 99% of all donor pledges have been honoured by donors). Any non-payment of amounts pledged or failure to extend pledges would adversely impact the forecast of resources. 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

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. There is a lower appetite for the risk that such variability might reduce manufacturer or donor confidence. Current exposure is therefore just within risk appetite and therefore requires ongoing attention. To further mitigate this risk, 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. To maintain manufacturer and donor confidence despite inherent year-on-year forecast variabilities, recent forecasts have included portfolio adjustments to count for backsliding risks. These portfolio adjustments have contributed to balance more equally the under/over-forecasting variability risks while still ensuring the optimisation of the use of the available resources. In addition, 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 and implemented 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 and implemented 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	⟺	⟺

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 compared to routine services (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, integrated 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, integrated 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 integration and 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 and develop follow-up action plans after the completion of the SIAs. However, ensuring completion and timely submission of technical reports and post-campaign coverage survey reports and the use of this data to improve quality and follow-up on missed communities 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 have also been some innovative approaches to integration such as in countries like Nigeria, Zambia and Nepal that should be further socialised and applied with a focus on improving the overall quality. 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. The Alliance is also encouraging countries to continue to use Supplemental Immunisation Activities (SIAs) to reach zero-dose children. SIAs offer opportunities to identify zero-dose children (e.g., through micro-planning and rapid convenience monitoring, and by using outbreaks as flags for RI gaps), reach them with various messages and vaccines (e.g., through targeted and integrated campaigns and Periodic Intensification of Routine Immunisation (PIRI)), measure and monitor progress (e.g., use SIA monitoring to track RI vaccination status) and advocate for the zero-dose agenda with governments and partners.

Current risk exposure

Current exposure to this risk remains high. While acknowledging an upward trajectory in the quality of campaign plans and budgets, the IRC continues to observe inconsistent use of data in planning campaigns, missing links between identification of barriers to immunisation and specific strategies to reach missed children, and proposals for nationwide campaigns in countries with high measles-containing vaccine (MCV) coverage, amongst others. Budget quality is improving, however some continue to omit key activities (e.g. microplanning) and include inflated costs in some areas (e.g. human resources and transport). As more campaigns resume to clear the backlog created by the pandemic, 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. To further mitigate this risk, the impact of COVID-19 on

planned campaigns continues to be closely monitored together with partners. Alliance partners on the ground have recognised the need to step up their support for countries to improve campaign planning. The Secretariat has sharpened its programme funding guidelines and IRC pre-screening processes to encourage stronger plans and budgets. Measles/Measles-Rubella campaigns should now be grounded in a differentiated delivery strategy. Countries are expected to put a more deliberate focus on identifying target populations, for example based on past outbreak data, implementing tailored strategies for reaching zero-dose and under-immunised children during the campaign, and bringing them into the routine immunisation programme following campaigns. Countries are also expected to plan and deliver campaigns integrated with other vaccines or primary health care (PHC) interventions where feasible. Ten applications for measles campaigns have been approved under these recommendations by the Independent Review Committee (IRC) with implementation starting in Q4 2022. However, 12 applications were rejected or removed during application pre-screening in line with the Board's low risk appetite for poor quality campaigns.

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
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	⟺	⟺

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 each of the Gavi-supported vaccines. Other risk factors are the total production buffer capacity for each market, manufacturers' level of engagement with global health and development aid, their assessment of commercial risks associated with supplying any given market, 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 or outbreaks). 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. Of greater risk are a number of vaccine programmes for epidemic diseases where inherent and wider-ranging demand volatility can lead to insufficient supply for campaigns and also new programmes and vaccine categories that might be supported in the future where supply may not be able to support all introductions and number of suppliers and supply security may be limited. Also, as countries transition out of Gavi support, they may opt for self-procurement instead of procuring through UNICEF, potentially exposing those countries to higher supply risk than when their demand was pooled and more predictable.

Existing mitigation

To manage this risk, the Secretariat and Alliance partners work closely with industry to ensure engagement and confidence in demand, and to improve the health of vaccine markets, which may entail incentivising increased production capacity to meet demand and/or buffer capacity, through provision of long-term demand forecasts and other strategic information and incentives. This can involve encouraging existing manufacturers to expand overall and/or buffer capacity or new manufacturers 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 robustness of forecasting integrated into grant renewal, for example providing countries a standard realistic starting point and more guidance on justification expected in forecast requests. There continues to be triangulation of renewal forecasts with other data sources to identify over-ambitious assumptions and multiple review points before forecasts are proposed to the HLRP and CEO. 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 are also being explored to improve predictability of demand (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) or predictability of future product presentation preferences. 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 executes long-term agreements (LTAs) for supply with manufacturers, allowing them to plan production 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 (with vaccine production lead-times being much too long for timely outbreak response).

Current risk exposure

Current exposure to this risk remains high. Last year, stock-outs and programme interruptions (due to shortages linked to COVID-19 disruption, country demand volatility and manufacturers holding low buffer inventory) had been averted due to partners successfully working with countries and suppliers to accelerate country decisions on alternative products and to fragment shipment plans ensuring minimal impact on programme continuity. This year was facing high risks of Rotavirus vaccine stockouts which actually materialised for a ~5 month period, following last year's decision by the supplier of the most used rotavirus product to reduce its overall volume offer to Gavi-supported countries. This caused significant supply pressures and at least ten countries have had to switch to different presentations (this interim solution however carries a high transaction cost as healthcare workers will need to be trained twice due to a high risk of confusion between the two presentations). Supply-side disruptions highlight the need for continuous review and improvement of Gavi processes to avoid bottlenecks in time-sensitive situations where country product switches are often the only immediate solution. IPV and HPV markets have welcomed new suppliers that are still relatively unproven, and whose reliability is being closely monitored. A supply/demand imbalance for OCV over the short to mid-term exposes the programme to the risk of preventative campaign delays and potentially a loss of country momentum to take a planned and preventative approach to cholera thereby perpetuating demand unpredictability. Both the COVID-19 pandemic and the Russia-Ukraine crisis have further highlighted the need to geographically diversify vaccine supply and stockpiles in order to be resilient against geopolitical risks. In the longer term, initiatives to increase regional and local manufacturing on the African continent are expected to contribute to broader diversification and hence supply security, both regional and global. However, if not carefully planned, this could also serve to undermine accumulated market-shaping gains and create new risks of market distortions and price increases.

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. To further mitigate this

risk, Alliance partners are currently exploring interventions to mitigate the short/mid-term risk of a supply/demand imbalance in the OCV market. To further mitigate risks associated with Yellow Fever Vaccine (YFV) supply, the only Gavi vaccine sourced from Russia, Gavi's alternate YFV suppliers have been engaged in efforts at buffering overall supply in the event that YFV supply from Russia is compromised. Furthermore, to avoid scenarios where future Gavi-supported vaccines (especially those without "dual markets" in HIC/LIC) are already in "market failure" by the time the category makes it through VIS, a mandate to intervene in markets pre-VIS and support the VIS process is being explored, as well as plans for a more integrated approach with CEPI and engagement in WHO-led TB discussions. As an example, it is likely that the low malaria volumes we are now experiencing as we launch the programme could have been averted with a much earlier mandate to intervene in the supply-side of the market pre-VIS. The Secretariat also continues to increase robustness of forecasting integrated into grant renewal. During the 2022 rollout of Multi Year Approvals, most countries received 5-year approvals as part of the renewal process for on-going programmes. It is expected that some flexibility to shift approved doses between years will provide a helpful tool for managing temporary fluctuations in demand. As Gavi shifts from annual renewals towards more regular monitoring of its overall portfolio, opportunities are being identified with partners to strengthen country capacity for regular forecast updates and improved stock management to identify early when more or less doses are necessary.

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
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		JUST WITHIN		

Risk description

Gavi support for strengthening health systems is 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. Gavi was on track to meet many of its HSS-related goals of the 4.0 strategy prior to the COVID-19 pandemic and in the initial years of 5.0 strategy it has focused largely on supporting countries to maintain and restore immunisation to pre-pandemic levels. During Gavi 5.0, the Alliance is projected to invest over 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 targeted country assistance (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. The scale-up of new vaccines outside of the traditional infant schedule (e.g., HPV, C19) also poses new challenges to health systems and calls on Gavi's HSS support to reach new populations and utilise new approaches, potentially detracting resources from the zero-dose agenda and ongoing routine immunisation programmes. Some of the key barriers to coverage and equity and improved life-course vaccination 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. 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 learning plan to better track progress. All HSS grants have performance frameworks with intermediate indicators measuring direct outputs as well as outcomes, and

countries will report a core set of common indicators to analyse progress at portfolio level. Furthermore, learning hubs have been established in key countries to enable deeper understanding of progress and challenges on HSS grants. A unit cost and benchmarking database ensures economy in HSS grants. The Secretariat has revised its programme funding guidelines into a single, integrated document to provide countries with clear guidance on the objectives for which Gavi support should be used in line with Gavi 5.0 goals and examples of activities and best practices that can be considered. 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) and the Alliance has developed new strategies and tools in key programmatic areas including updating its supply chain strategy, developing new thinking and approaches to demand and gender, developing a digital health information strategy, and updating its approach to leadership, management and coordination. The Board also approved the Civil Society & Community Engagement (CSCE) approach which requires that 10% of all HSS and TCA are allocated to civil society organisations to support shifts towards more equitable and sustainable programmes. 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 $100M 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. Foundational support and strategic focus area funding through the Partners' Engagement Framework have been comprehensively updated for Gavi 5.0 to support and enable many of these shifts and the Secretariat has also reorganised its Country Support and health systems teams with reprioritised support to high impact and fragile countries with increased resources through the organisational review. To manage risks related to life-course immunisation Gavi will integrate HPV support within the HSS funding envelope to foster complementarity with existing investments and planning processes, and continue to drive towards more integrated support as part of the longer-term routine COVID-19 programme.

Current risk exposure

Current exposure to this risk has increased due to the pandemic switching the focus in many countries away from routine immunisation and towards COVID-19. Both country teams and partner capacity have been significantly diverted to the COVID response and COVID vaccine scale-up. There have also been major other sources of disruption in several larger Gavi-supported countries (e.g., massive flooding in Pakistan, internal conflict in Afghanistan, Ethiopia and Myanmar). This has resulted in significant delays in programming of new Gavi support for health systems (e.g., very few full portfolio planning processes were completed in 2020 and 2021) as well as slowed down implementation of existing grants. Therefore, while the Alliance has laid strong foundations for pivoting its support for health systems in line with Gavi 5.0, there have been significant delays in this translating into active programmes while roll out of the new Monitoring & Learning plans is also delayed. The COVID-19 pandemic has also resulted in backsliding of immunisation coverage in many countries, which means that they will need to catch-up those children missed during the pandemic as well as working to reach

zero-dose children within their available resource envelopes. This will be a particular challenge in countries which saw their HSS ceilings fall in Gavi 5.0 (e.g., due to having increased coverage or GNI per capita in Gavi 4.0).

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 just within risk appetite and requires ongoing attention. To further mitigate this risk, the Secretariat and Alliance will continue to make concerted efforts to work with countries to accelerate FPP, EAF and TCA planning processes, ensuring that new grants which align to the Alliance's 5.0 goals are approved and begin implementation as soon as possible.