

THE VACCINE  
ALLIANCE  
RISK &  
ASSURANCE  
REPORT 2019



## Risk & Assurance Report 2019

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## 1. Introduction

### 1.1. Purpose of this report

Today's connected world remains volatile with accelerating change posing real uncertainties for the future. Gavi is exposed to this through its ambitious mission in some of the world's poorest and most fragile countries and is preparing for a new strategic period and financial replenishment in this context. To successfully navigate uncertainty, there is an ongoing need for robust risk management to confidently take the risks required to achieve the Alliance's mission, safeguard Gavi's investments and secure sustainable impact. A proactive and risk-aware Alliance can effectively anticipate potential future events, manage expectations, reduce vulnerabilities and harness opportunities for impact.

This is the fourth annual Risk & Assurance Report which 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. the willingness to accept being exposed). Detailed information including analysis of each top risk and corresponding mitigation is included in the annexes. Furthermore, links are made with findings from audits, evaluations and other reviews where these provided assurance on the effectiveness of current mitigation measures and / or identified risks.

This year's report shows that Gavi's overall risk profile has remained relatively stable with 16 top risks from last year still included and one having decreased to become a medium risk. The levels of some individual risks have evolved, and the understanding of existing risks has been enhanced throughout the year by risk owners and colleagues across the Alliance and reviews in the Secretariat's Risk Committee. The report also highlights four risks that continue to stay outside of risk appetite and require continued intensive mitigation efforts.

The Board recently approved the 2021-2025 strategy framework ("Gavi 5.0") with the vision to leave no-one behind with immunisation, and discussions on its operationalisation are ongoing. Consequently, this year's report also includes an additional section that shares some preliminary thoughts on how Gavi's risk profile may shift under Gavi 5.0, highlighting potential new, shifted or reframed risks associated with the new strategy and operating model, as well as potential implications for Gavi's risk appetite. This serves to inform Board members' views on key risks for Gavi 5.0 as well as thoughts on Gavi's appetite for being exposed to these risks and how to appropriately balance potential trade-offs. It is anticipated that risks and risk appetite implications will also be highlighted and discussed as an integral part of other Board discussions on strategy operationalisation over the coming year. The 2020 Risk & Assurance Report will capture these discussions and (being issued immediately before the start of the new strategic period) present an updated set of top risks for Gavi 5.0. As required the risk appetite statement may also be updated to appropriately reflect risk and reward trade-off discussions.

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

Last year's Risk & Assurance Report described a number of initiatives undertaken to instil a risk-aware culture; ensure active management of top risks; embed risk management in daily operations, planning and decision-making; engage partners more closely and systematically on risk; and share approaches and experiences on risk management with peer organisations. There is now a strong foundation for risk management within the Secretariat with a high level of risk awareness, colleagues incorporating risk more routinely in their thinking, and risk being more integrated and embedded in key processes.

The Risk function continues to build on this foundation in each of these areas. Last year's Risk & Assurance Report was broadly disseminated within the Secretariat (with notifications in the Deputy CEO newsletter and on the office screens), sparking interest from a number of colleagues to make connections with their own areas of work (e.g. to identify areas where innovative partnerships may be able to play a role in mitigating risk). Gavi's top risks were also presented to the Independent Review Committee (IRC) to make them aware of the most critical risks when reviewing countries' applications for Gavi support. Integration of risk into the Secretariat's corporate and team priority-setting and performance management process has been further solidified (and now also connects with budget and team health priorities, which are set and monitored through the same process). There was a particular focus on supporting and challenging teams to build out team risk registers to include new risks associated with their priorities and ensure mitigation of key risks is included as part of team objectives. This increases risk awareness and ensures that risks are not only recorded, but also monitored, mitigated, and informing planning and target-setting.

Regular Secretariat Risk Committee meetings (chaired by the CEO with senior leadership from across the organisation) continue to review top risks presented by risk owners, and in some cases include Alliance partner representation (e.g. for the risks of Insufficient demand and Sub-optimally planned campaigns). As nearly all top risks have come to the Risk Committee at least once now, the focus is gradually shifting from aiming for high coverage of top risks over the year, to bringing back only those that require further attention and leaving space to explore other (medium, new or emerging) risks, as well as risk-related topics such as reviewing the three lines of defence model, risk culture and cross-cutting themes (e.g., those emerging from audit findings). The Risk Committee continues to track shifts in exposure and progress on actions agreed in the Risk Committee for all top risks with a periodic top risk dashboard.

The Risk function has actively engaged during the development of the new strategy to highlight risk appetite considerations, and continues to be involved with relevant strategy operationalisation workstreams, e.g., exploring how risk can best be reflected in the Gavi 5.0 theory of change and measurement framework, how to mainstream risk appetite considerations in revised funding policies, and how to ensure redesigned grant management processes incorporate adequate risk management (with risk as a basis for differentiation and risk appetite implications of simplification and differentiation clearly articulated). The Risk function also conducted a top risk re-assessment survey and workshops in the Secretariat over the summer to obtain preliminary thoughts on key risks associated with Gavi 5.0. In addition, the Risk function has begun preparing for the development of a longer-term vision and roadmap for risk management across the Alliance for the next strategic period<sup>1</sup>, as well as a rethink of the Three Lines of Defence model<sup>2</sup> based on learnings and in line with the latest Secretariat structure and potential future changes to the operating model.

The role of Alliance partners in risk management was a central theme in the Gavi 5.0 Partner Retreat, which concluded that this is an under-served area that requires more attention. Partner representatives felt that there is a need to create a common understanding of risk, turn a culture of risk avoidance into one of risk management and that risk analyses need to be shared, issues flagged and risk considerations integrated into operationalisation (e.g. by a deeper discussion on risk every year during the joint appraisal, and by incorporating risk mitigation into annual plans and technical assistance). Some, however, also questioned whether it is a fair expectation of partners to act as the eyes and ears in-country and flag risks, given that they need to maintain relationships at the country level. This raises the question of whether other models need to be explored for in-country oversight and assurance.

<sup>1</sup> Results of the Enterprise Risk Management (ERM) audit being finalised by Internal Audit will serve as an input.

<sup>2</sup> The best practice Three Lines of Defence model separates roles and responsibilities across first line functions to understand, monitor and actively manage risks, second line functions to provide objective specialist advice and appropriate checks and balances, and a third line audit function to provide independent assurance on the effectiveness of risk management by the first and second lines, see Annex I.

Lastly, the Risk function continues to share approaches and experiences on risk management with donors and peer organisations. Information on Gavi's risk approach has now been published more centrally on Gavi's public website<sup>3</sup>, and Gavi's Risk function is regularly liaising with risk functions from other international and global health organisations. For example, Gavi was recently asked by the Cross Functional Risk Management Task Force from the United Nations High Level Committee on Management to provide input and examples for a high level guidance document to advise UN organisations on how to implement risk appetite, given that only a handful of UN agencies have implemented risk appetite so far and Gavi is seen as being relatively advanced. Furthermore, a report by the U4 Anti-Corruption Research Centre<sup>4</sup> (funded by eight donors) reviewed six funds including Gavi and the Global Fund, and recommended that donors learn from Gavi's risk appetite process and review their own policies and procedures against a more holistic understanding of risk (seeing possible trade-offs between risk taking and results achievements) to achieve a shared understanding of risk appetite and risk sharing between stakeholders.

<sup>3</sup> See <https://www.gavi.org/about/risk-management/>

<sup>4</sup> See: <https://www.u4.no/publications/addressing-corruption-risks-in-multi-partner-funds>

## 2. Alliance-wide risk exposure

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

The Alliance operates 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<sup>5</sup> on global trends and risks identified in other organisations to evaluate the extent to which these factors could represent important drivers of risk to the Gavi mission and strategic objectives. Where applicable, the trends and developments summarised below have been captured as risk factors for Gavi's top risks.

Global growth has continued to weaken and remains fragile with low inflation despite unconventional monetary policies. Financial markets have been volatile amid escalating trade tensions (notably between the US and China), slowdowns in several major economies, and bond yields falling (even into negative territory) in ways that have historically signalled a recession is coming. Global debt is nearly 50% higher than before the financial crisis. Central banks have restarted interest rate cuts and monetary stimulus, despite concerns of continued effectiveness, which further constrains their ability to counter future shocks. The ongoing economic uncertainty puts investment growth in developing countries at risk, which is already below historical averages, and commodity exporters in particular remain vulnerable to lower prices from dampened demand combined with a stronger US dollar. Limited growth opportunities could affect domestic financing and political prioritisation of immunisation and heightens the risks of co-financing defaults and backsliding.

Economic uncertainty, foreign exchange fluctuations and the risk of a recession continue to heighten donor funding risk during Gavi's fundraising drive for replenishment. This is compounded by political change and uncertainty in many donor countries, driven by continued support for populist and nationalist parties and general discontent in many electorates (e.g., last year saw the rise of the yellow vest movement in France). With Gavi's mid-2020 pledging conference being hosted in the UK, further Brexit-related uncertainty or turmoil (e.g. related to a no-deal exit or government changes) could possibly distract attention or affect Gavi's ability to engage and convene. Furthermore, this year saw an increase in geopolitical rivalry between global powers over economics, military and technology, as well as increasingly over values. Increased polarisation and deglobalisation can put the effectiveness of the multilateral system at risk and potentially complicates the effectiveness and neutrality of international organisations in pursuing global goals.

While fatalities due to armed conflict continued to decrease this year (mostly due to Syria), the world saw a new peak in the number of active conflicts with non-state conflict remaining at a high level. Risks of escalating regional conflicts remain particularly high in the Middle East and East Asia. The risk of terrorism disrupting immunisation programmes is particularly high in Sub-Saharan Africa, the Middle East, South and Southeast Asia. Also, several Gavi countries will hold elections next year that could result in unrest or significant changes of policy direction. Migration will likely continue to fuel social and interstate tensions globally. The number of people becoming displaced within their own national borders continues to increase due to conflict and climate change. Displacement of people not only causes strain on governments' ability to care for their domestic populations, but it also creates challenges for immunisation programmes to locate under-immunised populations and ensure completion of vaccine schedules. Furthermore, increasing population growth in Africa may outpace improvements in the capacity to deliver services and increase immunisation coverage, especially since the most fragile countries have the highest fertility rates and countries with the lowest coverage rates have growing birth cohorts.

Climate change poses increasingly tangible risks as the world sees more intense and variable extreme weather

<sup>5</sup> Amongst others World Economic Forum Global Risks Report 2019; Eurasia Group Top Risks 2019; World Bank Global Economic Prospects 2019; IMF World Economic Outlook 2019; Office of National Intelligence Global Threat Assessment 2019; Uppsala Conflict Data Program.

events (this year cyclone Idai was one of the worst tropical cyclones on record to affect Africa and cyclone Fani was the strongest cyclone in 20 years affecting India and Bangladesh), an accelerating sea level rise (particularly affecting urban coastal areas in South and Southeast Asia and the Western Hemisphere) and increasing water and food insecurity. This can change disease epidemiology and accelerate the spread of certain diseases, disrupt immunisation programmes and global supply chains and lead to social unrest, conflict and further migration (extreme weather displaced 7 million people alone during the first 6 months of 2019).

Infectious disease outbreaks are also anticipated to increase due to climate change in combination with globalisation, urbanisation and deforestation, and control efforts may be hindered by the complex challenge of addressing vaccine hesitancy (a factor in this year's three-fold increase in measles cases, particularly in middle and high income countries) and anti-microbial resistance. The ongoing Ebola outbreak in the Democratic Republic of the Congo also underscores the risks posed by the nexus of infectious disease outbreaks, violent conflict, and high population density, including large numbers of internally displaced persons.

## 2.2. Changes to the Alliance-wide top risks in 2019

This is the fourth year this report has been prepared. Last year's report<sup>6</sup> prioritised 17 top risks. This year's analysis showed that the Alliance's overall risk profile has remained relatively stable; 16 of the 17 top risks remain and one (Strategic relevance) decreased to become a medium risk. Some risk definitions have been redefined, the levels of some individual risks have evolved as illustrated by the arrows next to each top risk below and the understanding of existing risks has been enhanced through work by risk owners and colleagues across the Alliance and reviews in the Secretariat's Risk Committee (see Annex IV for detailed information including analysis of each top risk and corresponding mitigation plans).

The 3 top risks rated as **very high** are:

- a) **Country management capacity**  
Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity
- b) **Data quality**  
Continued lack of availability and use of quality data for immunisation
- c) **Ability to reach the under-immunised**  
The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached

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

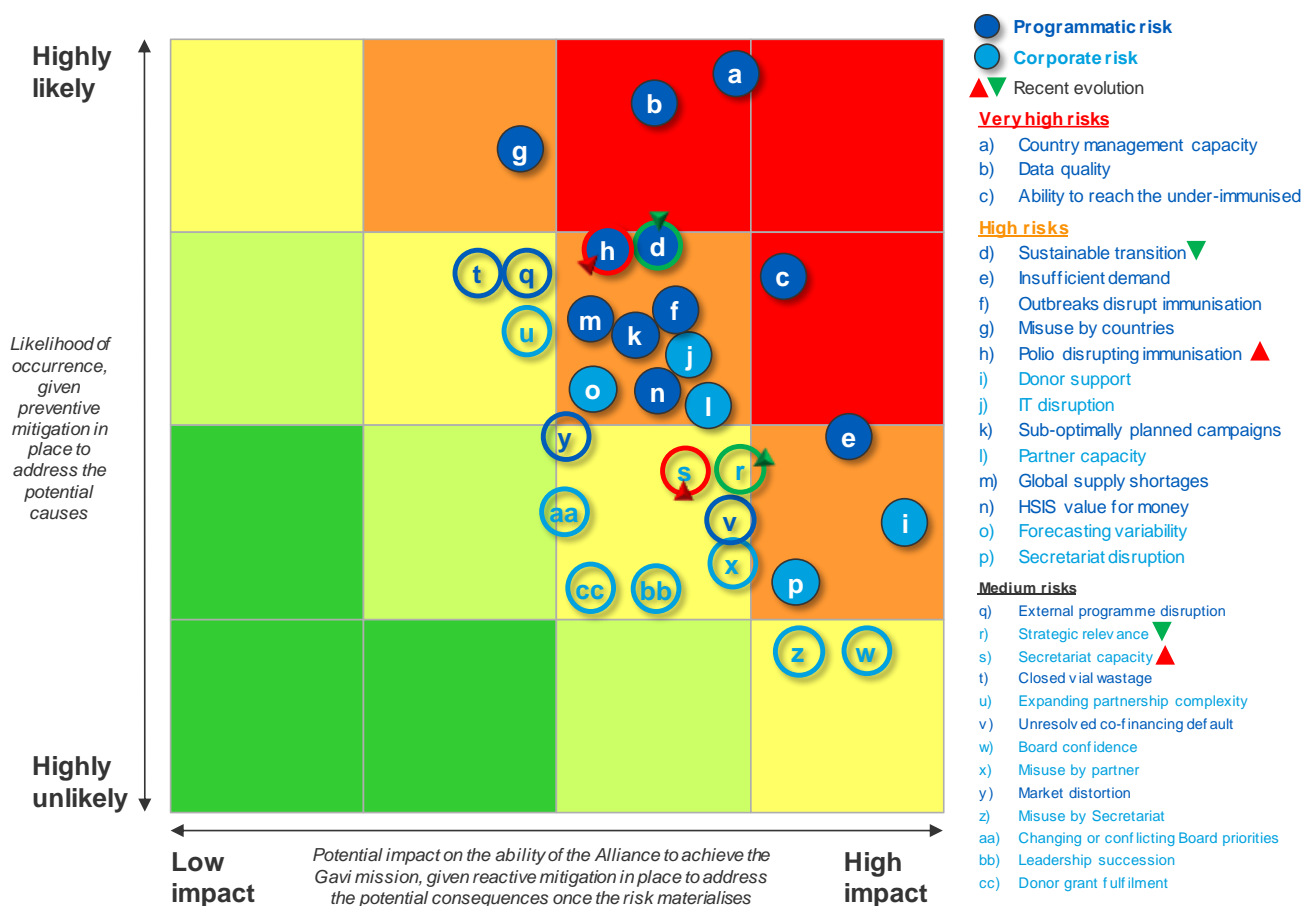
- d) **Sustainable transition ▼**  
Some countries fail to sustain progress of their immunisation programmes after transition
- e) **Insufficient demand**  
Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation
- f) **Outbreaks disrupt immunisation**  
Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries
- g) **Misuse by countries**  
Deliberate misuse of Gavi support in many Gavi-supported countries
- h) **Polio disrupting immunisation<sup>7</sup> ▲**  
Polio resurgence or the winding-down of polio eradication resources adversely affects routine immunisation
- i) **Donor support**  
Reduction in donor support

<sup>6</sup> See for the 2018 Risk & Assurance Report: <https://www.gavi.org/library/gavi-documents/strategy/gavi-risk-and-assurance-report-2018/>

<sup>7</sup> Previously called "Polio transition"

- j) **IT disruption**  
Critical information systems or data significantly compromised by cyber-attack or technology failure
- k) **Sub-optimally planned campaigns<sup>8</sup>**  
Multiple large preventive vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services
- l) **Partner capacity**  
Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries
- m) **Global supply shortages**  
Shortages in the global vaccine supply
- n) **HSIS value for money**  
HSIS investments do not materially improve programmatic outcomes
- o) **Forecasting variability**  
Gavi forecasting variability drives inappropriate decision-making
- p) **Secretariat disruption**  
Significant disruption of Secretariat operations

## Alliance top risks ranked against likelihood and impact 2019 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2019 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 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). Risks are not strictly ranked within each segment as any ranking is subjective

<sup>8</sup> Previously called "Frequent or unplanned campaigns"



## Alliance-wide top risks summary

Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a <b>Country management capacity</b> Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption</li> <li>Disease outbreaks disrupting immunisation</li> <li>Political change (devolution)</li> </ul>	VH		OUTSIDE		
b <b>Data quality</b> Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"> <li>Data quality not routinely monitored</li> <li>Weaknesses in data and measurement systems</li> <li>Fragmented initiatives without measurable outcomes</li> <li>Short time-frame improvement strategies</li> <li>Limited country-ownership &amp; sustainable technical capacity</li> <li>Limited attention to data use and the needs of end users</li> </ul>	VH		OUTSIDE		
c <b>Ability to reach the under-immunised</b> The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached	<ul style="list-style-type: none"> <li>Poor data to find and target the unreached</li> <li>Inadequate supply and cold chains into remote areas</li> <li>Insufficient health care workers</li> <li>Lack of demand in underserved communities</li> <li>Lack of political commitment and health budgets</li> </ul>	VH		OUTSIDE		
d <b>Sustainable transition</b> Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> <li>Lack of (subnational) ability/capacity/fiscal space</li> <li>Poor preparation for transition by Alliance</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Overreliance on external support</li> <li>External programme disruption (economic, outbreak)</li> <li>Lack of access to global markets and expertise</li> </ul>	H		SOMEWHAT OUTSIDE		
e <b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation	<ul style="list-style-type: none"> <li>Lack of knowledge / social norms</li> <li>Mistrust or fear (due to safety issue or hesitancy)</li> <li>Not actively prioritised / complacency</li> <li>Poor access to convenient and acceptable health services</li> </ul>	H		SOMEWHAT OUTSIDE		
f <b>Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Climate change, urbanisation, deforestation, globalisation, migration and human displacement, population growth</li> <li>Low population immunity, anti-microbial resistance</li> <li>Lack of capacity/tools to detect, prevent and respond</li> <li>Population behaviour, vaccine hesitancy</li> </ul>	H		BROADLY WITHIN		
g <b>Misuse by countries</b> Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Culture of gifts/corruption</li> <li>Opportunity for personal gain</li> <li>Weak monitoring/deterrence</li> <li>Weak institutions / systems</li> </ul>	H		SOMEWHAT OUTSIDE		
h <b>Polio disrupting immunisation</b> Polio resurgence or the winding-down of polio eradication operations adversely affects routine immunisation	<ul style="list-style-type: none"> <li>Eradication challenges / Vaccine-derived outbreaks</li> <li>Reliance on GPEI staff/assets, weak national systems</li> <li>Delayed transition plans, incomplete polio asset mapping</li> <li>GPEI funding cuts / uncertain fund-raising for new strategy</li> </ul>	H		SOMEWHAT OUTSIDE		
Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
i <b>Donor support</b> Significant reduction in donor support to Gavi	<ul style="list-style-type: none"> <li>Reduction in development budgets</li> <li>Competing priorities in development</li> <li>Competing priorities within health</li> <li>Loss of donor confidence in Gavi</li> </ul>	H		SOMEWHAT OUTSIDE		
j <b>IT disruption</b> Critical information systems or data significantly compromised by cyber-attack or technology failure	<ul style="list-style-type: none"> <li>Cyber-attack, phishing and malware</li> <li>Internal or external data breach</li> <li>Systems failure and data loss</li> </ul>	H		SOMEWHAT OUTSIDE		
k <b>Sub-optimally planned campaigns</b> Multiple large preventive vaccination campaigns that are often sub-optimally planned undermine capacity to manage and deliver routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>	H		OUTSIDE		
l <b>Partner capacity</b> Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> <li>Lack of accountability / performance</li> </ul>	H		BROADLY WITHIN		
m <b>Global supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption (epidemiological, political, technical)</li> </ul>	H		SOMEWHAT OUTSIDE		
n <b>HSIS value for money</b> HSIS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSIS</li> <li>HSIS grants not designed to target key bottlenecks</li> <li>HSIS grants duplicative with other donor funding</li> <li>HSIS grants not large enough to have significant impact</li> <li>HSIS not disbursed in timely fashion</li> <li>Programmes funded by HSIS not well-managed</li> <li>Misuse of HSIS resources</li> </ul>	H		BROADLY WITHIN		
o <b>Forecasting variability</b> Gavi forecasting variability drives inappropriate decision-making	<ul style="list-style-type: none"> <li>Uncertainty over vaccine demand</li> <li>Financial uncertainties (e.g., prices, FX)</li> <li>Complexity of process</li> <li>Sub-optimal systems</li> </ul>	H		BROADLY WITHIN		
p <b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>Loss of workplace and facilities</li> <li>Incident or loss of life in the workplace</li> <li>Security threats and kidnapping during travel</li> <li>Departures of key staff with critical knowledge</li> <li>Unforeseen catastrophic event or crisis situation</li> </ul>	H		BROADLY WITHIN		

depending on how the relative importance of impact and likelihood are weighted. The next segment of risks in the yellow zone are medium risks (depicted with hollow circles), shown for comparison purposes only and not designated as top risks. The Secretariat also maintains a register containing a broader set of lower risks and their associated mitigation strategies, which are identified and managed at a team level. The levels of some individual risks have evolved since last year's report, as illustrated by the arrows next to each top risk.

Annex III shows the trajectory of the evolved top risks since last year in more detail. Annex IV contains a detailed description of each top risk, existing mitigation, current exposure and risk appetite. The major changes since last year are summarised below:

**d) Sustainable transition ▼** – The risk that some countries fail to sustain progress of their immunisation programmes after transition has decreased from very high to high. By now, 15 countries have transitioned out of Gavi support out of the 18 projected to do so in this strategic period. Most are performing well, as evidenced by continuing high or improving coverage levels, and the risk to the sustainability of their programmes is low. Board-approved tailored approaches to mitigate post-transition risks in Angola and Timor-Leste have been developed, while Congo Republic, due to the significant drop in its GNI per capita, became Gavi-eligible again in 2019. Other countries that transitioned with high coverage and strong financing performance may still have specific challenges linked to their institutional development. Recognising this, the Board approved an approach to post-transition engagement at its November 2017 meeting, and the Alliance is now actively working with transitioned countries to mitigate these residual risks through time-limited, catalytic support. Eight out of fourteen eligible countries (excluding Angola, Timor-Leste, which are being addressed through tailored strategies per above, and Uzbekistan and Nicaragua, which are transitioning only at the end of 2020) have applied successfully for post-transition support, and additional support is under development and review. Among countries that will transition but were identified by the Board as being at high risk for transition, tailored strategies have been developed and Board-approved for Nigeria and Papua New Guinea, with Accountability Frameworks being developed. Gavi is now also working with countries to prepare them to undergo the transition process before they enter the accelerated transition phase. Furthermore, the new Gavi 5.0 strategy also represents an important evolution, clearly incorporating programmatic sustainability as a core element of Gavi's approach and exploring how programmatic sustainability criteria should also be considered when determining timelines for countries' transition in the ongoing policy review. It will also institutionalise post-transition support while additional work is underway to more clearly identify programmatic theories of change, which should further strengthen the alignment and focus of Gavi's investments around financial and programmatic sustainability.

**h) Polio disrupting immunisation ▲** – The risk that routine immunisation is adversely affected by polio resurgence or the winding-down of polio eradication operations is increasing. The eradication effort has experienced recent setbacks in Pakistan and Afghanistan where there has been a resurgence of wild poliovirus transmission (Nigeria has been polio-free since August 2016 and may be certified polio-free by mid-2020). In addition, in an increasing number of countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2 (and some type 1) outbreaks are increasing. This is particularly the case in countries with low type 2 immunity, following the global switch from trivalent to bivalent oral polio vaccine in 2016 (and IPV providing individual protection but not preventing further spread). Outbreak response activities using oral polio type 2 vaccine risk themselves to cause further vaccine-derived poliovirus cases in under-immunised populations (especially in areas with poor sanitation and hygiene), until a new, more genetically stable vaccine is developed (there are two candidates under development). While pre-clinical data is promising, it still must be proven in real-life circumstances, and, if no alternative delivery strategies are utilised than the current single antigen outbreak response campaigns, this could result in increased community resistance. Furthermore, the new vaccine will have regulatory and supply hurdles to overcome before it can be used. Potential increased emergence and spread of wild and vaccine-derived poliovirus would place a growing strain on donor and government budgets since they had been anticipating a ramp-down. There was an expectation that approval

of the new extended Polio Endgame strategy (2019-23) would resolve some of the polio transition funding issues in the near term, but it is uncertain whether the plan will be fully funded. Furthermore, GPEI's outbreak response budget has been outstripped by more cVDPV2 outbreaks than anticipated, necessitating budget cuts in other areas, possibly affecting immunisation-critical resources. It also could 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 have an impact on Gavi's fundraising (with continued needs to resource the polio programme posing uncertainties for donor pledges to Gavi) and lead to reputational damage regarding immunisation (with Gavi now engaged through IPV and the Polio Oversight Board) if we fail to deliver the promise of a world free of polio. The current situation also has the potential to further accelerate the wind-down of polio assets in some countries if resources need to be reprogrammed to respond to outbreaks. A negative impact from polio transition is more likely in a small number of fragile countries where the footprint of GPEI is relatively large and national systems are very weak. Chad, Somalia and South Sudan have been assessed as very high risk, and DRC, Ethiopia, and Sudan as high risk. In most other non-endemic countries, routine immunisation programmes are less reliant on polio assets, but polio transition may affect specific capacities, particularly in disease surveillance. This further emphasises the need to better understand the contribution of polio assets to routine immunisation programmes and to determine urgently where gaps will arise if those activities cease (or where this presents an opportunity to strengthen routine immunisation by repurposing assets). While priority countries now have mapped polio assets, they have not always realistically captured the range of immunisation functions that polio is performing on the ground, and numbers will need to be updated with the adoption of the new GPEI strategic plan. Important country-level polio budget information and the impact on immunisation-critical functions are still not systematically incorporated into Joint Appraisal preparations and planning discussions.

**r) Strategic relevance ▼** – The (previously high) risk that Gavi becomes less relevant to global development priorities has decreased to become a medium risk and is now within risk appetite. The Gavi 5.0 strategy development outcome ensured that Gavi's strategy remains in line with and relevant to the broader development agenda. The Gavi 5.0 vision of 'leaving no one behind with immunisation' with a focus on equity and reaching zero-dose children is highly aligned with the SDG ambition of leaving no one behind. Immunisation, which already has the highest coverage of any routine health intervention, is a critical platform for extending basic primary healthcare (PHC) services to all communities including the most marginalised, and ultimately for universal health coverage. Gavi also remains very relevant to the success of other Sustainable Development Goals and other health priorities, such as global health security and anti-microbial resistance, given a new focus on outbreaks in Strategic Goal 1 in a time of growing outbreaks and climate change. Formalising post-transition engagement means that Gavi will continue to engage with a broad community of countries, and the Gavi community may grow further with the Board's decision to explore engagement with middle-income countries. The growing vaccine pipeline, including new vaccines approved as part of the new Vaccine Investment Strategy (VIS), means engagement at more points in time and new vaccines in the pipeline such as TB, mean that immunisation will have a growing potential to protect against other major diseases. Gavi is furthermore closely engaged in the "Global Action Plan for Healthy Lives and Wellbeing for All" process and the development of the Immunisation Agenda 2030 to ensure that the Alliance's strategy and work contribute to these important agendas (and vice versa), and to further expand and systematise coordination with other health actors within the broader global health architecture (e.g., the Global Fund, the Global Financing Facility, and UNITAID) to ensure a strong common focus across health actors on achieving impact at the ground level. At a time when there is more focus than ever on partnership, the Alliance is a proven model of how to do this.

**s) Secretariat capacity ▲** – The medium risk that Secretariat capacity, capabilities and processes are inadequate to deliver on the new strategy is increasing in the short-term. It remains a medium risk, but has the possibility to become a high risk in the future if the Gavi 5.0 operationalisation process fails to sufficiently

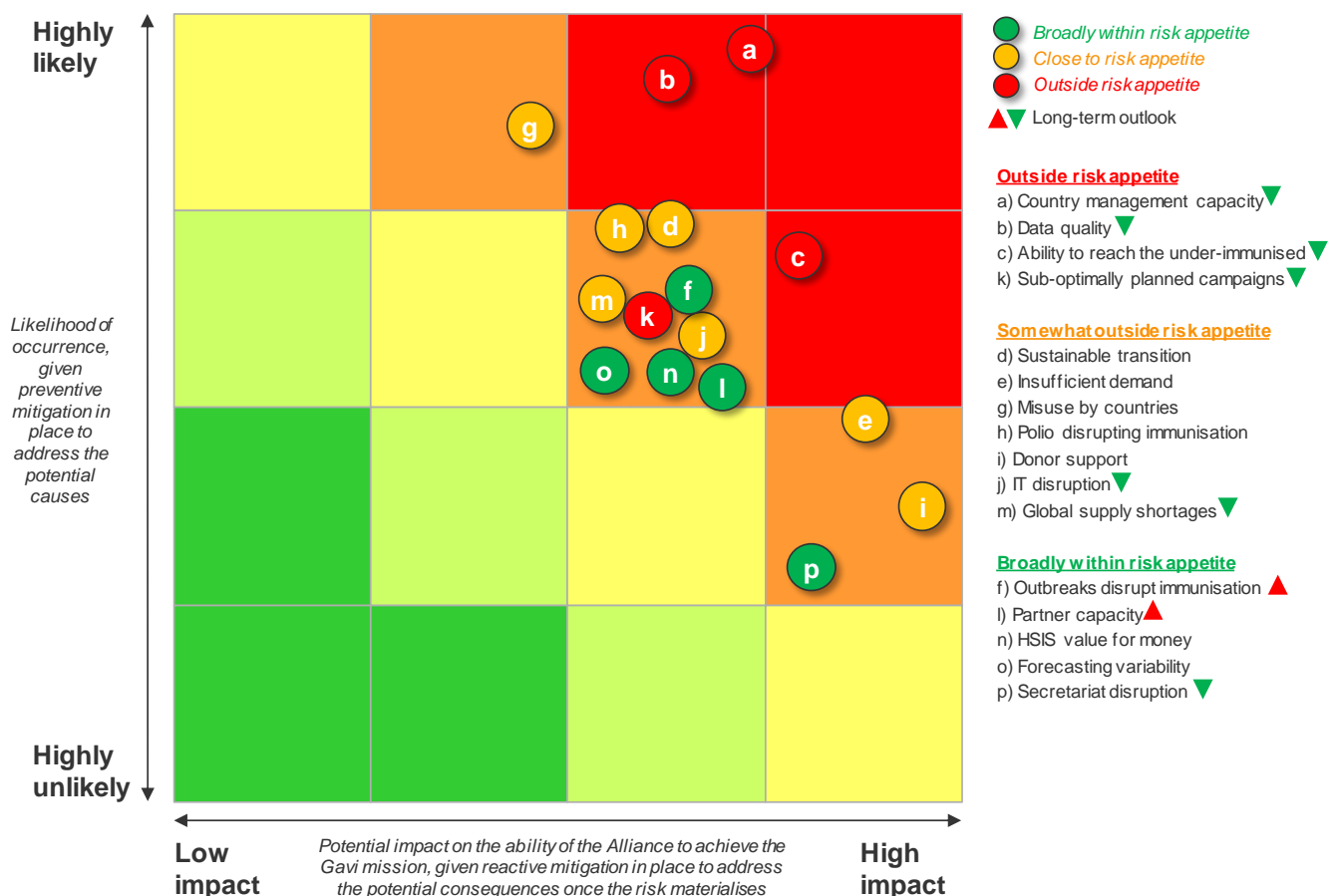
transform Gavi's policies, strategic approaches, processes and tools to ensure alignment with the new strategy, and if the Alliance's operating model and the Secretariat's organisational structure, competencies and resourcing fail to match the new targets and ambitions of Gavi 5.0. For example, the increased focus on working in emergency, conflict and otherwise difficult operating contexts; providing more differentiated, tailored and targeted support for countries; ensuring coordination and collaboration with other health actors; and strengthening accountability, oversight and risk management across the Alliance all have the potential to significantly increase transaction costs and workload, and may require different competencies and expertise. The need for staff to engage on operationalising the new strategy (structured around six workstreams) in parallel with continuing to deliver the existing programme of work under Gavi 4.0, itself poses a risk, given the limited bandwidth and flat headcount. In addition, many other changes to Secretariat operations and continued governance and donor needs require focus and attention, such as the implementation of the new financial management system (FIND) and the upcoming replenishment.

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

Being exposed to a high likelihood and/or potential impact of a risk can be acceptable, even if this does not mean the actual occurrence of the risk is desirable. This can be because the downside of the risk, if it were to materialise, is manageable or acceptable in light of the rewards being pursued, because exposure to the risk is required to achieve Gavi's mission, or because the costs of mitigation or trade-offs with other risks are deemed too high. As per Gavi's Risk Appetite Statement (see Annex II), the Alliance embraces the need to take programmatic risk given its ambitious mission and operating model, but it has a lower appetite for organisational risks affecting Alliance processes, systems and management, as well as for fiduciary oversight and control, and brand and stakeholder confidence.

## Willingness to accept current top risk exposures

### Actual exposures reviewed against aspirational risk appetite





In order to compare Gavi's actual risk exposure (as presented in the previous section) with risk appetite (i.e. the willingness to accept these exposures), the Secretariat has interpreted how the high-level statement translates into an appetite for each of the Alliance's top risks as described below (and in more detail in Annex IV). As depicted in the risk appetite heat map above, the top risks have been classified in three risk appetite categories where risks are clearly outside of risk appetite (i.e. current exposure requires intensive mitigation efforts), somewhat outside of risk appetite (requires attention), and within risk appetite (current exposure is acknowledged and accepted). Where current exposures are not in line with the Board's risk appetite, further or more intensive mitigation measures may be 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 above show the expected long-term outlook of the risk exposures, which can increase (e.g. due to foreseeable trends in inherent or external risk factors), or decrease (due to trends in risk factors and / or due to the expected effect of ongoing or planned mitigation measures). Being outside of risk appetite for a period of time can be acceptable if the expected trajectory is in the right direction, and especially if this is due to the inherent risks in our business, which are to some extent outside the Alliance's control or required to achieve Gavi's mission. However, risks that are systematically outside of appetite should continue to be revisited and trigger a debate on whether this requires a more ambitious approach or radical change to the way the Alliance mitigates such risks, or whether a more realistic risk appetite should be set.

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

**a) Country management capacity** – Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that EPI management capacity does not improve across its portfolio. Having sufficient national and subnational capacity to manage immunisation programmes and funding is crucial for countries to achieve improvements in coverage and equity, and to be ready for a sustainable transition out of Gavi support. Current exposure to this risk remains very high. At an aggregate level, performance frameworks, country risk assessments and institutional capacity scores show slight improvements, in particular in countries with LMC interventions. However transformative change has yet to be made as investments at the EPI team level take a long time to take effect and depend on government ownership and basic capacity (or lack of it). Broader efforts across the health sector are also necessary for more sustainable mitigation, and gains can be easily lost due to vacant posts or high turnover of staff, as well as external programme disruption due to political change and disease outbreaks. As the current exposure remains outside of risk appetite, this risk continues to require intensive mitigation efforts. New approaches under Gavi 5.0 (e.g. reaching zero-dose children, VIS vaccines) will require even greater capacity. The Secretariat is therefore planning to relook at the LMC approach in 2020 in preparation for Gavi 5.0 and will consider whether an ambitious scale-up is needed, including potentially increased investments, as well as increased collaboration with other key partners.

**b) Data quality** – Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that data availability, quality and use do not improve across its portfolio. Given that immunisation now reaches most of the population in Gavi countries, achieving coverage and equity goals increasingly requires a "precision public health" approach with more precise data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. This will be even more true in Gavi 5.0 with the enhanced focus on reaching zero-dose children. Furthermore, the Alliance is dependent on data for decision-making at all levels, planning of supply and delivery of vaccines, allocation of Gavi support, and the ability to accurately measure and demonstrate impact.

Current exposure to this risk remains very high, but is expected to decrease slowly over time as mitigation efforts – both building more robust data systems and creating a culture of data use and data-driven decision-making – take time to have an effect and require country level political will, and the Alliance’s investment in data is limited compared with the level of inherent risk. There are also challenges with the lack of longer-term strategic planning and sustainability, as well as absorptive capacity of countries and the need to focus on data use and analysis, which is not the traditional focus of countries and partners providing technical assistance. A longer-term vision that is attentive to the multi-year and multi-pronged approaches necessary to achieve real improvements in the space is necessary. As the current exposure remains outside of risk appetite, this risk continues to require intensive mitigation efforts. The Secretariat is therefore planning to identify which parts of the risk are inherent (and would likely remain a challenge for a long time) and which parts can be mitigated further, to better define a realistic risk appetite. It will also develop thinking on the ideal level of investment in the context of Gavi 5.0 to bring the risk within that risk appetite.

**c) Ability to reach the under-immunised** – The Alliance has a low appetite for the risk of not being able to achieve equitable coverage improvements, since this is key to its mission. It recognises that improving coverage and equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations and that this often requires political (as well as technical) change, which goes beyond the immunisation programme. Current exposure to this risk remains very high. In 2018, more children were immunised with three doses of pentavalent vaccine (penta3) and a first dose of measles (MCV1) than ever before, and since 2015, there has been a 6% reduction in the number of under-immunised and an 8% reduction in the number of zero-dose children despite a growing birth cohort. Despite this progress, Penta1 and Penta 3 coverage have each improved by only one percentage point over the strategy period so far, reflecting the challenge posed by population growth to increasing coverage rates. Furthermore, a growing number of the children who are under-immunised live in fragile settings – and fragile countries have seen coverage stagnate, due to the acute problems they face and because of rapid population growth – and many are displaced. These challenges are set to grow as the countries remaining in Gavi’s portfolio are more likely to be fragile and conflict-affected and have weaker health systems. The number of children born annually will grow nearly twice as fast in these countries due to higher fertility rates. Further acceleration of progress is needed to achieve the coverage and equity goals by the end of the 2016–2020 period. As the current exposure remains outside of risk appetite, this risk continues to require intensive mitigation efforts. Given the aspiration of the Gavi 5.0 strategy on equity as an organising principle (as opposed to just coverage), the Alliance will need to develop new ways of working to deliver on the ambition of reaching unreached communities and zero-dose children.

**k) Sub-optimally planned campaigns** – The Alliance has a low appetite for the risk of preventive immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term. Well-planned preventive campaigns are an important mechanism to close immunity gaps among populations not reached through routine immunisation, however, overreliance on campaigns can distract from efforts to strengthen routine immunisation and sub-optimally planned campaigns may fail to reach the full target population. Current exposure to this risk remains high. While MCV1 coverage reached 81% in 2018 (three percentage points above the 2015 baseline against a target of 2.4 percentage points, while previously stagnant, rising only 1 percentage point between 2011 and 2015), 95% coverage with two doses is needed to achieve herd immunity for measles. Very few Gavi countries meet this herd immunity threshold, which means follow-up campaigns will continue unless intensive efforts are made to reach a high number of measles zero dose children (among 10 Gavi supported countries conducting nationwide measles and/or rubella SIAs in 2018, only one country achieved the 95% coverage target as determined by a post-campaign coverage survey). An analysis of specific reasons for sub-optimal coverage in campaigns identified that delayed disbursement of funds from national to subnational level and from global to national level, and sub-optimal use of readiness assessment tools at subnational level compromised the quality

of campaigns. The Risk Committee expressed its ongoing concern with campaigns being inherently high-risk activities, both from a fiduciary risk perspective and a programmatic quality, sustainability, and value-for-money perspective. It was agreed that more analysis is needed to understand how to best strengthen both programmatic and fiduciary measures, including looking at which components of operational costs are critical and sustainable to reduce perverse incentives, drawing on early lessons from the use of Monitoring Agents in a few countries. Alliance Partners agreed to strengthen support for campaign and budget planning and to ensure that post-campaign coverage surveys happen systematically and in a timely manner. These efforts are anticipated to reduce the risk in this area moving forward, but operationalisation is pending. As the current exposure remains outside of risk appetite, this risk continues to require intensive mitigation efforts. Therefore, in Gavi 5.0, efforts will be made to incentivise countries to select the most appropriate delivery mechanism to close immunity gaps, using both routinised and supplemental mechanisms (including campaigns as appropriate), based on country performance and immunisation programme maturity with a lens to long-term sustainability.

### Top risks somewhat outside of risk appetite – requiring ongoing attention

Seven top risks are currently assessed as being somewhat outside of risk appetite. Two of these are rated high – and somewhat outside of appetite – mainly because of their high potential impact, while their likelihood of occurrence is lower. This is the case for **e) Insufficient demand**, and **i) Donor support**. Since it is generally harder to mitigate the impact of a risk than its likelihood, such exposure may be more acceptable. However, it is important to monitor closely whether these risks increase in likelihood, which may move them more clearly outside of appetite and justify further and more intensive mitigation efforts. Another five are somewhat outside of appetite on the overall portfolio level, with variable levels of risk in underlying individual countries or markets. This is the case for **d) Sustainable transition**, **g) Misuse by countries**, **h) Polio disrupting immunisation** and **m) Global supply shortages**. The remaining risk **j) IT disruption** is currently still high but expected to decline due to ongoing mitigation efforts.

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

Exposures for the remaining group of top risks fall broadly within risk appetite. These are **f) Outbreaks disrupt immunisation**, **l) Partner capacity**, **n) HSIS value for money**, **o) Forecasting variability**, and **p) Secretariat disruption**. It should be noted, however, that the long-term outlook is expected to increase for **f) Outbreaks disrupt immunisation** (due to climate change, globalisation, urbanisation, and deforestation) and for **l) Partner capacity** (due to the increasing complexity of managing a broader partnership with more and new types of partners and more collaboration between global health actors). It is important to continue to monitor whether the risk will move at some point more outside risk appetite, and to discuss whether further mitigation is required before that point since implementation typically takes time.

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

### 3. Shifting risk exposures and risk appetite under Gavi 5.0

The Board recently approved the 2021-2025 strategy framework (“Gavi 5.0”) with the vision to leave no-one behind with immunisation, and discussions on its operationalisation are ongoing. Following a top risk re-assessment survey and multiple workshops in the Secretariat, this section shares some preliminary thoughts on how Gavi’s risk profile may shift under Gavi 5.0. It highlights potential new, shifted or reframed risks associated with important shifts in the new strategy and the Alliance’s operating model, as well as potential implications for Gavi’s risk appetite and important trade-offs that need to be balanced. The high-level results summarised below are grouped by a number of key strategic shifts that are perceived as important drivers of change in Gavi’s risk profile under Gavi 5.0.

#### Shift to focus on reaching zero-dose children, with a need to work more sub-nationally and in challenging environments

- Risks related to **country management capacity, data availability, quality and use** and **ability to reach the un(der)-immunised** will likely increase inherently. The ability to reach missed communities and zero-dose children will require new service delivery strategies and will likely require greater country management capacity, as well as more precise data to identify where unreached populations are and to measure the impact of interventions to reach them. As these three risks were already very high top risks during Gavi 4.0 and remained outside of risk appetite, Gavi will need to further enhance mitigation (building on lessons from this strategic period), or revisit its risk appetite and explicitly accept what is outside of its control. Furthermore, the strategy’s enhanced focus on demand, communities and gender will be critical to manage risks related to **insufficient demand**, including vaccine hesitancy, with demand generation becoming even more important to achieve the equity agenda and reach missed communities.
- Risks related to **funds absorption and funds flowing to the service delivery level** and **misuse and wastage of support** will likely increase inherently due to weak financial and programmatic management capacity in remote areas, underserved communities and challenging operating environments, where many zero-dose children live. A reframed or higher fiduciary risk appetite may be required in some areas to reach zero-dose children and to enhance financial management capacity and fund flows. Gavi may need to better articulate trade-offs between fiduciary risk mitigation, programmatic needs, sustainability (including building financial management capacity) and country ownership, and approval and disbursement timelines.
- Risks related to **health systems strengthening, partner capacity** and **expanding partnership complexity** will likely increase inherently. There is a risk that HSIS allocation may not be sufficient to deliver on the Alliance’s equity ambition or cover the increased costs of working in more challenging contexts. There may also be risks around changing partners’ traditional technical assistance (TA) approaches in line with the strategic shifts, as well as risks related to accountability, coordination and measurability of cross-cutting TA priorities like equity in a broader partnership that is more complex to manage with more expanded and private sector partners and new types of partners (e.g. international non-governmental organisations) in conflict environments. The strategy operationalisation workstream on reviewing the Alliance partnership model will be critical in mitigating these risks.

#### Shift to support vaccines with a need for new immunisation touchpoints, enhanced support for countries in prioritising vaccines, and enhanced focus on outbreak preparedness and response

- New Vaccine Investment Strategy (VIS) vaccines are moving beyond the traditional focus on infant and second year of life vaccination, to vaccination across the life-course (e.g. birth, 2nd year of life, school entry, adolescence, pregnancy). This exposes the Alliance to new risks related to **sustainable uptake and coverage of VIS vaccines**, particularly for those vaccines without established contact points (i.e. schools) or with programming with insufficient coverage (i.e. birth). The strategy’s enhanced focus on supporting countries in prioritising vaccines appropriate to their context will be critical to mitigate the risk



of **vaccine introduction decisions** not being suitable for epidemiologic, economic or programmatic reasons. In addition, removal of the programme filter that requires meeting a coverage threshold before introducing new vaccines (to be discussed at this Board) could create risks of weak countries introducing new vaccines and exacerbating inequities by reaching already covered children with new vaccines while continuing to miss zero-dose children. Ensuring that vaccine-specific criteria for introduction are established at the operational guidance level will be critical to mitigate this risk.

- Gavi 5.0 recognises a stronger role in Global Health Security (GHS) with a particular focus on stockpiles to mitigate the risk of **disease outbreaks**, which are on the rise due to climate change, globalisation, urbanisation and deforestation. Gavi may need to better articulate its appetite for the risk of outbreaks given limited disease surveillance capacity and investments, as well as potential interdependencies between outbreaks, preventive campaigns, and routine immunisation.

#### Shift to increased focus on programmatic sustainability, and institutionalising post-transition support

- Risks related to a **sustainable transition** of countries out of Gavi support and potential back-sliding post-transition will likely decrease further with post-transition support being institutionalised and an increased focus on programmatic sustainability under Gavi 5.0. This includes a focus on early dialogue for transition and programmatic sustainability and requires that countries deliver immunisation in a sustainable manner, programmatic approaches are efficient and cost-effective, and there are strong institutions to maintain performance after transitioning.

#### Shift to more differentiated, tailored and targeted support for countries, and enhanced focus on innovation and collaboration

- There is a risk that **Gavi's operating model**, including competencies, processes and resourcing across the Alliance will not be fit for delivering on 5.0, as this requires more differentiated and tailored approaches at the subnational level, strengthened accountability of Alliance partners, more coordination and collaboration with other health actors, and the ability to respond quickly in fragile environments and emergencies. Gavi may need to better articulate its risk appetite related to a lean Secretariat without in-country presence, and with respect to providing **differentiated country support**, in particular whether it is willing to accept more risk in lower priority countries with lower resourcing and less (fiduciary) oversight and engagement.
- Reaching zero-dose children will require countries and the Alliance to develop and test new approaches, without certainty that they will be successful, and potentially at higher costs. Gavi may therefore need to better articulate its appetite for the inherent risk of **innovation failing** and investments not always providing **value for money**. A more deliberate approach to innovation will be critical to mitigate risks related to the inability to **scale up and sustain innovations** in country, as well as risks related to private sector partnerships, e.g. conflicts of interest and reputational risks.
- The strategy's focus on better **collaboration and coordination across health actors** will be critical to leverage the immunisation platform to strengthen primary health care (PHC) and achieve synergies across different components of health service delivery. However, there may be a risk that inefficient coordination and accountability for multisectoral approaches across multiple organisations may slow down Gavi's impact, as well as potentially increase the administrative burden and transaction costs for countries. It can also create a dilution of focus, being unable to prioritise effectively between many different objectives from various actors with varying perspectives and interests.

This preliminary assessment suggests that **Gavi's overall risk profile under Gavi 5.0 is inherently increasing**, while new approaches are being developed as part of the operationalisation of the 5.0 strategy to bring residual risk exposures within risk appetite. It also may require a different risk appetite in some areas, with an explicit understanding of what Gavi accepts as being outside of its control. The Risk function continues to be involved with relevant strategy operationalisation workstreams. It is furthermore anticipated that risks and

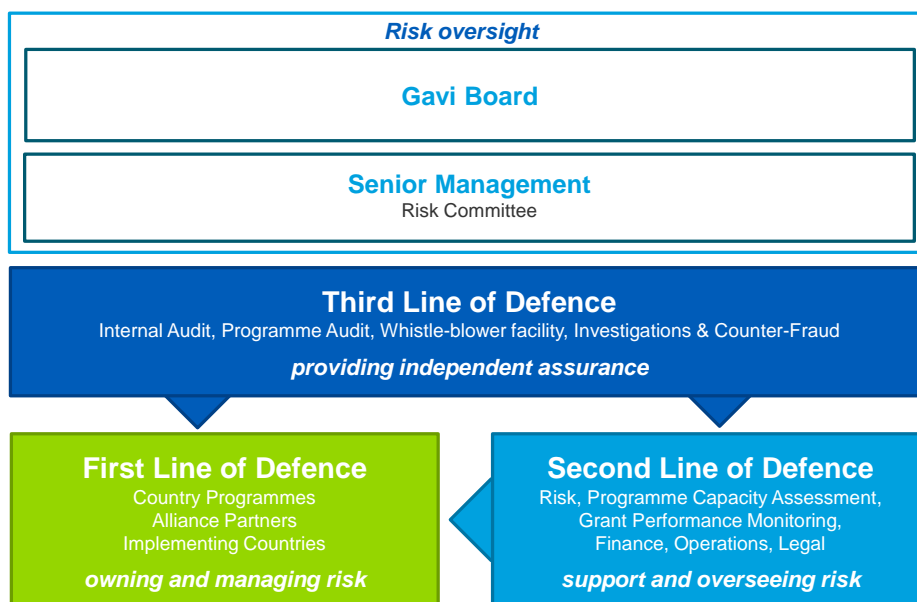
risk appetite implications will be highlighted and discussed as an integral part of other Board discussions on strategy operationalisation over the coming year. The 2020 Risk & Assurance Report will capture these discussions and (being issued immediately before the start of the new strategic period) present an updated set of top risks for Gavi 5.0. As required the risk appetite statement may also be updated to appropriately reflect risk and reward trade-off discussions.

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

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

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

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



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

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

*The current model will be reviewed in preparation for Gavi 5.0, based on learnings and in line with the latest Secretariat structure and potential future changes to the operating model.*

## Annex II – Gavi’s Risk Appetite Statement

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

### Gavi’s Risk Appetite Statement

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

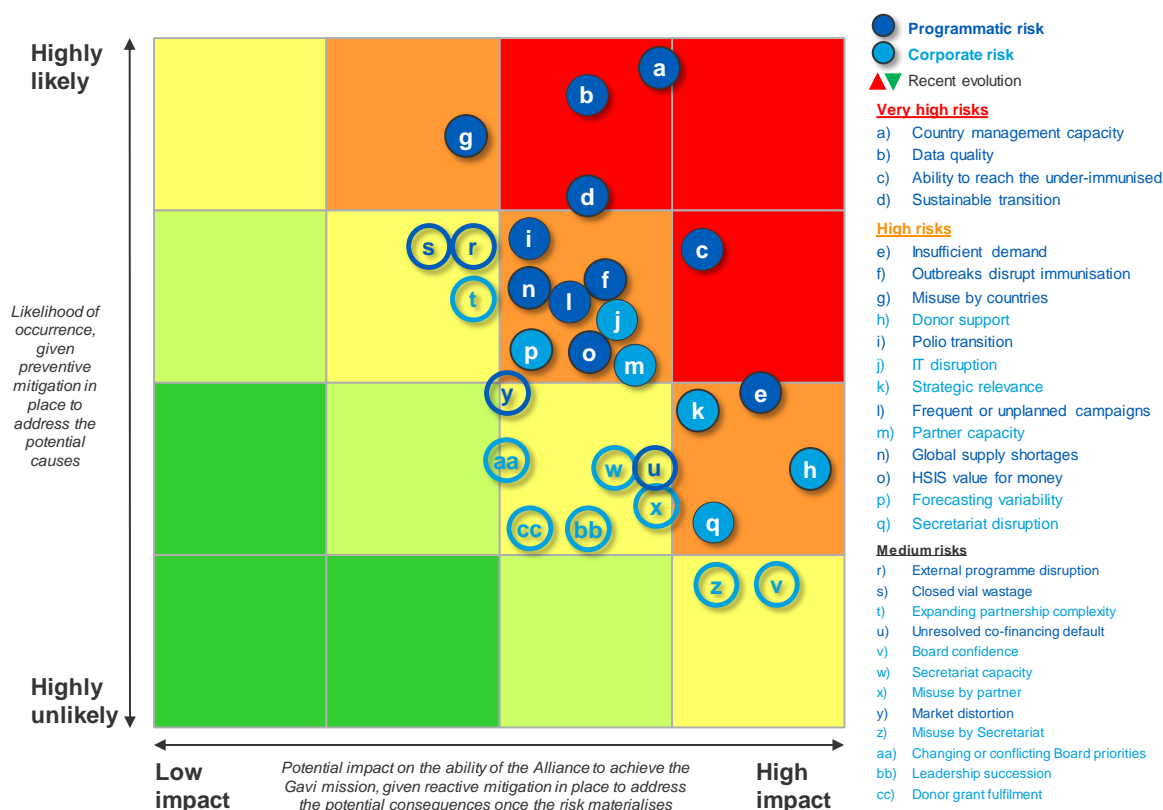
<b>Mission &amp; Organisation</b>	The Alliance embraces the need to take <b>programmatic risk</b> given its ambitious mission and operating model, but has a <b>lower appetite for organisational risks</b> impacting Alliance processes, systems and management; fiduciary oversight and control; and brand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

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

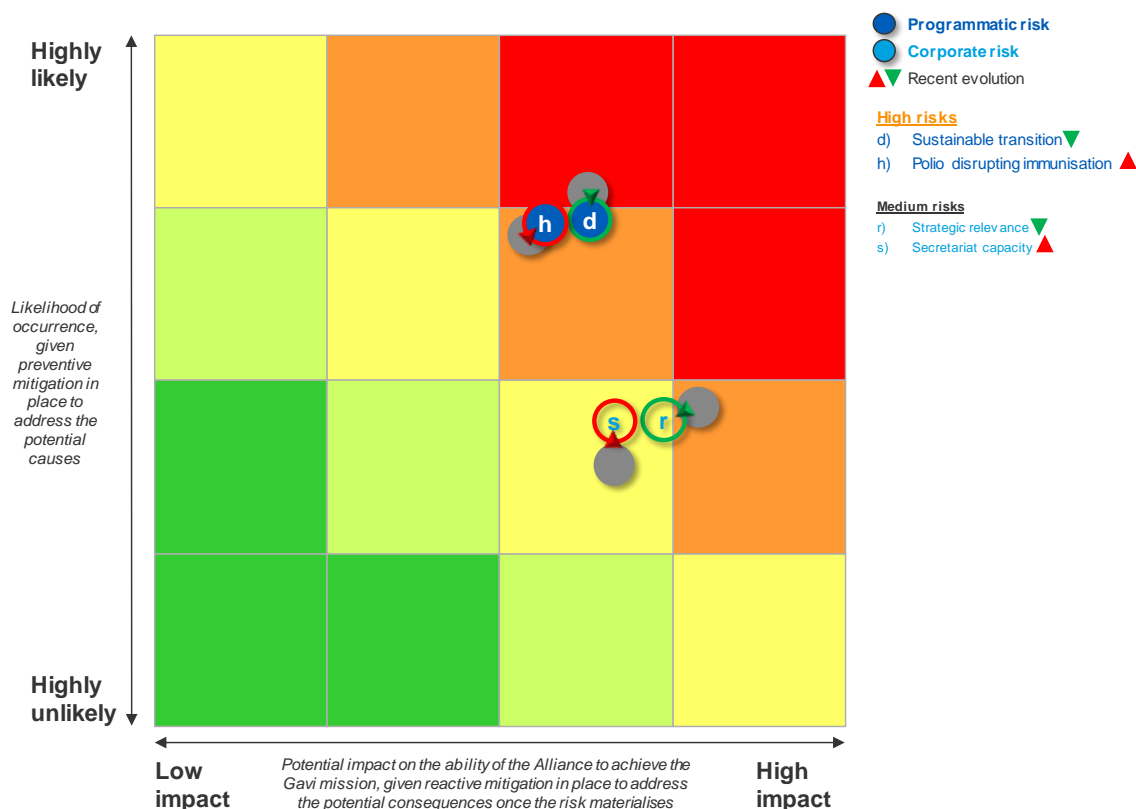


## Annex III – Last year's top risk profile and trajectory of changes this year

### Alliance top risks ranked against likelihood and impact 2018 residual risk exposure, taking into account existing mitigation



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



## Annex IV – Individual top risk descriptions

### a) Country management capacity

*Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a	<b>Country management capacity</b> Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption</li> <li>Disease outbreaks disrupting immunisation</li> <li>Political change (devolution)</li> </ul>			OUTSIDE		

The Alliance is working in the poorest countries in the world, many of which face fragility challenges. Naturally, many Gavi countries have weak management capacity, even more so at subnational levels. Existing capacity can also easily be disrupted due to instability, shocks or political change (such as devolution), or due to retention challenges. Developing sufficient and robust national and subnational capacity to manage immunisation programmes is crucial for countries to achieve improvements in coverage and equity, manage Gavi support, and to be ready for a sustainable transition out of Gavi support. The impact of (continued) weak capacity in areas such as leadership, management and coordination, technical and policy decision-making, 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.

Gavi continues to assess capacity-building needs that can be addressed with Gavi support through a range of tools including Joint Appraisals, Programme Capacity Assessments, Effective Vaccine Management assessments, Transition Assessments and country visits. Furthermore, there has been a steady increase in demand from countries for technical assistance to improve leadership and management capacities in the Expanded Programme on Immunisation (EPI) unit (with embedded management support and performance management strengthening), to strengthen country coordination fora for immunisation (revising mandate, membership and oversight function of national Inter-Agency Co-ordinating Committee (ICCs)), and to enhance financial management (some capacity building measures were initiated and discussions on collaboration with the World Bank and the Global Fund are underway). By the end of this year, 39 countries will be benefitting from Leadership, Management, and Coordination (LMC) support (with sub-national interventions in 5 large, federated countries). The most promising interventions include institutional restructuring of EPI units, embedding project managers to set up a data-driven EPI performance management system, and providing management training programmes. The LMC approach will be refined based on an independent review of early learnings to allow better integration and targeting of interventions, and to understand which interventions work best with a proven theory of change and which are scalable and sustainable.

Current exposure to this risk remains very high. At an aggregate level, performance frameworks, country risk assessments and institutional capacity scores show slight improvements, in particular in countries with LMC interventions. However transformative change has yet to be made as investments at the EPI team level take a long time to take effect and depend on government ownership and basic capacity (or lack of it). Broader efforts across the health sector are also necessary for more sustainable mitigation, and gains can be easily lost due to vacant posts or high turnover of staff, as well as external programme disruption due to political change and disease outbreaks.

Current exposure remains outside of risk appetite and therefore continues to require intensive mitigation efforts. Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it

cannot accept a very high risk that EPI management capacity does not improve across its portfolio. Having sufficient national and subnational capacity to manage immunisation programmes and funding is crucial for countries to achieve improvements in coverage and equity, and to be ready for a sustainable transition out of Gavi support. New approaches under Gavi 5.0 (e.g. reaching zero-dose children, VIS vaccines) will require even greater capacity. The Secretariat is therefore planning to relook at the LMC approach in 2020 in preparation for Gavi 5.0 and will consider whether an ambitious scale-up is needed, including potentially increased investments, as well as increased collaboration with other key partners.

## b) Data quality

### *Continued lack of availability and use of quality data for immunisation*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>b Data quality</b> Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"> <li>Data quality not routinely monitored</li> <li>Weaknesses in data and measurement systems</li> <li>Fragmented initiatives without measurable outcomes</li> <li>Short time-frame improvement strategies</li> <li>Limited country-ownership &amp; sustainable technical capacity</li> <li>Limited attention to data use and the needs of end users</li> </ul>			OUTSIDE		

Many Gavi-supported countries have weak capacity to generate, report and use accurate data in critical areas such as programme data and disease surveillance. This can happen for many reasons, including a lack of coherent data systems with poor capabilities, ill-defined indicators and data points, and data collection challenges from the front line to the aggregation points in the data delivery chain. Useful data may not be shared with decision-makers due to a lack of a reporting system, incentives or a culture of data use. Data is often not leveraged to improve service delivery and can also be deliberately manipulated due to perverse incentives, including in the establishment of denominators that are critical to accurate reporting. Persistent challenges with the quality and use of data can lead to misinformed decision-making at all levels, from poor planning of supply and delivery of vaccines, to misallocation of Gavi support, and the inability to accurately measure and demonstrate impact. It also increases several other risks, such as misuse of Gavi support, closed-vial wastage, disease outbreaks and insufficient demand. Improvements are important in order to deliver on all four of Gavi's strategic goals, as well as for strong ongoing programme monitoring and evaluation.

Gavi continues to work with countries, core and expanded partners to strengthen the availability and use of quality data for immunisation. The Secretariat has institutionalised an enhanced focus on data in its grant management processes, particularly through the Grant Performance Framework, and partners have incorporated data programmes into technical assistance and capacity-building initiatives. A partner coordination group is active with a joint vision and strategy, and it regularly monitors progress and discusses risks in the areas of data for coverage and equity, surveillance and safety. Cross-cutting Data Strategic Focus Area (SFA) investments, combined with PEF TCA, LMC, and HSS grants, continue to support countries' transition to electronic district health information systems, led by efforts to implement and improve DHIS2 which has been implemented in more than 50 countries with immunisation programme data integrated in over 30 countries, and a further 25 countries now being assisted in various stages of roll-out. Gavi has supported the creation of additional DHIS2 functionality to support immunisation data strengthening, triangulation and analysis including an immunisation e-tracker, improved mobile phone applications, and vaccine preventable diseases (VPD) surveillance. Routine analyses are now produced at the district level to inform planning and reviewing of routine immunisation activities, and the Secretariat is triangulating coverage estimates and country-reported data against supply data (shipment and receipt). Expanded partners are developing sub-national data improvement intervention guidelines (e.g. triangulation at subnational level), and innovative training solutions and e-supervision is in progress. Furthermore, additional special investments are in progress to strengthen monitoring of global immunisation performance to inform dialogue with national governments and manage accountability, enable better planning and implementation of immunisation activities to support

evidence-based decisions and system efficiencies, and develop stronger methodologies of data collection to capture unimmunised populations to enable design of targeted equity-orientated interventions. Effectiveness of interventions are monitored, and additional learning and evaluation of specific investments generated. Within the Gavi 5.0 broader country segmentation, segmentation of countries based on the strengths of data and information systems has started, with different data risk mitigation strategies proposed according to the typology of countries. The learnings from these efforts will contribute to a refreshed strategy for the Data Strategic Focus area in 2020, which along with continued partner coordination and technological improvements, will contribute to mitigating the risk.

Current exposure to this risk remains very high, but is expected to decrease slowly over time as mitigation efforts – both building more robust data systems and creating a culture of data use and data-driven decision-making – take time to have an effect and require country level political will, and the Alliance's investment in data is limited compared with the level of inherent risk. The number of countries meeting the data quality criteria, which seek to institutionalise data strengthening efforts, has decreased slightly from 27 of 57 countries in 2017 to 26 in 58 countries in 2018, declining from 47% of reporting countries to 45%, equivalent to the 2015 baseline. But country compliance with Gavi's data quality requirements has increased. In 2016, only 10 countries had a data improvement plans, whereas now 19 countries have developed a strategy for data strengthening which are costed and funded. There are also still challenges with the lack of longer-term strategic planning and sustainability, as well as absorptive capacity of countries and the need to focus on data use and analysis, which is not the traditional focus of countries and partners providing technical assistance. A longer-term vision that is attentive to the multi-year and multi-pronged approaches necessary to achieve real improvements in the space is necessary.

Current exposure remains outside of risk appetite and therefore continues to require intensive mitigation efforts. Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that data availability, quality and use do not improve across its portfolio. Given that immunisation now reaches most of the population in Gavi countries, achieving coverage and equity goals increasingly requires a "precision public health" approach with more precise data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. This will be even more true in Gavi 5.0 with the enhanced focus on reaching zero-dose children. Furthermore, the Alliance is dependent on data for decision-making at all levels, planning of supply and delivery of vaccines, allocation of Gavi support, and the ability to accurately measure and demonstrate impact. The Secretariat is therefore planning to identify which parts of the risk are inherent (and would likely remain a challenge for a long time) and which parts can be mitigated further, to better define a realistic risk appetite. It will also develop thinking on the ideal level of investment in the context of Gavi 5.0 to bring the risk within that risk appetite.

### c) Ability to reach the under-immunised

*The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>c Ability to reach the under-immunised</b> The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached	<ul style="list-style-type: none"> <li>Poor data to find and target the unreached</li> <li>Inadequate supply and cold chains into remote areas</li> <li>Insufficient health care workers</li> <li>Lack of demand in underserved communities</li> <li>Lack of political commitment and health budgets</li> </ul>			<b>OUTSIDE</b>		

Gavi's initial focus on reducing inequities between countries by bringing new vaccines to the poorest countries has now expanded to include improving the equitable coverage of immunisation within countries in order to reach every child. This requires immunisation services to reach every community, including building out the



service delivery infrastructure, supply chain, and data systems, and generating demand and ensuring funds flow to previously underserved communities. Reaching the under-immunised depends on Gavi's ability to identify and scale-up access for the remaining pockets of under-immunised children (an estimated 25–50% of all under-immunised children are “zero-dose children”), who are increasingly in under-served areas such as conflict areas, remote rural communities or in urban slums. This ability can be hindered by shortages of frontline health workers, poor infrastructure including the absence of health facilities and adequate supply chains, weak programme management and accountability, poor data, weak institutional capacity, social, cultural and gender barriers, conflict, political turmoil and mass population displacement. These barriers often go beyond the immunisation programme itself, requiring political commitment to reach neglected populations that are often underserved by a broad range of public services.

The Alliance has been scaling and reinforcing its tools and approaches to identify and reach the under-immunised. In the last 12 months, this has included revisiting the approach to supporting countries to conduct coverage and equity assessments; launching a new demand hub and Strategic Focus Area to strengthen our understanding of demand-side barriers to immunisation and scale-up innovative practices to address these; and beginning to develop a more strategic approach and new programming guidance to inform investments in human resources for health (an important enabler of coverage and equity not focused on historically). Furthermore, the equity lens has been applied into all processes, including HSS grants (over 70% of which today include specific targeting to geographies or populations with lower coverage or large numbers of under-immunised). The Alliance is also supporting countries to develop more robust and comprehensive theories of change for how they will improve coverage and equity, using all levers of Gavi support. There is significant demand from countries for the HSS flexibilities approved by the Board in 2018, with 23 countries from 26 country applications received already approved by the IRC using a strong focus on coverage and equity bottlenecks as key review criteria. Flexibilities under the Fragility, Emergencies and Refugees policy are used to further address potential coverage and equity bottlenecks in fragile and emergency countries. Partners have scaled up their capacity to support countries with over 340 WHO and UNICEF staff in country offices funded through the Partners' Engagement Framework and countries are also increasingly requesting technical support at the subnational level. Within the Secretariat, the Accelerating Coverage & Equity (ACE) group has continued to lead deep dives on specific countries, which has helped to unlock bottlenecks and to bring focus on some core cross-cutting issues (e.g., fragility, pooled funds) to help develop new thinking and approaches.





Current exposure to this risk remains very high. In 2018, more children were immunised with three doses of pentavalent vaccine (penta3) and a first dose of measles (MCV1) than ever before, and since 2015, there has been a 6% reduction in the number of under-immunised and an 8% reduction in the number of zero-dose children despite a growing birth cohort. Despite this progress, Penta1 and Penta 3 coverage have each improved by only one percentage point over the strategy period so far, reflecting the challenge posed by population growth to increasing coverage rates. Furthermore, a growing number of the children who are under-immunised live in fragile settings – and fragile countries have seen coverage stagnate, due to the acute problems they face and because of rapid population growth – and many are displaced. These challenges are set to grow as the countries remaining in Gavi's portfolio are more likely to be fragile and conflict-affected and have weaker health systems. The number of children born annually will grow nearly twice as fast in these countries due to higher fertility rates. Further acceleration of progress is needed to achieve the coverage and equity goals by the end of the 2016–2020 period.

Current exposure remains outside of risk appetite and therefore continues to require intensive mitigation efforts. The Alliance has a low appetite for the risk of not being able to achieve equitable coverage improvements, since this is key to its mission. It recognises that improving coverage and equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations and that this often requires political (as well as technical) change, which goes beyond the immunisation programme. Given the aspiration of the Gavi 5.0 strategy on equity as an organising principle

(as opposed to just coverage), the Alliance will need to develop new ways of working to deliver on the ambition of reaching unreached communities and zero-dose children.

#### d) Sustainable transition

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

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

Gavi support is intended to be time-limited and catalytic. Countries are therefore expected to finance a growing share of the cost of their programmes as their gross national income (GNI) approaches the eligibility threshold, while the share of country co-financing increases until they are fully self-financing. Both programmatic and financial sustainability are key elements to support successful transitions from Gavi support. This model is being tested at scale for the first time during the current strategic period with approximately 18 countries projected to have transitioned by the end of 2020. Failure to successfully transition or a regression after transition would diminish the return on Gavi's investments and could have an impact on Gavi's reputation and the perceived viability of the model. Furthermore, it may affect manufacturers' pricing decisions for countries post-transition if they perceive a higher risk that countries will not sustain their programmes.

Gavi's approach to sustainability has evolved considerably over previous strategic periods, and now clearly emphasises the importance of engaging early with countries to build and strengthen the financing, systems, and capacities needed to deliver on sustainable coverage and equity. These issues are now more firmly embedded into different Gavi systems and processes (e.g., Joint Appraisal's, TCA support, Full Portfolio Planning), which promotes a more comprehensive approach to sustainability from the beginning of a country's engagement with Gavi. All transitioning countries have a transition plan with active support and monitoring. Among countries that will transition but were identified by the Board as being at high risk for transition, tailored strategies have been developed and Board-approved for Nigeria and Papua New Guinea, with Accountability Frameworks being developed. Gavi is now also working with countries to prepare them to undergo the transition process before they enter the accelerated transition phase. For example, in Cote d'Ivoire (expected to enter accelerated transition phase in 2022), Gavi has been engaging with the government, partners, and other domestic stakeholders through the Full Portfolio Planning Process to map any remaining political, health system and capacity constraints, and to provide tailored and targeted support. This integrated approach should further ensure that Gavi's support is well designed and coordinated to enhance sustainable coverage and equity. A forum to facilitate the exchange of knowledge and best practices among transitioned and transitioning countries has been established, and joint capacity-building on health financing and transitions, done alongside the World Bank and the Global Fund, has been designed and piloted. The GAP Financing Accelerator promotes harmonisation of different global coordination processes, which should improve their effectiveness. Furthermore, Board-approved tailored approaches to mitigate post-transition risks in Angola and Timor-Leste have been developed, while Congo Republic, due to the significant drop in its GNI per capita, became Gavi-eligible again in 2019. Other countries that transitioned with high coverage and strong financing performance may still have specific challenges linked to their institutional development. Recognising this, the Board approved an approach to post-transition engagement at its November 2017 meeting, and the Alliance is now actively working with transitioned countries to mitigate these residual risks through time-limited, catalytic support. Eight out of fourteen eligible countries (excluding Angola, Timor-Leste, which are being addressed through tailored strategies per above, and Uzbekistan and Nicaragua, which are transitioning only at the end





of 2020) have applied successfully for post-transition support, and additional support is under development and review.

Current exposure to this risk has decreased from very high to high. By now, 15 countries have transitioned out of Gavi support out of the 18 projected to do so in this strategic period. Most are performing well, as evidenced by continuing high or improving coverage levels, and the risk to the sustainability of their programmes is low. Furthermore, the new Gavi 5.0 strategy also represents an important evolution, clearly incorporating programmatic sustainability as a core element of Gavi's approach and exploring how programmatic sustainability criteria should also be considered when determining timelines for countries' transition in the ongoing policy review. It will also institutionalise post-transition support while additional work is underway to more clearly identify programmatic theories of change, which should further strengthen the alignment and focus of Gavi's investments around financial and programmatic sustainability.

Gavi's Risk Appetite Statement expresses a moderately low risk appetite for countries reaching the point of transition without having built sufficient financial and programmatic capacity to sustain their programmes and for significant reduction in immunisation programme performance after transition. Although the Alliance does not have an appetite for the risk of *many* countries across the portfolio failing sustainable transition, it also recognises that it cannot completely guarantee that every country is ready to transition, in spite of its best efforts, and to avoid the risk of moral hazard. It is therefore willing to consider tailored approaches to support countries who are at high risk of not being ready for transition and have strong political commitment to immunisation, but it is also willing to consider a few countries failing where this is not the case (and therefore has a higher appetite for the risk that a *limited number of countries* may not transition successfully). The current high risk exposure for *some countries* failing sustainable transition is still somewhat outside risk appetite, but may come within appetite as we start seeing the impact of the new approaches discussed above.

#### e) Insufficient demand

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

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
e	<b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation	<ul style="list-style-type: none"> <li>Lack of knowledge / social norms</li> <li>Mistrust or fear (due to safety issue or hesitancy)</li> <li>Not actively prioritised / complacency</li> <li>Poor access to convenient and acceptable health services</li> </ul>			<b>SOMEWHAT OUTSIDE</b>		

Active demand for immunisation by communities and other caregivers is critical to ensure that every child is immunised. It can be affected by vaccine hesitancy (which ranges from accepting only some vaccines to delaying to outright refusal) as well as being insufficient for parents to actively seek immunisation at the health facility 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 policy-makers. Adverse events following immunisation (AEFIs) can also rapidly undermine confidence in vaccines, especially without capacity to respond robustly to AEFIs with adequate crisis communications and social media management. Rumours and anti-vaccine sentiment, typically based on misinformation, can spread rapidly on social media and are often actively promoted by anti-vaccine movements driven by ideology, religion, false beliefs, and increasingly political or commercial motives, against which traditional vaccine science-based responses are ineffective. Gavi countries may not be well-equipped to manage a concerted anti-vaccine campaign. Populations may be particularly susceptible to negative messages about vaccines with which they are less familiar or linked to sensitive issues (e.g. HPV, for which even transitioned countries with strong programmes (e.g., Georgia, Armenia) have seen significant demand-side challenges) or for which the disease incidence is becoming rare (e.g. polio). Demand

can be hindered by lack of knowledge about the value of vaccines, lack of prioritisation or complacency, or lack of convenient access to health facilities. In areas that have been the focus for many immunisation campaigns, households may become accustomed to services being delivered at their doorstep and therefore less willing to actively seek immunisation at a health facility. Similarly, poor service quality, long waiting times, a lack of toilets or distance from facilities may deter some families from seeking immunisation.

A significant drop in demand for vaccines or an insufficient increase in demand among those who are not yet actively seeking immunisation, would have a significant impact on Gavi's ability to achieve its coverage and equity ambitions. Lack of demand can adversely impact vaccine introductions and / or coverage, which in turn leads to increased morbidity and mortality and reduced programme impact. A drop in demand or less actual demand than planned can furthermore lead to programme delays and vaccine wastage. Gavi could also face reputational challenges and Alliance staff could become the target of extreme anti-vaccine movements. Ultimately, a significant and sustained loss of demand for vaccines could affect political will and reduce support among donor and implementing countries for Gavi's mission.

To address this risk, the Secretariat and partners are operationalising the new demand generation framework which includes building vaccine confidence and trust as a central component. A partner Demand Hub coordinates support to countries (including India, Pakistan, Nigeria and Indonesia), clarified partner roles and responsibilities, and agreed a roadmap with priority workstreams on digital interventions, service experience, equity and gender, CSO engagement and behavioural interventions. A Data for Demand expert group has been established to improve quality, analysis and use of metrics and to develop quantitative and qualitative tools. Partners are reviewing country risk communication plans and preparedness, and interpersonal communication skills training package will be rolled out to countries and as well as journalist training for post transition countries. The Alliance is adopting a new integrated approach to communities, demand and gender, with recruitment of focal points for CSOs and gender, and adapting or developing programming guidance for investments in demand-related areas. Furthermore, innovative private sector initiatives are being operationalised to test, learn and scale new demand approaches (e.g., the pilot phase of the Unilever partnership has successfully raised coverage rates and partnerships with Girl Effect (on gender) and Audacious (tech-enabled front line workers) are contributing to useful learnings). An open innovation platform ("be:cause") has also been launched to generate innovative ideas to build trust and confidence in vaccines. Global media monitoring and social listening intelligence is shared, and more systematic and innovative global and regional approaches are being explored. A crisis protocol and response group stand ready in case of sudden threat escalation. Finally, the Secretariat is engaged with partners on the emerging risk of fake vaccines.





Current exposure to this risk remains high mostly in terms of potential impact. Analysis of available data suggests that demand-side issues may be contributing more significantly to un- and under-immunised children than was previously understood – potentially up to two thirds. There also continues to be growing evidence of the impact of vaccine hesitancy globally, especially in developed countries (e.g. 98 countries reporting an increase of measles cases in 2018, and Albania, Czech Republic, Greece and the UK having lost their eradication status), and global awareness of the issue is increasing (WHO has named vaccine hesitancy as one of the world's top ten global health threats, and social media companies such as Facebook and YouTube are now actively working to prevent misinformation regarding the effectiveness and safety of vaccinations). Furthermore, the growth in vaccine doses supported by Gavi over the coming years, combined with a focus on reaching remote areas with weaker health systems, increases the risk of an episode with serious AEFIs. Additionally, while anti-vaccine campaigning remains mostly contained within the US and related risks seem higher in developed countries, campaigners are seeking to target other countries and some attempts have been made to reach out internationally. Civil society organisations and Ministries of Health continue to highlight vaccine hesitancy as a major risk, with concerns growing about anti-vaccine sentiment in countries such as the US, the UK and continental Europe spreading through online communications and having an impact in

Gavi countries. The Strategic Advisory Group of Experts on Immunization (SAGE) is tracking indicators to assess vaccine hesitancy worldwide as part of the Global Vaccine Action Plan (GVAP), which showed that only seven countries reported a complete absence of hesitancy, indicating that the issue has become a truly global challenge. An emerging concern is the number of vaccine-derived poliovirus (VDPV) outbreaks in countries such as Indonesia and Philippines (see also the risk of “Polio disrupting immunisation”) being covered on global news channels, with the continued use of the descriptor ‘vaccine-derived poliovirus’. This could potentially become a lightning rod for anti-vaxxers to seize upon continued use of a vaccine that has the potential to itself paralyse unprotected children.

The Alliance has a low appetite for the risk of a sustained decline in demand and public confidence in vaccines in implementing countries, or in donor countries where this might impact their support to Gavi. Because current exposure is high due to potential impact rather than likelihood, the risk is currently only somewhat outside risk appetite. However, it is important to monitor closely whether the risk increases in likelihood especially in Gavi countries, which may move it more clearly outside appetite and justify further and more intensive mitigation efforts.

## f) Outbreaks disrupt immunisation

*Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>f Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Climate change, urbanisation, deforestation, globalisation, migration and human displacement, population growth</li> <li>Low population immunity, anti-microbial resistance</li> <li>Lack of capacity/tools to detect, prevent and respond</li> <li>Population behaviour, vaccine hesitancy</li> </ul>			<b>BROADLY WITHIN</b>		

Outbreaks of infectious diseases are occurring with increasing frequency. Climate change is one of the drivers for this trend as the range of disease-transmitting insect vectors such as mosquitoes increases and climate-related disasters create the conditions for outbreaks (e.g., cholera). Furthermore, increasing urbanisation, globalisation, travel, and population movement make it easier for diseases to spread further and faster, and more difficult to control (e.g., by ensuring sufficient immunisation coverage). Together with deforestation, urbanisation and population growth is also increasing human exposure to zoonotic disease reservoirs as cities expand into more rural areas. There are unpredictable disease outbreaks from new pathogens or ones for which no current vaccine exists (such as Zika), and more predictable outbreaks of vaccine preventable diseases (VPD) for which Gavi provides support through stockpiles or routine immunisation. Both are exacerbated by weak country capacity for surveillance and disease diagnosis, and the latter also by low routine immunisation coverage and a reliance on outbreak response instead of prevention. Control efforts may also be hindered by the increasing trend of vaccine hesitancy and anti-microbial resistance. Disease outbreaks can be hugely disruptive as they usually require an intense response effort, diverting health care workers away from routine immunisation. In more serious cases, outbreaks can also cause broader economic and social disruption, interrupt the provision of health and immunisation services and significantly undermine confidence in the health system (including potentially in the effectiveness of vaccines). This impact can also spread to neighbouring countries and beyond as other countries manage the potential or actual spread of the disease.

Through its HSS grants, Gavi contributes to long-term efforts to increase the resilience of health systems and routine immunisation programmes, helping to make them more capable of withstanding, detecting (through robust disease surveillance) and responding to disease outbreaks (including through immunisation campaigns, social mobilisation and contact tracing). Disease surveillance is a key area for the Data Strategic Focus Area, and work is underway to implement support for strengthening yellow fever diagnostic capacity in Africa through a diagnostics procurement mechanism. The Gavi 5.0 strategy has a deliberate focus on disease surveillance and outbreak detection and response. Gavi also provides vaccine support for many diseases with outbreak



potential including measles, meningitis, cholera, yellow fever, typhoid, and polio. For many of these diseases, Gavi supports multiple elements of disease control including routine immunisation, preventive campaigns, and outbreak response (including vaccine stockpiles). The Fragility, Emergencies and Refugees policy provides flexibilities to conduct preventive immunisation for refugees. The Alliance also signed an advance purchase commitment to accelerate the availability of the Ebola vaccine (which has been instrumental in responding to the Ebola outbreaks in the Democratic Republic of Congo) and will discuss potential future support of Ebola vaccines during this Board meeting. Through the Coalition for Epidemic Preparedness Innovations (CEPI), the availability of vaccines to prevent or respond to outbreaks may also increase in the future.

Current exposure to this risk is high as Gavi-eligible countries remain particularly vulnerable to outbreaks since they are home to reservoirs for many diseases and often have weak public health capacity to prevent, detect, and respond to them. Moreover, global immunisation efforts are stagnating, in part because of population growth, with fertility rates the highest within fragile, displaced, extremely poor or conflict-affected communities (which are the hardest for health workers to reach), and countries with lowest coverage rates seeing growing birth cohorts. This year saw a worrying three-fold increase in the number of measles cases, following consecutive increases over the past two years. Many countries are in the midst of sizeable measles outbreaks, with all regions of the world experiencing sustained rises in cases, causing many deaths – mostly among young children. The ongoing Ebola outbreak in the Democratic Republic of the Congo also continues to see substantial rates of transmission within the outbreak affected areas of the North Kivu and Ituri provinces, extending to new high risk areas and, in recent months, across borders; there is a high risk of further geographical spread due to persistent delays in detection and isolation of cases, challenges in accessing some communities due to insecurity and pockets of community reticence, and population movement. Given the devastating impact on the overall health system due to Ebola, the majority of deaths witnessed are due to lack of access for prevention, treatment and care for other diseases. Outbreaks of other diseases from new pathogens are also increasingly occurring with the potential to be disruptive for health systems and immunisation programmes. For example, in June 2018 there were – for the first time ever – outbreaks of six of the eight categories of disease in the WHO's R&D Blueprint list, which determines priority diseases with epidemic potential for which there are no, or insufficient, countermeasures such as vaccines.

Gavi continues to ensure that countries at-risk from VPD outbreaks introduce the vaccine, and continues to emphasise the importance of preventing, rather than responding to, outbreaks with in-country coordinating bodies and partners. However, fully addressing the significant gaps in Gavi-eligible countries' health systems and critical public health capacities, particularly in a short time-frame, would require engagement beyond Gavi's current mission and resources (although a stronger role in global health security is part of Gavi 5.0). Furthermore, outbreaks due to new pathogens are beyond Gavi's capabilities to anticipate or intervene. The Alliance therefore accepts that there is significant risk that outbreaks may continue to impact routine immunisation, and current exposure is therefore within its risk appetite. The Alliance has a lower appetite for the risk of outbreaks of diseases for which Gavi provides vaccine support and for outbreaks having a sustained adverse impact on routine immunisation coverage after the outbreak is over.

## g) Misuse by countries

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

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

Gavi uses country systems (supply chains for vaccines and financial management systems for funds) whenever possible, in order to ensure country ownership of programmes (and encourage commitment, accountability, budget visibility, and domestic and donor funding harmonisation and alignment) and to build the sustainable capacity of countries to manage those programmes, which is critical for development especially as countries approach transition. However, as the Alliance works with the poorest countries in the world, many have weak systems, low capacity, poor governance and management, and / or prevailing corruption, and this exposes the Alliance to the risk of its support being misused (deliberately as well as by mistake). The inherent risk is particularly high for cash programmes which account for 25-30% of Gavi's programmatic expenditure – the remainder being vaccines procured through UNICEF (vaccines are less prone to theft and diversion, due to a lack of secondary markets and the need for a sophisticated cold chain to manage them). Inherent exposure is increasing – both due to the increase in the value of cash grants (which are forecast to reach US\$ 1.3 billion 2016-2020) and the increasing concentration of those grants in countries with weaker systems (as stronger countries transition). Misuse can have a financial cost to Gavi if not reimbursed and it reduces the programmatic impact of its investments. It can result in the suspension of cash support to countries, undermining their programmes, and create significant transaction costs to manage that support and address fiduciary risks. Significant or sustained cases of misuse can impact the reputation of the Alliance, potentially undermining donor and Board confidence. Misuse can also be an indicator of weak overall systems which may impede countries' ability to effectively manage their programmes and successfully transition out of Gavi support.

To manage this risk, the Secretariat has strengthened grant oversight by Senior Country Managers and budget, expenditure and financial reporting reviews by a specialist Programme Finance team. Furthermore, before a new grant cycle starts, Programme Capacity Assessments (PCAs) assess a country's capacity to manage support and, together with other intelligence (internal knowledge of the country context and risks, internal and external audit reports, and external assessments if available), these inform Gavi's grant management requirements (GMRs) and fiduciary measures. When government systems are insufficiently robust, Gavi can require strengthening measures to ensure strong fiduciary monitoring and assurance. These can be conditional to disbursement and / or to be addressed during implementation. For countries that lack basic capacity, Gavi can also decide to channel funds through alternative channels, while continuing to strengthen country systems with financial management capacity-building, so the Alliance can revert to using them. Historically, core Alliance partners have been used for this purpose, but Gavi is currently testing alternative fiduciary risk mitigation models, complementary to the programmatic role of core partners, that can provide more embedded fiduciary monitoring and assurance, potentially with capacity-building (an independent assessment of models is planned to inform potential scale-up during Gavi 5.0). In an increasing number of countries, a 'hybrid' approach is adopted, whereby low-risk grant activities are channelled through governments, while high-risk activities (such as procurement) are channelled away until higher levels of assurance on country systems can be obtained. Gavi also aims to more deliberately leverage and reinforce countries' own capacity, by engaging with Ministries of Finance, Budget and Planning, ensuring that all Gavi funds are "on-budget" to ensure they come under the oversight of national assurance mechanisms, and ensuring strong government oversight mechanisms and robust external audits by national audit institutions or recognised contractors (e.g., the Secretariat commenced engagement with the supreme audit umbrella





organisation for the Anglophone African countries AFROSAI-e). As GMRs are being implemented by countries and tracked by SCMs, the PCA team have moved the focus to carrying out follow-up Monitoring Reviews to assess progress on implementation of agreed action points to ensure that national systems continue to be robust enough to meet fiduciary requirements. Furthermore, Programme Audits are conducted periodically with higher risk programmes being covered more frequently. Gavi also has an anonymous and confidential whistle-blower hotline to which anyone can report suspected wrongdoings, and has a dedicated fraud investigator to follow up on any suspected cases.

Current exposure to this risk is high, mostly in terms of likelihood given the inherent risk in Gavi-supported countries. It is less high in terms of potential impact, given the limited inherent exposure with cash support programmes only accounting for 25-30% of programmatic expenditure, and due to Gavi's zero tolerance policy when it finds actual misuse, which ensured that to date close to 100% payments have been received against scheduled reimbursement for misuse found by Programme Audits. However, audits continue to identify persistent financial management weaknesses in many Gavi supported countries. Analysis suggests that procurement and campaign activities account for over 60% of misuse found. To some extent these are symptoms of the light-touch approach of the past (as audits are retrospective), and identification of these weaknesses helps strengthening country systems and fiduciary oversight (e.g., Monitoring Agents are now recommended for larger campaigns, and procurement, principally for Cold Chain Equipment or Rehabilitation, continues to be outsourced) – and therefore reduce residual risk going forward. There are some very initial indications that two repeat audits where additional risk assurance investments were made (using monitoring and fiduciary agents) showed improved audit conclusions. While significant enhancements in fiduciary measures have been implemented, it also has become clear that there are limitations to Gavi's current approach to managing fiduciary risks, including channelling still a significant portion of funds through Alliance partners in many countries (on average 69% between 2015-2018, with 39% for fiduciary reasons). This arrangement has worked well in several settings (e.g. in countries facing emergencies or fragility) and for certain activities (e.g. for managing procurement activities), however, the scope and quality of partners' fiduciary assurance can be inconsistent across the Gavi portfolio and sometimes insufficient. Based on guidance from the Board in November 2018, Gavi continues to explore alternative mechanisms to enable funds to flow through governments. The current forecast sees the overall proportions channelled to partners reducing over time, but the solution space will be constrained by appetite for fiduciary risk and the level of ambition to build financial management capacities in countries.

Current risk exposure is still somewhat outside risk appetite. The Alliance has a preference to channel support through government systems when these are sufficiently robust and acknowledges that this comes with inherent risks. However, the Alliance has a low appetite for the risk of deliberate fraudulent misuse occurring, or for any form of misuse occurring at scale. When government systems are insufficiently robust, alternative mechanisms need to be used to ensure strong fiduciary oversight. Gavi continues to explore and test options that allow for striking a better balance between using and building country systems and staying within acceptable levels of fiduciary risk, as defined by the Board's risk appetite, including with technological innovations such as the use of mobile money. It is also pursuing increased collaboration with other development partners (such as the World Bank and the Global Fund) on broader strengthening of public financial management systems (an area broader than Gavi and immunisation alone), recognising that other organisations have a clear comparative advantage, and much larger financing, for this. Furthermore, Gavi 5.0 may require a redefined and more differentiated risk appetite for this risk (or a reframing of the risk itself, e.g. as unreimbursed misuse), given the aspiration of reaching zero-dose children and working more in challenging operating environments with very weak financial management capacity. Risk appetite implications of a more differentiated approach to portfolio management also need to be carefully considered and articulated, with analysis of current audit findings already showing slightly higher loss rates in lowest priority countries, linked to lower investment in oversight.

## h) Polio disrupting immunisation

*Polio resurgence or the winding-down of polio eradication operations adversely affects routine immunisation*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
h	Polio disrupting immunisation Polio resurgence or the winding-down of polio eradication operations adversely affects routine immunisation	<ul style="list-style-type: none"> <li>• Eradication challenges / Vaccine-derived outbreaks</li> <li>• Reliance on GPEI staff/assets, weak national systems</li> <li>• Delayed transition plans, incomplete polio asset mapping</li> <li>• GPEI funding cuts / uncertain fund-raising for new strategy</li> </ul>			SOMEWHAT OUTSIDE		

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

However, the eradication effort has experienced recent setbacks in Pakistan and Afghanistan where there has been a resurgence of wild poliovirus transmission (Nigeria has been polio-free since August 2016 and may be certified polio-free by mid-2020). In addition, in an increasing number of countries that have eliminated wild poliovirus, circulating vaccine-derived poliovirus (VDPV) type 2 (and some type 1) outbreaks are increasing. This is particularly the case in countries with low type 2 immunity, following the global switch from trivalent to bivalent oral polio vaccine in 2016 (and IPV providing individual protection but not preventing further spread). Outbreak response activities using oral polio type 2 vaccine risk themselves to cause further vaccine-derived poliovirus cases in under-immunised populations (especially in areas with poor sanitation and hygiene), until a new, more genetically stable vaccine is developed (there are two candidates under development). Potential increased emergence and spread of wild and vaccine-derived poliovirus would place a growing strain on donor and government budgets since they had been anticipating a ramp-down. It also 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 have an impact on Gavi's fundraising (with continued needs to resource the polio programme posing uncertainties for donor pledges to Gavi) and lead to reputational damage regarding immunisation (with Gavi now engaged through IPV and the Polio Oversight Board) if we fail to deliver the promise of a world free of polio.

The current situation also has the potential to further accelerate the wind-down of polio assets in some countries if resources need to be reprogrammed to respond to outbreaks. This further emphasises the need to better understand the contribution of polio assets to routine immunisation programmes and to determine urgently where gaps will arise if those activities cease (or where this presents an opportunity to strengthen routine immunisation by repurposing assets). Gavi's annual Joint Appraisals are including this information in country discussions to understand risks and opportunities to immunisation programmes associated with polio budget decreases and prioritise the functions they wish to maintain. GPEI's participation in Joint Appraisals,

particularly in endemic and polio high-risk countries, is encouraged by both partnerships. Through HSIS and PEF TCA, Gavi can provide time-limited bridge-funding support to countries to mainstream key functional areas of polio into routine immunisation programmes. While priority countries now have mapped polio assets, they have not always realistically captured the range of immunisation functions that polio is performing on the ground, and numbers will need to be updated with the adoption of the new GPEI strategic plan. Important country-level polio budget information and the impact on immunisation-critical functions are still not systematically incorporated into Joint Appraisal preparations and planning discussions.

Gavi's current exposure to this risk is high and increasing due to the number of cVDPV2 outbreaks occurring and the possibility that GPEI budget allocations will decrease without appropriate planning from national immunisation programmes and partners. There was an expectation that approval of the new extended Polio Endgame strategy (2019-23) would resolve some of the polio transition funding issues in the near term, but it is uncertain whether the plan will be fully funded. Furthermore, GPEI's outbreak response budget has been outstripped by more cVDPV2 outbreaks than anticipated, necessitating budget cuts in other areas, possibly affecting immunisation-critical resources. To respond more effectively to cVDPV2 outbreaks, GPEI counts on a new vaccine to be licensed that is more genetically stable with less risk of causing vaccine-derived poliovirus cases. While pre-clinical data is promising, it still must be proven in real-life circumstances, and, if no alternative delivery strategies are utilised than the current single antigen outbreak response campaigns, this could result in increased community resistance. Furthermore, the new vaccine will have regulatory and supply hurdles to overcome before it can be used. A negative impact from polio transition is more likely in a small number of fragile countries where the footprint of GPEI is relatively large and national systems are very weak. Chad, Somalia and South Sudan have been assessed as very high risk, and DRC, Ethiopia, and Sudan as high risk. In most other non-endemic countries, routine immunisation programmes are less reliant on polio assets, but polio transition may affect specific capacities, particularly in disease surveillance.

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, overall, it is somewhat outside risk appetite (with the six countries identified most at risk more clearly outside). Continued proactive engagement with countries and partners is needed to determine the immunisation-critical functions most at risk, support transition planning with full country ownership and funding sources post bridge-funding, and incorporate aspects of polio transition into Joint Appraisals. The Gavi CEO furthermore joined the Polio Oversight Board to ensure better collaboration across the partnerships through discussion and development of the Endgame Strategy accountability framework for the integration pillar and to highlight the need for closer linkages between routine immunisation and the polio programme.

## i) Donor support

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

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

Donor support is crucial to enable Gavi to sustain approved programmes and fund new programmes. However, continued economic uncertainty, shifting political ideologies, increasingly aid-hostile media in some countries, and competing priorities in development and health (such as refugees, security, climate, and education, but also the creation of other health initiatives) mean Gavi will face an increasingly challenging environment to secure donor support. Elections in key donor markets can bring new leaders that take different directions from their predecessors and need to respond to a growing segment of discontented voters with increasing mistrust



of established institutions. Reduced budget for Gavi programmes could lead to disruption of countries' immunisation programmes and reduced health impact. It could also prevent the Board from opening support windows for new vaccines that are developed. Reduced donor support would likely also increase the effort and cost of mobilising resources and servicing donors.

Gavi has been working to diversify its donor base and its support is less concentrated from a few large donors than in the past. The Secretariat invests significant efforts in engaging 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, as well as last year's Mid-Term Review. This year's replenishment launch presented a compelling investment case in the lead up to Gavi's 3rd replenishment in mid-2020. Gavi also works to increase the Alliance's profile (through communications and advocacy organisations) in donor countries. There is a particular focus on key markets experiencing political and economic uncertainties with tailored strategies 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.

Current exposure to this risk remains high, mostly due to its potential impact. Multiple competing replenishments will take place in the health and development sector this year (Global fund, IDA, GPEI), just before Gavi's replenishment in 2020. The fact that the Board includes key donors and other stakeholders in global development, helps to ensure Gavi's continued relevance to donor priorities. With Gavi's mid-2020 pledging conference being hosted in the UK, further Brexit-related uncertainty or turmoil (e.g. related to a no-deal exit or government changes) could possibly distract attention or affect Gavi's ability to engage and convene. The economic uncertainty, foreign exchange fluctuations and the risk of recession continues to heighten donor funding risk during Gavi's fundraising drive for replenishment. This is compounded by political change and uncertainty in many traditional donor countries, driven by continued support for populist and nationalist parties and general discontent in many electorates (e.g., last year saw the rise of the yellow vest movement in France). An ongoing focus on engaging newer donors therefore remains important but increased geopolitical rivalry and risks of political escalation in new donor countries and regional conflicts require careful navigation.

The Alliance has a low appetite for risks affecting the sustainability of donor funding in order to safeguard predictable financing of vaccines, as this is crucial to sustaining Gavi's existing programmes and the Alliance's ability to fund new vaccines. The current exposure is low in terms of likelihood but high in terms of potential impact, so is still somewhat outside risk appetite and requires ongoing attention, especially as Gavi approaches replenishment in 2020.

## j) IT disruption

*Critical information systems or data significantly compromised by cyber-attack or technology failure*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
j) <b>IT disruption</b> Critical information systems or data significantly compromised by cyber-attack or technology failure	<ul style="list-style-type: none"> <li>Cyber-attack, phishing and malware</li> <li>Internal or external data breach</li> <li>Systems failure and data loss</li> </ul>			<b>SOMEWHAT OUTSIDE</b>		

The Secretariat continues to invest in its knowledge management and information systems aimed at enhancing processes (especially with regard to grant management and financial management) and enabling better engagement with countries and partners. The increasing use of automated systems and centralised cloud-





based data repositories to support collaboration and maximise work efficiency mitigates risks related to human error and process delays, but the increasing reliance on technology also exposes the Secretariat to technology-related risks. A significant IT systems failure, data loss or sensitive data breach could happen due to cyber-attacks, internal or external data leaks, technology glitches, or new system implementation challenges. 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.

The Secretariat has implemented several measures which include internet traffic monitoring and filtering, single sign-on with multi-factor authentication, a Windows 10 roll-out with local file encryption, an improved network landscape in the Global Health Campus, application security testing and annual security scans. The Secretariat is furthermore implementing a Security Operations Centre and system event analytics in collaboration with the Global Fund. Digital security training and awareness sessions have also been rolled out. Gavi's cloud-based systems provide a level of redundancy and back-up across key systems. In addition, the Secretariat has implemented an independent back-up solution which provides the ability to restore key data at a transactional level. A data classification project is underway with the aim to introduce a formal framework for data classification and implement tools and controls for information protection. A next step will be to identify independent hosting arrangements where data could be restored in the event of a catastrophic failure of a cloud-based system. Gavi is also implementing a comprehensive business continuity and disaster recovery plan which will include testing and verification of IT systems recovery. Furthermore, a new IT project governance framework is being put in place and a Business Continuity and IT Security Committee has been established to oversee the implementation of security policies, validate data classification and review incident response plans.

Current risk exposure remains high with external threats of cyber-attacks, phishing and malware continuing to increase globally (combined with Gavi's growing profile, especially during replenishment, potentially attracting extremists), and with the increasing reliance on technology, including the implementation of new financial and grant management systems in the Secretariat (the new SAP financial management system "FIND" is going live in October). Remediation of outstanding audit findings is progressing, and it is expected that completion of these measures will result in this risk reducing over time. 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. During a recent discussion in the Risk Committee it was agreed that a strategic discussion is needed on risk appetite and recovery timeline objectives, balancing risk with mitigation costs and trade-offs with efficiency and user experience.

## k) Sub-optimally planned campaigns

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

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

In Gavi's current strategic period, large preventive campaigns account for a higher proportion of Gavi supported activities than in the previous period (with campaign expenditure now representing 15% of overall

expenditure), following a 2015 funding decision to support measles campaigns, reflecting Gavi's stronger engagement in epidemic and accelerated disease control initiatives. By immunising a large target population in a short period of time, campaigns are meant to supplement routine immunisation (also known as supplementary immunisation activities (SIAs)) 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. And when the planning of the campaign is sub-optimal, the quality of implementation can vary significantly, resulting in the need to repeat campaigns due to a failure to achieve sufficient coverage among the target population. Campaigns are also expensive (with per diems for training, supervision, service delivery, and transport typically a major cost driver), resulting in large sums of money being disbursed in a short period of time, increasing the risk of misuse (especially in sub-optimally planned campaigns due to the lack of sufficient monitoring systems). Sub-optimal planning can furthermore increase risks of immunisation errors and episodes with adverse events (especially in larger mass preventive/catch-up campaigns because of the sheer number of children being vaccinated). Well-planned, targeted and tailored campaigns, as part of a comprehensive immunisation delivery strategy, remain valuable and necessary to close immunity gaps, vaccinate missed children, and mitigate risks of outbreaks. While therefore justified under certain circumstances, reliance on large campaigns to close immunity gaps, often to compensate for poor routine immunisation coverage, is not sustainable given their cost and disruptive impact. All members of the Alliance are expected to work with countries to ensure that campaigns are justified, well-planned and executed in a manner that safeguards – and ideally strengthens – the broader immunisation programme.

The Secretariat and Alliance partners are working to improve the quality of campaigns through more careful planning and preparation, including the mandatory use of readiness assessments before moving ahead with a campaign, and proper microplanning (requesting quantitative data on zero dose or under-immunised children reached). The Alliance will ensure that the country receives appropriate and quality technical assistance and conducts the required coverage surveys to evaluate the quality of implementation and independent monitoring for mop up activities. Furthermore, country-tailored strategies are promoted that reinforce routine delivery (e.g., Periodic Intensification of Routine Immunisation (PIRI)) and combine multiple antigens and health interventions in a single campaign as appropriate. The health system and immunisation strengthening (HSIS) framework requires all countries to articulate how they will use operational cost support for campaigns to strengthen their routine immunisation programmes and health systems. Additional flexibilities have recently been approved by the Board recently allowing Measles/Measles-Rubella operational costs to be used to enhance routine immunisation activities targeted at reaching missed children. To date, Zambia, as one of the 4 countries to pilot has applied and opted for a nationwide SIA with some innovation of selective vaccination in a district. Another 3 countries, Lesotho, Senegal and Burundi are now forecasted to apply in January 2020, instead of May 2019 as previously expected. The data quality and criteria of 2 dose routine coverage set by WHO before considering a targeted approach remains a challenge in moving forward this flexibility. The Secretariat is also reviewing campaign budgets before disbursing funds to minimise perverse incentives and misuse. Monitoring Agents are being used for some countries to provide real time information on issues that can be brought up with partners and countries for discussion and mitigation.





Current exposure to this risk remains high. While MCV1 coverage reached 81% in 2018 (three percentage points above the 2015 baseline against a target of 2.4 percentage points, while previously stagnant, rising only 1 percentage point between 2011 and 2015), 95% coverage with two doses is needed to achieve herd immunity for measles. Very few Gavi countries meet this herd immunity threshold, which means follow-up campaigns will continue unless intensive efforts are made to reach a high number of measles zero dose children (among 10 Gavi supported countries conducting nationwide measles and/or rubella SIAs in 2018, only

one country achieved the 95% coverage target as determined by a post-campaign coverage survey). An analysis of specific reasons for sub-optimal coverage in campaigns identified that delayed disbursement of funds from national to subnational level and from global to national level, and sub-optimal use of readiness assessment tools at subnational level compromised the quality of campaigns. The Risk Committee expressed its ongoing concern with campaigns being inherently high-risk activities, both from a fiduciary risk perspective and a programmatic quality, sustainability, and value-for-money perspective. It was agreed that more analysis is needed to understand how to best strengthen both programmatic and fiduciary measures, including looking at which components of operational costs are critical and sustainable to reduce perverse incentives, drawing on early lessons from the use of Monitoring Agents in a few countries. Alliance Partners agreed to strengthen support for campaign and budget planning and to ensure that post-campaign coverage surveys happen systematically and in a timely manner. These efforts are anticipated to reduce the risk in this area moving forward, but operationalisation is pending.

Current exposure remains outside of risk appetite and therefore continues to require intensive mitigation efforts. The Alliance has a low appetite for the risk of preventive immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term. Well-planned preventive campaigns are an important mechanism to close immunity gaps among populations not reached through routine immunisation, however, overreliance on campaigns can distract from efforts to strengthen routine immunisation and sub-optimally planned campaigns may fail to reach the full target population. Therefore, in Gavi 5.0, efforts will be made to incentivise countries to select the most appropriate delivery mechanism to close immunity gaps, using both routinised and supplemental mechanisms (including campaigns as appropriate), based on country performance and immunisation programme maturity with a lens to long-term sustainability.

## I) 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
I Partner capacity Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> <li>Lack of accountability / performance</li> </ul>			BROADLY WITHIN		

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

To address this risk, the Partners' Engagement Framework (PEF) model has focussed on delivering more partner capacity directly to countries (with now over 340 PEF-funded staff of WHO and UNICEF providing technical assistance at country level), and further enhanced the effectiveness, efficiency and transparency of collaboration with core partners. Core partners (WHO, UNICEF, World Bank and CDC) remain the prime recipients of PEF funding, however Gavi now has more than 120 contracts with over 60 expanded partners, bringing new areas of comparative advantage. Technical Assistance (TA) guidance now includes a specific section on 'Transfer of skills' detailing the objective and approach for it, and the PEF Management Team



oversees TA delivery in 20 priority countries with continued attention to lessons learned based on independent reviews. Gavi is continuing to empower countries to assess their technical assistance needs and the quality of technical assistance provided, as well as expanding the pool of providers including local institutions, where appropriate. Furthermore, PEF milestones have been aligned with the countries' Theory of Change and the Grant Performance Framework indicators, to reinforce alignment of PEF Targeted Country Assistance (TCA) with Gavi's other in-country investments.

Current exposure to this risk is high. This year there has been a greater diversification of partners and coverage estimates show greater progress on routine coverage in countries where overall Alliance engagement has been highest (the PEF Tier 1 countries), bringing together health systems strengthening investments, higher levels of technical support and increased political engagement. Preliminary results of independent assessments of TCA in Nigeria, PNG, Zambia, Myanmar and DRC, Ethiopia show that quality of TCA plans have improved with more inclusive planning processes, and that while TA for vaccine introductions, campaigns and outbreak response is overall of good quality, it is not yet meeting the needs for a diverse set of skill sets, especially for support to management, implementation oversight and innovation. It is also recommended to reconsider the balance between immediate results and capacity-building for sustainable longer-term results. This highlights the need for innovative approaches to address specific challenges with reaching zero-dose children and highly differentiated needs of countries to be further pursued.

The overall risk exposure is currently broadly within risk appetite. The Alliance has overall a lower appetite for organisational risks that could impede its ability to deliver on the mission, for which partner capacity is critical. However, appetite for risks associated with the processes, systems and management of Alliance partners is moderately low, recognising that the Gavi Secretariat has less ability to directly influence this. It is important to continue to monitor whether the risk will move at some point more outside risk appetite, especially with the increasing complexity of managing expanding partnerships and the ambitions of Gavi 5.0 requiring working with new type of partners (e.g. in conflict situations), and increased collaboration between global health actors.

## m) 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
m	<b>Global supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption (epidemiological, political, technical)</li> </ul>			<b>SOMEWHAT OUTSIDE</b>		

Secure and reliable vaccine supply is essential for immunisation programmes to run uninterrupted, to enable new vaccine introductions, and to meet countries' vaccine presentation preferences. However, vaccine production is a technically challenging process and there are only a limited number of vaccine manufacturers for many of the Gavi-supported vaccines. Other factors are the total production buffer capacity for each market, manufacturers' engagement with global health and development aid, their assessment of commercial risks associated with investments, market entry barriers, and the strength of National Regulatory Authorities (NRAs). Country demand may also delay or surge depending on country introduction readiness and disease outbreaks, conflict and natural disasters, while the production of vaccines and increasing production capacity is a long-term process. There is also natural volatility in demand, especially for newer vaccines and those with more sporadic use (e.g. with vaccines delivered for campaigns). The risk of supply shortages is generally decreasing for Gavi's more mature routine vaccine programmes (e.g., pentavalent and PCV) as supply capacity has increased over time and demand is more stable owing to more predictable usage patterns in countries where immunisation programmes are established. However, it remains a high risk for a number of vaccines and the inherent risk may grow when new vaccines will be supported in the future, especially for epidemic diseases.



Also, as countries transition out of Gavi support, they may opt for self-procurement instead of procuring through UNICEF, potentially affecting demand predictability and making market shaping more complex.

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





Current exposure remains high but stable on a global portfolio level, with eight vaccine markets out of eleven having had sufficient and uninterrupted supply of appropriate vaccines. Supply challenges persist for Rotavirus (RV), Inactivated Poliovirus (IPV), and Human Papillomavirus (HPV). Following major supply challenges in 2018 and the 1st half of 2019, the supply situation of the Rotavirus market has started to improve with new manufacturers prequalified by WHO and previous bulk production issues resolved. Countries that suffered delays due to the lack of supply are expected to start introducing the vaccine in Q4 2019. For IPV, all countries had access to IPV supply for at least 1 dose in 2018, although supply was not adequate for the global catch-up bolus. However, a new IPV vaccine candidate now got licensed and has been submitted for prequalification. For HPV, the growing country demand is still outpacing supply. There is potential for additional pressure on supply if countries increasingly adopt gender-neutral vaccination, expansion to older ages, and shift towards 9-valent vaccine usage. Supply challenges for Gavi-eligible countries are expected to persist in the short- and mid-term. Doses available to Gavi from the major global supplier of HPV vaccines increased in 2018 (to 5 million doses) and in 2019, but availability is still significantly below programme requirements. Alliance partners are now prioritising single age cohorts and delay multi-age cohort (MAC) implementation. In order to improve future HPV supply availabilities, Alliance partners have been closely engaging and communicating with both current and pipeline manufacturers, and the risk exposure is expected to come down in the long term due to new entrants into the market and/or increasing supply availability from incumbents.

The overall risk exposure is currently somewhat outside appetite. The Alliance has a moderately low appetite for the risk of supply shortages, especially if this may impact existing programmes. While ensuring sufficient and uninterrupted supply of vaccines is essential, it is also acknowledged that demand and supply are

inherently volatile. Future supply security is dependent on assumptions of supplier production capacity scale-ups and new market entrants that introduce sufficient buffer capacity and supplier diversity into the markets. Also, mitigation is constrained by limitations in degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges.

## n) HSIS value for money

*HSIS investments do not materially improve programmatic outcomes*

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

HSIS grants are one of the key financing tools for the Alliance to help strengthen coverage and equity and build sustainability in immunisation programmes, and are therefore critical to delivering the Gavi strategy. HSIS includes grants for health system strengthening, vaccine introductions and operational support for campaigns. The Alliance is projected to invest over US\$ 2 billion in HSIS between 2016 and 2020, including at least US\$ 1.3 billion in health system strengthening grants. Nonetheless, Gavi's HSIS 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 HSIS grants depends on them being well-designed and focused the key bottlenecks, timely disbursed and well-implemented and utilised by countries, and delivering measurable results. Some of the key barriers to coverage and equity may not be addressable through HSIS grants (e.g., design of the overall health system). Even when HSS grants are well-used, many factors impact the performance of immunisation programmes, so Gavi can contribute but not fully attribute its investments to outcomes and impact. Without robust management and oversight – including aligned technical support where required from Alliance partners – HSIS 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.

Gavi has continued to strengthen its processes for the design, monitoring and improvement of grants. New and updated programming guidance has been published in a number of critical systems areas to better inform grant design, and for each new grant a clear Theory of Change will be developed. There is significant demand from countries for the HSS flexibilities approved by the Board in 2018, with 23 countries from 26 country applications received already approved by the IRC using a strong focus on coverage and equity bottlenecks as key review criteria. There is also an increasing focus on other key systems areas which have historically been less of a focus (e.g., demand, human resources for health (HRH)). Progress of the Full Portfolio Planning process is reviewed together with partners, and Joint Appraisals – annual reviews by all in-country stakeholders - have now become a valuable part of the annual EPI cycle in most countries, and are strengthening linkages between Gavi HSS, NVS and PEF grants. The Partners' Engagement Framework (PEF) has helped ensure that technical support is based on country needs, better connected to Gavi's other grants and has increased the transparency and accountability of partner support. As part of the annual cycle of review and monitoring of grants, there is a deliberate discussion on identifying technical support priorities for the next year, and consideration of whether adjustments are needed to ensure that grants are optimally targeted towards coverage and equity. This has also enabled countries to accelerate implementation of grants in countries that have experienced challenges in absorbing HSS funding. All HSIS grants have performance frameworks with intermediate indicators measuring direct outputs as well as outcomes and a portfolio analysis has started to review the design of HSS grants and GPFs in priority countries. A unit cost and benchmarking





database will be launched to ensure economy in HSS grants, and a more systematic approach to programmatic efficiency in priority areas (e.g., supply chains and campaigns) is being developed. The Secretariat is furthermore working with the Global Fund and the Global Financing Facility to jointly work with a subset of countries to conduct integrated planning behind common Primary Health Care (PHC) strengthening plan responsibilities.

Current risk exposure remains high. HSS grants increasingly target key immunisation bottlenecks with over 75% of active grants having a portion targeted at specific sub-national areas or sub-populations and nearly 60% of budgets being targeted at Strategic Focus Areas (SFAs). Also, a growing share of HSS proposals are focused on health systems strengthening instead of support. HSS disbursements have increased six-fold since 2011, despite continued delays in the first disbursement of grants. There are indications of impact of HSS on the portfolio-level, where numbers of under-immunised children in Gavi countries are falling despite a significant increase in birth cohorts, and an HSS review conducted by Swiss TPH showed that there is a positive, small but statistically significant association between HSS grants and increases in coverage. Also, the indicators under Strategic Goal 2 are on track, and the supply chain area the greatest improvements are seen in the areas with the greatest HSS investments. There is however limited data on in-country implementation and impact (which is now addressed with new theories of change linking grant objectives and activities to Grant Performance Framework indicators). These efforts will strengthen the quality of grant monitoring, but will take time to show results. Furthermore, the funding policy review will have a fundamental look at the current model in preparation for Gavi 5.0. The overall application, review, disbursement and monitoring process for grants will also be reviewed and streamlined as part of Gavi 5.0 portfolio management workstream.

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

## o) Forecasting variability

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

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

The Secretariat develops forecasts of future country demand, vaccine supply and pricing, and financial expenditure to inform annual procurement of vaccine doses and funding decisions. These also inform the Alliance's impact projections as well as key policy and strategy decisions (e.g., vaccine investment strategy). Forecasts are based on a number of inputs and assumptions including on vaccine demand (projected vaccine introduction dates and uptake, estimates of target population and immunisation coverage in each country, wastage estimates depending on product presentations, and countries' projected Gross National Income (GNI) defining their co-financing share and transition date); on vaccine pricing (market dynamics, pipeline assumptions, and exchange rates); on vaccine supply (manufacturing capacity); on cash disbursements (country absorptive capacity, fiduciary risk conditions) and vaccine disbursement timing; on Partner and Secretariat operating costs; on resource inflows (donor contributions, innovative financing proceeds, and investment income); and on potential Gavi policy changes. Each of these has inherent uncertainties and, in some cases (e.g., for population and coverage estimates in some countries), challenges with data quality.

Gavi's forecasts inform planning decisions by a range of stakeholders including countries (who plan introductions based on their understanding of availability of Gavi funding and vaccine supply), donors (demand and impact forecasts inform their decisions on the size and timing of their pledges), manufacturers (who use Gavi forecasts to plan their production schedules) and the Secretariat and Alliance partners (who use them for financial, strategic and operational planning). Significant deviation from forecasts could therefore result in Gavi having inadequate financial resources to fund country demand (or conversely being perceived to have "excess" funding), countries having to delay introductions (or conversely have excess supply potentially leading to wastage), and manufacturers producing inadequate or excess volumes of vaccine. It may also result in Gavi failing to deliver on its targets if these turn out to be overly aggressive.





To mitigate this risk, the Secretariat has strengthened forecasting processes and workflows with systematic collaboration across key teams responsible for vaccine supply, market shaping, co-financing and transition, and finance – informed by and validated with Alliance partners. Checks and balances are built into the process with more systematic analysis of accuracy and variability being integrated into this year's vaccine forecasting cycle and Senior Country Manager (SCM) knowledge integrated into a revised vaccine renewals process. In addition, there has been more systematic triangulation of renewal projections with other information sources (allowing dose allocations to be adjusted for accumulation of stock). In addition, efforts will be made towards encouraging countries to adopt more realistic vaccine need planning and renewals requests. Key assumptions are pressure tested and variance drivers communicated. HSS forecasting has also been strengthened with the 2018 actuals ending up very close to the forecast. Efforts are ongoing to strengthen the Cold Chain Equipment (CCE) forecast, which is generally reliable in terms of total procurement at portfolio level, but timing of procurement within the year and awards to individual manufacturers have been more volatile. Financial forecasting updates are regularly provided to senior management, the Audit & Finance Committee (AFC) and the Board with transparency on the key drivers of change between forecast versions. Potential financial impact is further mitigated with a cash and investments reserve, equivalent to eight months' future expenditure at least, and a surplus for expected future requests for programme funding.

Current risk exposure is limited for the overall long-term financial forecast, but inherent variability and uncertainty is higher in programmatic forecasts. Short-term variability risks (through 2020) continue to lessen naturally as a result of more firm information (e.g. more vaccine supply has been tendered, prices have been agreed, and applications are in preparation or submitted for vaccine introductions in this period). Longer-term risks continue to be heightened, e.g. due to demand, supply, and price uncertainty inherent in new vaccine investment options and from the intrinsic variability associated with longer forecast time horizons. Risk exposure is higher for newer vaccine programmes and those that are delivered through campaigns. The timing and size of country demand, as well as the availability of supply, is harder to forecast for these programmes (and changes in demand impact both vaccine support and HSIS support due to the knock-on effect on vaccine introduction grants or operational cost support).

Overall, this exposure is broadly within risk appetite and can be effectively managed through existing processes. The Alliance has a higher appetite for the risk of forecasts being too high – to ensure availability of sufficient supply and funding – than for forecasts being too low and recent forecasts have been consistent with this. It has a lower appetite for the risk that such variability might reduce manufacturer or donor confidence and therefore seeks to actively and regularly communicate the assumptions, uncertainties and changes in its forecasts.

## p) Secretariat disruption

### Significant disruption of Secretariat operations

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

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

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

Current risk exposure remains stable but is expected to decrease further as measures are further implemented. Travel security is the highest risk element due to the increase in the number of trips to high and extreme risk locations over the past few years. Furthermore, with an increasing number of incidents occurring in previously deemed 'safe' locations and a majority of Gavi travel occurring in low and medium risk locations, enhanced tracking of medium risk locations is in place along with technological resources and training for all travellers, since the highest travel risk is for unexpected events and sudden changes in relatively safe environments. No major incidents have happened so far, but there has been about one near miss per year (including staff on private travel).

The Alliance has a low appetite for risks to Secretariat processes, facilities and people, since these are critical to coordinate the Alliance. The Secretariat seeks to maintain robust processes and management to prevent interruption of business-critical operations. Given the current ongoing mitigation plans, current exposure is broadly within risk appetite.