

THE VACCINE ALLIANCE RISK & ASSURANCE REPORT 2017



Risk & Assurance Report 2017

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1. Introduction

1.1. Purpose of this report

Gavi is naturally exposed to many risks as it operates in a dynamic and often uncertain context, pursues an ambitious mission in poor and fragile countries, and is set up as an Alliance with a lean Secretariat without in-country presence. Gavi also needs to consciously take calculated risks to achieve impact. By systematically understanding, acknowledging and anticipating what might happen (before it actually does happen) and proactively monitoring and managing Gavi's exposures to potential future events, risk management helps Gavi to optimise its impact and appropriately balance risk and reward.

Gavi's annual Risk & Assurance Report discusses the critical risks that could potentially impact the ability of the Alliance to achieve its mission and strategic goals. The Board approved the first ever Risk & Assurance Report at its meeting in December 2016. The top risks identified in that report have since been allocated to "risk owners" in the Secretariat who are responsible for overseeing how the Alliance monitors and manages them. Based on their work throughout the year to coordinate further analysis of these risks, this year's report is able to provide a more nuanced understanding of these risks and to capture progress on their mitigation. It furthermore focuses on how Gavi's top risks have evolved since last year and on how Gavi's actual risk exposure compares to risk appetite (i.e. the willingness to accept these exposures), informed by the Risk Appetite Statement approved by the Board at its last June meeting. The report also provides an update on risk management at Gavi. Responding to feedback on last year's report, this year's report is more concise (with detailed information including analysis of each top risk moved to the annexes) and includes an expanded analysis on exogenous factors and how these may impact Gavi's risk profile.

This year's report shows that Gavi's overall risk profile has remained relatively stable with 15 top risks and few new risks – although the level of individual risks has evolved and the understanding of risks prioritised last year further enhanced. It also highlights three key risks which are currently outside risk appetite for Board discussion. The Secretariat is seeking Board guidance on whether it feels existing mitigation measures can bring risk exposure within appetite fast enough, whether it is necessary to accelerate efforts to strengthen risk mitigation strategies or to adjust the Alliance's risk appetite.

1.2. Progress made on risk management

The Gavi Secretariat has now fully implemented the structural changes approved by the Board in December 2014 to strengthen risk management and assurance practices across three separate lines of defence (see Annex I). This aimed to significantly enhance capabilities in first line functions to understand, monitor and actively manage risks, supported by second line functions providing objective specialist advice and appropriate checks and balances, and validated by third line audits providing independent assurance on the effectiveness of risk management and mitigation by the first and second lines.

After a period of substantial change, the Secretariat's Risk function is currently stepping back and is undertaking an internal review to reflect on the current design and functioning of risk management at Gavi and to help management identify priority areas to build out further going forward. This review is still ongoing but initial findings indicate that the overall design of the risk and assurance model is broadly fit for purpose and that the Secretariat has effectively implemented the model, with new staff in place and supported by new tools and processes. The growth in resources in key functions has increased capacity to better manage and assess risks and the quality of risk management at Gavi has improved. There is a growing culture of risk awareness across the Secretariat leading to good risk-based discussions, albeit with some signs of increasing risk aversion. There is scope to further refine the model, tools and culture across the Secretariat, and further

engage with partners and countries. This needs to be managed carefully in the context of multiple change initiatives across the Alliance which have caused a degree of “change fatigue”.

The model has been implemented across the Gavi Secretariat, with key positions filled, supporting tools introduced, and a top-down and bottom-up process to identify risks established. Teams are seeing benefit from the structured tools and processes (with further refinement ongoing) and are now working to ensure these are more systematically embedded in daily operations to inform planning and decision-making. In the first line, Country Risk Matrices (CRMs) have been updated for all countries and calibrated across regions, allowing broader portfolio analysis to inform strategic decision-making. Country risks are now regularly discussed in country team meetings and regional review meetings and used to inform Gavi’s engagement with countries. In the second line, Grant Performance Frameworks (GPFs) are systematically tracking grant performance and informing grant renewal decisions and country risk assessments. Programme Capacity Assessments (PCAs) have been done for 38 countries and their assessment of capacity gaps informs conditional grant requirements and grant management practices, and they are an important input into decisions on channelling of funds and fiduciary measures¹. In the third line, audits and investigations are routinely executed, and remediation of key findings is tracked. Regular catch-ups take place between the Audit department and the Risk function to exchange risk information. Audit findings with important risk implications are presented to the Secretariat Risk Committee (chaired by the CEO with senior leadership from across the organisation) which discusses risk appetite, trade-offs, and prioritisation. While the model is working well overall, some elements could be clarified – particularly how the three lines of defence apply to corporate risks, how the second line of defence balances its role between supporting the first line and providing checks and balances, and the role of Alliance partners and countries in managing Alliance risks.

Each of the 15 top risks that were prioritised in the 2016 Risk & Assurance Report have now been allocated to a “risk owner” in the Secretariat. Risk owners are responsible for monitoring changes in exposure, coordinating further risk analysis and the development of more coherent mitigation strategies, working with colleagues across the Secretariat and the Alliance. The Secretariat Risk Committee is systematically reviewing the top risks to better understand risk exposure versus appetite, review mitigation and consider needs for additional action. This has led to rich discussions, ownership and better understanding of the top risks. To date, nine risk owners have presented and all top risks will have been reviewed by early 2018. Risk reporting has also been incorporated into Secretariat performance management processes and management conversations, allowing a cohesive conversation on both current performance and future risks.

At Board level, risk management is now a standing item on the agenda. At its June meeting the Board approved an updated risk appetite statement and risk – and particularly fiduciary risk – was a key theme of Board discussions throughout the meeting. Strategic issues are increasingly discussed in the Board and Committees through a risk lens, as was the case for the focus of the April Board Retreat on sustainability risks. The Secretariat is working to ensure that over time all top risks will be discussed in relevant Board Committees or by the full Board.

Partners have an essential role in monitoring and managing programmatic risks in country, and their roles and responsibilities in this area need to be further clarified and operationalised. To address this, PEF functions (core functions expected of partners at country level) are being reviewed and more closely tied to the highest Alliance risks and PEF funding is being prioritised to address key risk areas, while risk has also been discussed more systematically at the Alliance Coordination Team and in other Alliance fora. At its June meeting, the Board also indicated that partners are the preferred option to manage Alliance cash support in countries with weak systems. The Audit functions of Gavi, UNICEF and WHO are establishing arrangements for collaboration

¹ More detailed information on PCAs can be found in the PCA update paper available on BoardEffect.

on programme and other audits. Audits are currently being executed in liaison with UNICEF and discussions are being extended with WHO.

In summary, Gavi's risk and assurance model appears broadly fit for purpose and has been implemented effectively. Staff and tools are in place, with enhanced risk awareness in the Secretariat. There are, however, opportunities to further strengthen the model and risk management approach. The Risk function will be completing its review by the end of the year to validate these initial findings and explore more fully potential future priorities.

2. Alliance-wide risk exposure

2.1. Macro trends affecting Gavi's risk profile

The Alliance operates in a dynamic environment and is exposed to continuously changing exogenous and endogenous factors which could affect Gavi's risk profile. The Secretariat reviews various independent reports² on global trends and risks identified in other organisations, to evaluate to what extent 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.

Over the past year, the external environment has remained uncertain and turbulent. Although cautious economic optimism has returned in some developed countries, many uncertainties remain including potential asset bubbles, interest rate rises, and the retreat from quantitative easing by central banks. This could impact Gavi in multiple ways. A rapid increase in interest rates could trigger a debt crisis in some Gavi countries, many of which are already facing significant fiscal challenges due to low commodity prices. The economic uncertainty also continues to heighten donor funding risk. A new economic crisis, large foreign exchange rate fluctuations, or even a collapse of Sterling (as a result of Brexit) are not unimaginable. Elections in key donor countries have largely resulted in victories for traditional parties, but populist and nationalist sentiment is still present in many countries, and anti-aid and anti-vaccine voices are growing stronger. United Nations partners' funding also remains under pressure, and together with discussions on UN reform, this could impact the Alliance's future capacity to deliver.

The number of conflicts and political upheaval is increasing especially in the Middle-East, South-East Asia, and equatorial Africa³. This year has seen a surge in geopolitical tensions, including even nuclear threats. While all-out conflict remains unlikely, a significant increase in tension could disrupt economies and global supply chains especially in Asia, which is home to a large proportion of the Gavi birth cohort and a significant share of the Gavi vaccine supply base. The trend of increasing population displacement, with a tripling of displaced persons in the past decade (UNHCR), is a growing challenge to immunisation coverage and equity. Long-term trends such as climate change, globalisation and urbanisation are expected to increase the frequency and impact of natural disasters (UNISDR⁴) and infectious disease outbreaks (WHO⁵). The past year showed the disastrous impact events like hurricanes and floods can have on the economies and health of affected countries, and these are only likely to increase in frequency and intensity.

Gavi also faces a number of evolving risks which are inherent to its mission. Gavi's eligibility policy ensures its resources are concentrated in the poorest countries in the world. As wealthier countries transition, its investments will become more concentrated in weaker and more fragile states. Gavi's business – and risk exposure – is also becoming more complex as the number of Gavi-supported programmes continues to increase, and as we scale-up support for a broader portfolio of vaccines (which will likely increase further following the 2018 Vaccine Investment Strategy) as well as immunisation campaigns. The Alliance has also changed the model through which core partners support countries, and is scaling up the role of expanded partners (including the private sector) which is also contributing to an evolving risk profile. A more distinct and imminent upcoming change is the move of the Secretariat to the Global Health Campus in the summer of 2018. All these changes bring opportunities, but also have the potential for disruption if not well managed.

² Amongst others FEMA National Preparedness Report 2016, World Bank Global Economic Prospects 2017; World Economic Forum Global Risks Report 2017; National Intelligence Council Global trends 2017; Eurasia Group Top Risks 2017

³ Atlantic Council Global Risks 2035; Uppsala Conflict Data Program: conflicts doubled from 2010 to 2016

⁴ UNISDR, Sendai Framework for Disaster Risk Reduction 2015-2030 and PreventionWeb Disaster Risk Reduction

⁵ WHO Programmes on climate change and human health; urbanization and health; and globalization and health

2.2. Changes to the Alliance top risks in 2017

This is the second year this report has been prepared and it follows last year's report⁶ which prioritised 15 top risks. This year's analysis showed that Gavi's overall risk profile has remained relatively stable with again 15 top risks and few new risks – although the level of individual risks has evolved as illustrated by the arrows next to each top risk below, and the understanding of risks prioritised last year further enhanced (see Annex IV).

The 4 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
- d) **Sustainable transition ▼**
Some countries fail to sustain progress of their immunisation programmes after transition

The 11 top risks rated as **high** are:

- e) **Vaccine confidence ▲**
Significant loss of confidence in vaccine safety and efficacy
- f) **Outbreaks disrupt immunisation**
Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries
- g) **Misuse by countries**
Deliberate misuse of Gavi funds in many Gavi-supported countries
- h) **Donor support**
Reduction in donor support
- i) **Partner capacity**
Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries
- j) **Secretariat disruption ▲⁷**
Significant disruption of Secretariat operations
- k) **Strategic relevance**
Gavi becomes less relevant to global development priorities
- l) **Global supply shortages**
Shortages in the global vaccine supply
- m) **HSIS value for money**
HSIS investments do not materially improve programmatic outcomes
- n) **Frequent or unplanned campaigns**
Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services
- o) **Forecasting variability**
Gavi forecasting variability driving inappropriate decision-making

One risk is currently unranked pending further information becoming available to accurately assess exposure:

- **Polio transition**
Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations

⁶ See for the 2016 Risk & Assurance Report: <http://www.gavi.org/about/governance/gavi-board/minutes/2016/7-dec/minutes/11---risk-management-update/>

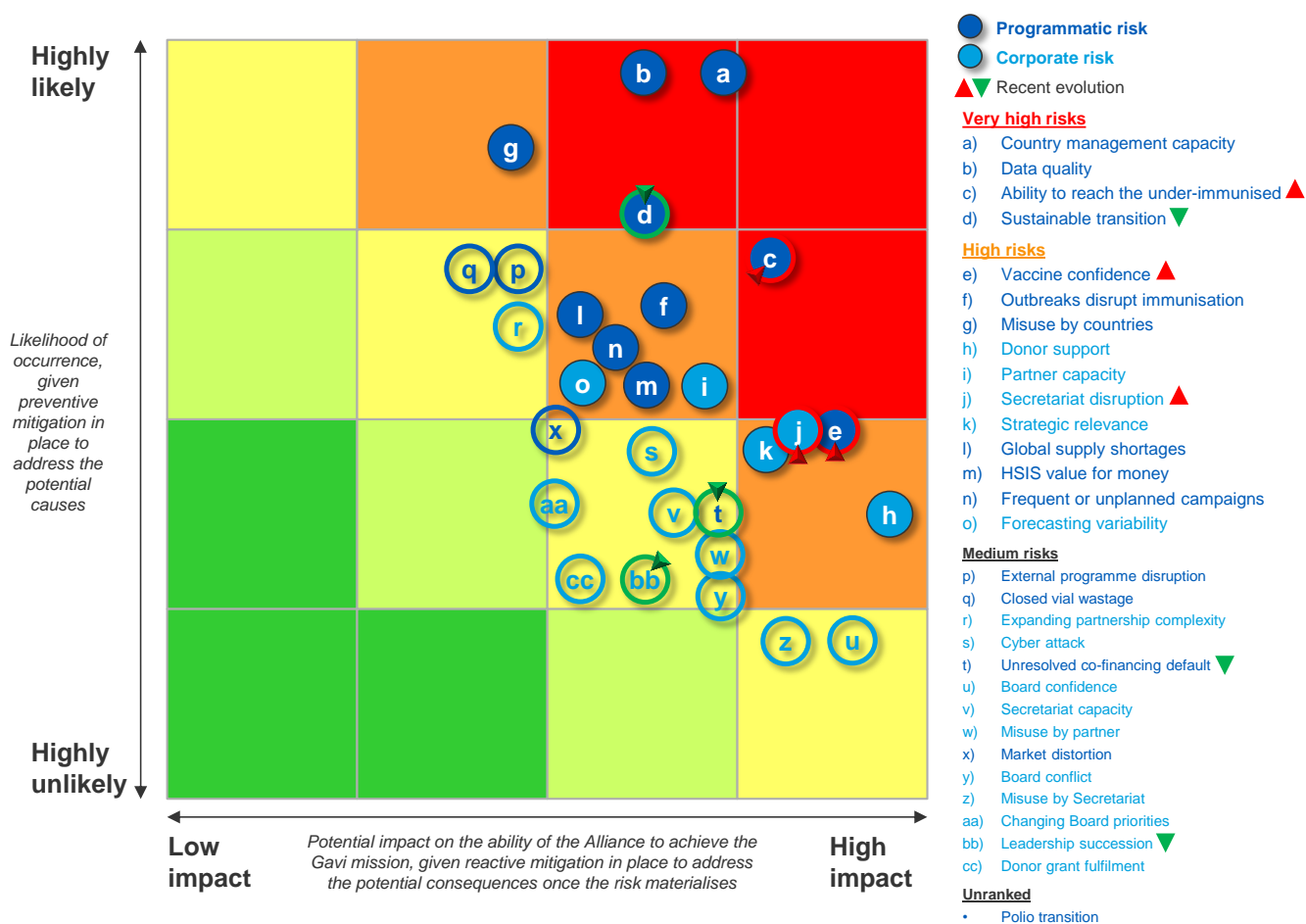
⁷ This risk is temporarily elevated due to the Secretariat's move to Health Campus in 2018 and would be expected to decline afterwards.

Alliance-wide top risks summary

Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a Country management capacity Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"> Weak existing systems and technical capabilities Weak management capabilities Insufficient human resources or retention challenges Insufficient prioritisation of health and immunisation Inadequate support from Alliance to build capacity External programme disruption Disease outbreaks disrupting immunisation Political change (devolution) 	VH		OUTSIDE		
b Data quality Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"> Data quality not routinely monitored Weaknesses in data and measurement systems Many fragmented initiatives without measurable outcomes Donor-driven activities not country-owned Not planned and implemented to ensure data for action 	VH		OUTSIDE		
c Ability to reach the under-immunised The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached	<ul style="list-style-type: none"> Poor data to find and target the unreached Inadequate supply and cold chains into remote areas Insufficient health care workers Lack of demand in underserved communities Lack of political commitment and health budgets 	VH		OUTSIDE		
d Sustainable transition Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> Lack of (subnational) ability/capacity/fiscal space Poor preparation for transition by Alliance Insufficient prioritisation of health and immunisation Overreliance on external support External programme disruption (economic, outbreak) Lack of access to global markets and expertise 	VH		SOMEWHAT OUTSIDE		
e Vaccine confidence Significant loss of confidence in vaccine safety and efficacy	<ul style="list-style-type: none"> Major safety issue Vaccine hesitancy and scepticism 	H		SOMEWHAT OUTSIDE		
f Outbreaks disrupt immunisation Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> Low population immunity Lack of capacity/tools to detect, prevent and respond Population behaviour 	H		BROADLY WITHIN		
g Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> Culture of gifts/corruption Opportunity for personal gain Weak monitoring/deterrence Weak institutions Weak systems 	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
h Donor support Significant reduction in donor support to Gavi	<ul style="list-style-type: none"> Reduction in development budgets Competing priorities in development Competing priorities within health Loss of donor confidence in Gavi 	H		SOMEWHAT OUTSIDE		
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"> Lack of alignment and coordination Lack of capacity / expertise Lack of availability 	H		SOMEWHAT OUTSIDE		
j Secretariat disruption Significant disruption of Secretariat operations	<ul style="list-style-type: none"> Catastrophic event Security threats and kidnapping Internal or external data breach Systems failure and data loss Departure of large number of key staff 	H		BROADLY WITHIN		
k Strategic relevance Gavi becomes less relevant to global development priorities	<ul style="list-style-type: none"> Prioritisation of other development causes Inability to remain innovative and adapt Reduced faith in Gavi's capacity to deliver Growing portion of unmet immunisation needs outside Gavi countries 	H		SOMEWHAT OUTSIDE		
l Global supply shortages Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> Manufacturing capacity inadequate to meet demand Lack of supply security External disruption 	H		SOMEWHAT OUTSIDE		
m HSIS value for money HSIS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> Key bottlenecks not addressable by HSIS HSIS grants not designed to target key bottlenecks HSIS grants duplicative with other donor funding HSIS grants not large enough to have significant impact HSIS not disbursed in timely fashion Programmes funded by HSIS not well-managed Misuse of HSIS resources 	H		BROADLY WITHIN		
n Frequent or unplanned campaigns Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> Periodic very large cash inflows for campaigns Front line workers diverted to implement campaigns Management capacity diverted to manage campaigns Infrastructure (e.g., supply chain, transport) repurposed for campaigns Poor planning and management undermine quality of the campaign, resulting in low coverage 	H		BROADLY WITHIN		
o Forecasting variability Gavi forecasting variability driving inappropriate decision-making	<ul style="list-style-type: none"> Uncertainty over vaccine demand Financial uncertainties (e.g., prices, FX) Complexity of process Sub-optimal systems 	H		BROADLY WITHIN		

Alliance top risks ranked against likelihood and impact 2017 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2017 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 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 team level.

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

c) Ability to reach the under-immunised – This risk has been redefined and was previously called “Ability to influence C&E drivers”. It describes the risk that countries are unable to adequately extend routine immunisation programmes and service delivery to reach unreached children and communities. It has increased from a medium risk to a top risk, given that Gavi is now almost two years into its 2016-20 strategy and the latest WHO/UNICEF Estimates of Immunisation Coverage (WUENIC) suggested no improvement in coverage with three doses of pentavalent vaccine or the first dose of measles in 2016. Moreover, as the Alliance has intensified its engagement with countries and risk management efforts, the scale and complexity of barriers to reaching the unreached – such as weak institutional capacity, poor data and inadequate supply

chains – have become more apparent. 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. While progress is being made in a number of countries and there is evidence of improved coverage in some countries which is not reflected in the latest WUENIC data, sustainable change is a long-term process and it is not yet clear that the pace of change is sufficient to secure the Alliance's coverage and equity goals by 2020.

d) Sustainable transition – This risk combines the “transition readiness” and “country performance post-transition” risks from last year's report, recognising that both are critical components of countries' successful transition out of Gavi support. Current exposure to this risk has decreased very slightly since last year as most countries are on track to transition successfully, a further four countries have successfully transitioned and because the Board is actively working to mitigate the highest risk areas – including through the strategies coming for decision at this Board meeting. However, the risk remains very high given that with its approach to transition Gavi is a pioneer in the field and a number of higher risk countries are approaching transition including Angola and Congo Republic at the end of this year.

e) Vaccine confidence – This risk increased in 2017 with growth in anti-vaccine campaigning most notably in the United States, Europe, and India. Vaccine hesitancy issues also contributed to the postponement of a planned measles campaign in Nigeria.

j) Secretariat disruption – This risk has increased temporarily as the Secretariat prepares to move to the Global Health Campus in the summer of 2018. It is expected to fall again once that move is completed.

t) Unresolved co-financing default (medium risk) – This risk has decreased as countries continue to demonstrate their ability to scale-up co-financing. Last year, nearly 95% of countries paid their co-financing on time, the most since the co-financing policy was introduced, despite an increase in their obligations. This trend appears to be being sustained in 2017, as countries that did not pay in 2016 already come out of default (one pending waiver). The Alliance continues to scale-up its systematic engagement with Ministries of Health and Finance to manage this risk, helped by the increased SCM capacity to follow up and to build relationships with in-country stakeholders, and by the commitment of partners, particularly UNICEF SD.

bb) Leadership succession (medium risk) – This risk has decreased with the reappointment of the Board Chair and CEO.

Polio transition (unranked) – This is a new risk currently unranked pending further information becoming available to accurately assess exposure (and therefore not actually appearing on the heat map). Feedback from both the Audit and Finance Committee (AFC) and the Programme and Policy Committee (PPC) suggested this to be a potential top risk. It reflects the potential impact of the winding-down of polio eradication operations on immunisation programmes in Gavi countries. If this is not well-managed, it could undermine critical capacities in some Gavi-supported countries such as surveillance, laboratories and service delivery in some communities. It may also impact WHO's capacity to support countries given a significant number of WHO staff are funded by the polio programme. However, there is currently not sufficient information available in most countries to accurately assess the specific likelihood and potential impact of this risk on Gavi. It therefore is not prioritised as a top risk in this year's report, but as further information becomes available and understanding improves of how much risk this actually poses to Gavi, this may or may not appear as a top risk in next year's report.

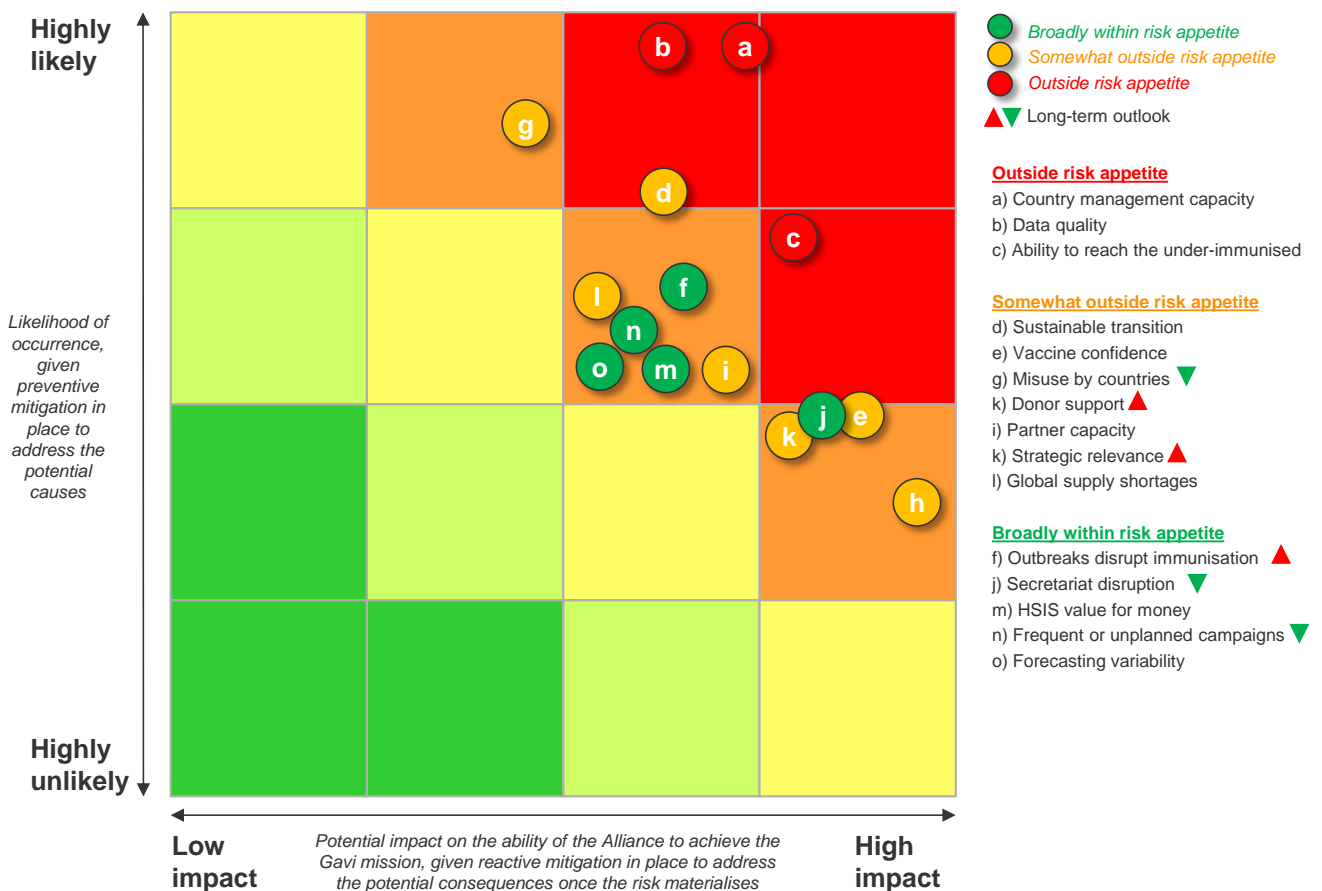
2.3. Gavi's willingness to accept the current top risk exposures

Being exposed to a high likelihood and/or potential impact of a risk can be acceptable, even if this does not mean 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 has a lower appetite for organisational risks impacting Alliance processes, systems and management, as well as for fiduciary oversight and control, and brand and stakeholder confidence.

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), and welcomes the Board's guidance on this. Where current exposures are not in line with the Board's risk appetite, further mitigation may be required to get 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). Alternatively, the Board could choose to increase its risk appetite.

Willingness to accept current top risk exposures

Actual exposures reviewed against aspirational risk appetite



Top risks outside risk appetite – may require a more ambitious approach

a) Country management capacity – 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. However, it cannot accept the risk that EPI management capacity does not improve across its portfolio, since 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. Moreover, the impact of (continued) weak capacity cuts across all in-country work and can increase a number of risks, such as misuse of Gavi support and poor data quality. This also means that mitigating this risk can reduce many other in-country risks. Current very high risk exposure is therefore outside risk appetite. The Alliance has scaled up its work to build management capacity in 2017 with the launch of an intensified approach to Leadership, Management & Coordination (LMC). While this will have a positive impact over time, its impact on portfolio risk exposure will be partially offset by the fact that many countries with stronger management capacity are transitioning out of Gavi support. The Secretariat and partners have begun to explore options for a more ambitious approach to build capacity, building on the existing work of the Leadership, Management & Coordination approach. This could require longer-term commitments, increased investment (especially at subnational level and in financial management capacity), embedding more staff funded through the Partners' Engagement Framework in EPI programmes, and cross-Alliance advocacy. Short-term gap-filling efforts to temporarily mitigate immediate consequences of critical capacity gaps may continue to be needed, but these should be balanced with long-term capacity-building to enable sustainable country ownership.

b) Data quality – The Alliance also 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. However, it does not accept the current very high risk that the data availability, quality and use does not improve across its portfolio. Given that immunisation now reaches the vast majority of the population in Gavi countries, achieving our coverage and equity goals increasingly requires a “precision public health” approach – using robust data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. Moreover, 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. Weak data also increases a number of other risks, such as misuse of Gavi support, closed-vial wastage, disease outbreaks, and vaccine confidence. This also means that mitigating this risk can reduce many other risks. Current very high risk exposure is therefore outside risk appetite, and although new approaches as part of the Data SFA are starting to have impact, it is unclear whether this will bring exposure within appetite fast enough, or whether there is a need to accelerate mitigation. The Secretariat and partners are exploring what more could be done to transform the availability and use of robust data in Gavi countries and whether additional investment is required. In the interim, where minimum levels of data quality cannot be achieved, data is increasingly being triangulated with, or based on, alternative data sources. Short-term efforts to overcome current challenges in data quality, or to mitigate other risks resulting from these, should be balanced with the long-term vision of building country capacity and sustaining the quality, availability and use of immunisation data.

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. The Alliance has mainstreamed coverage and equity into all its processes and introduced new ways of working to improve the speed and impact of its support (e.g., PEF, Joint Appraisals, regular reviews by the High Level Review Panel) over the past two years. While there is some evidence of progress in key countries, it is unclear whether the current rate of change is sufficient to bring risk

exposure within appetite fast enough, or whether there is a need to accelerate or for a more ambitious approach to achieve the targets of this strategic period.

Top risks somewhat outside risk appetite – requiring attention

Eight top risks are currently assessed as being somewhat outside risk appetite. Four of these are rated high – and somewhat outside risk appetite – mainly because of their high potential impact, while their likelihood of occurrence is lower. This is the case for **e) Vaccine confidence**, **h) Donor support**, **i) Partner capacity**, and **k) Strategic relevance**⁸. Since it is generally harder to mitigate the impact of a risk than its likelihood, such exposure may be acceptable. Moreover, the key drivers of vaccine confidence risk are currently concentrated in more developed countries, which has not historically been within Gavi's mandate to address. Exposure to the four other risks in this category – **d) Sustainable transition**, **g) Misuse by countries** and **l) Global supply shortages** – are expected to decline moderately due to ongoing mitigation efforts. Nonetheless, it is important to monitor whether these risks continue to increase, especially for risks where the long-term outlook is increasing, and to discuss whether further mitigation is required now since implementing such mitigation typically takes some time.

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**, **j) Secretariat disruption**, **m) HSIS value for money**, **n) Frequent or unplanned campaigns**, and **o) Forecasting variability**.

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

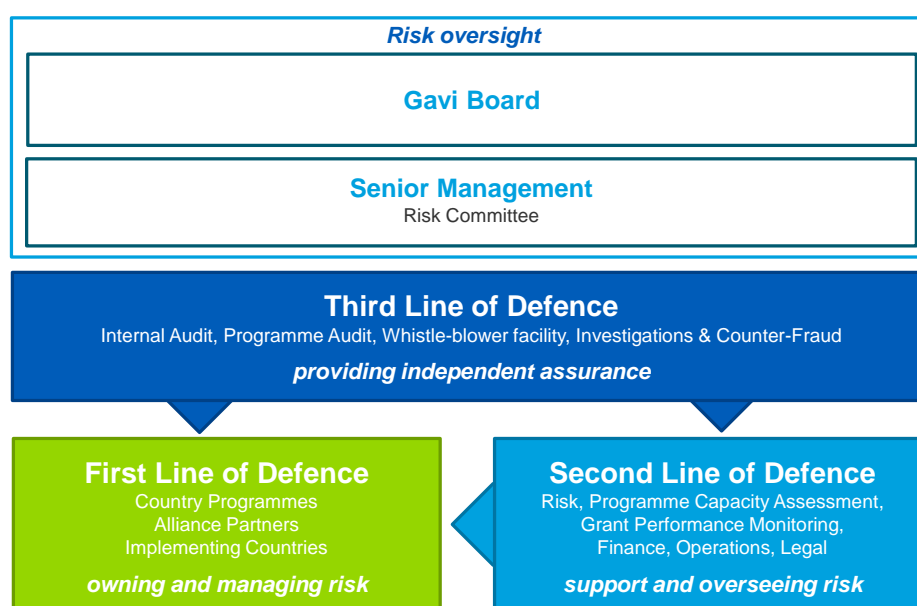
⁸ And for **j) Secretariat disruption**, but as this risk is temporarily elevated due to the Global Health Campus move, and the long-term outlook is decreasing as the Secretariat is currently rolling-out a comprehensive business continuity and IT disaster recovery project – exposure to this risk falls broadly within appetite.

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)

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

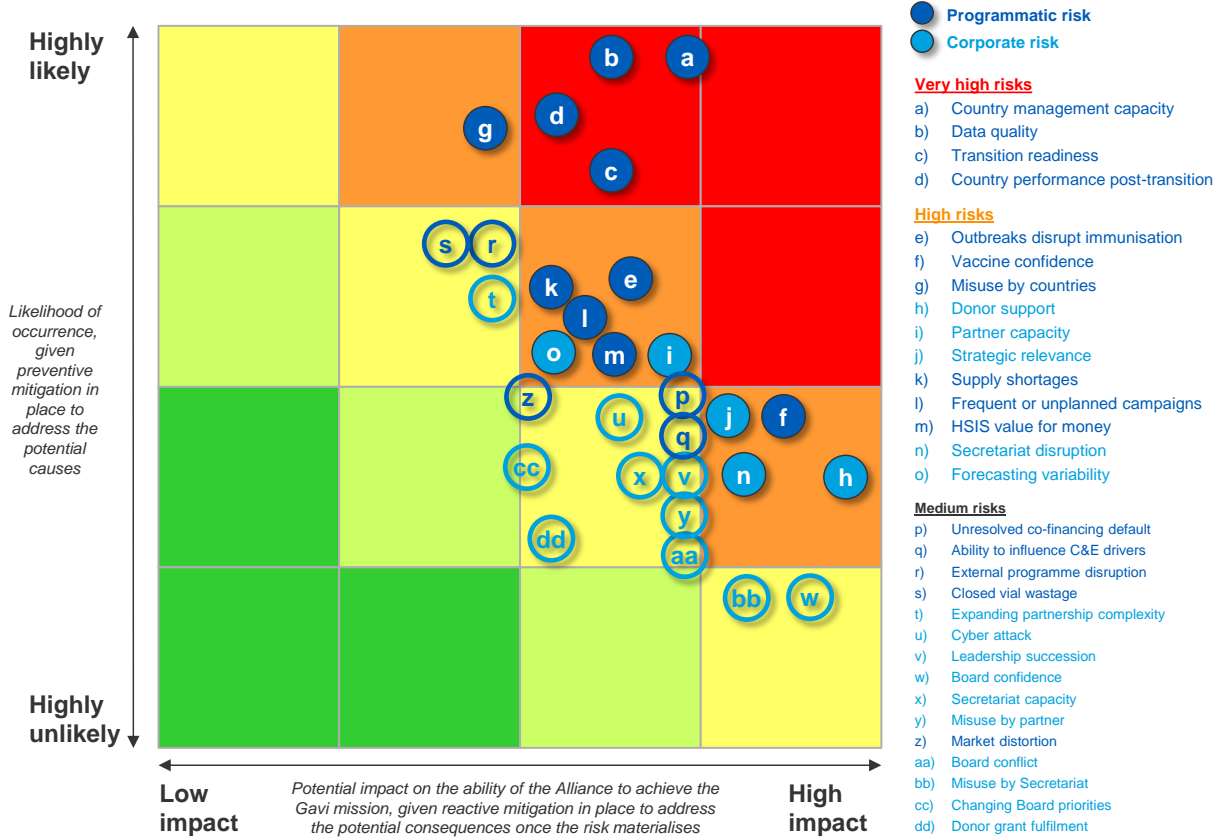
The amount of risk the Alliance is willing to take, accept, or tolerate to achieve its goals

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

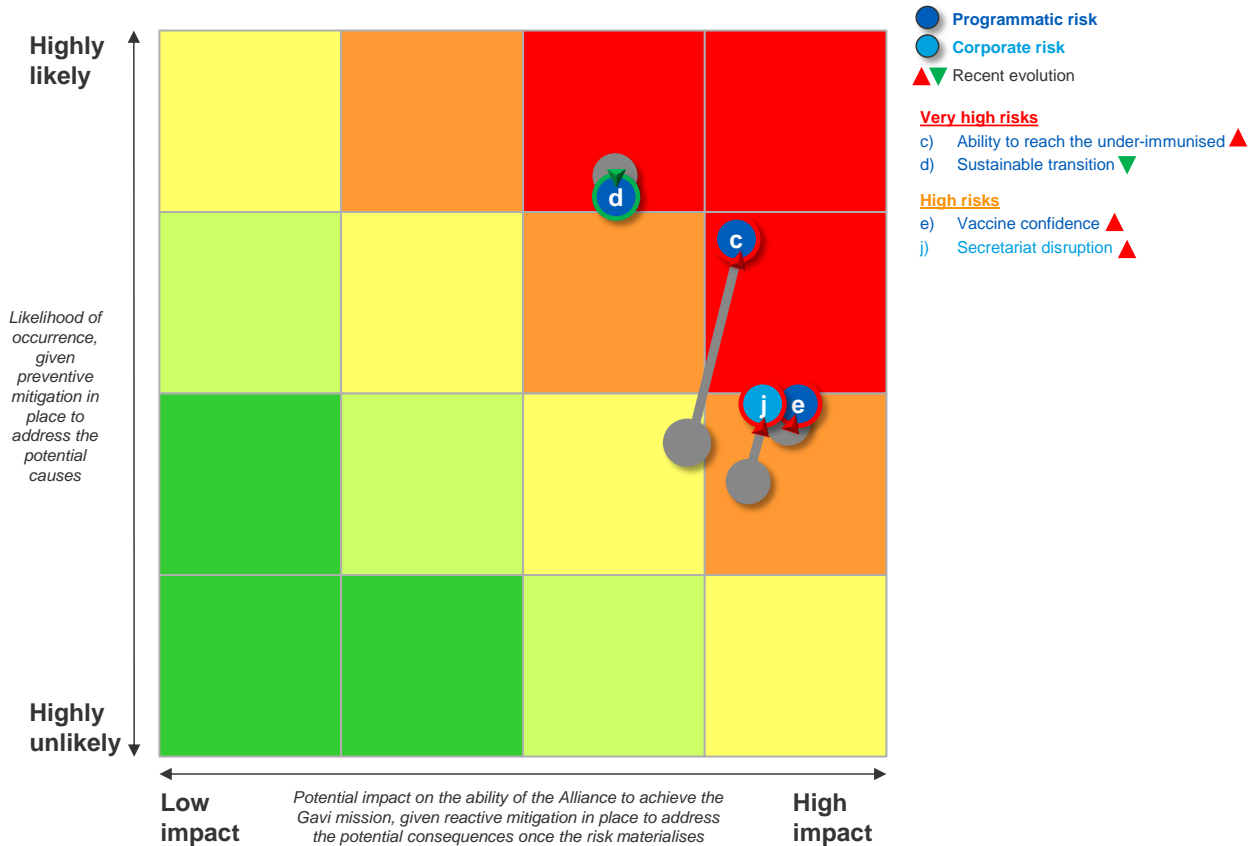
See for the full statement: <http://www.gavi.org/library/gavi-documents/policies/risk-appetite-statement/>

Annex III – Top risk profile evolution since last year

2016 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 Country management capacity 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"> Weak existing systems and technical capabilities Weak management capabilities Insufficient human resources or retention challenges Insufficient prioritisation of health and immunisation Inadequate support from Alliance to build capacity External programme disruption Disease outbreaks disrupting immunisation Political change (devolution) 			OUTSIDE		

The Alliance is working in the poorest countries in the world, many of which are fragile states. Naturally, many Gavi countries have weak 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, 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 has put in place a number of tools to better assess capacity-building needs e.g. through Joint Appraisals and Programme Capacity Assessments, to better target Gavi support to build capacity – including new approaches to strengthen leadership, management and coordination (LMC) – and to better monitor results over time. Direct investments towards management capacity-building remain however small and fragmented, and the more innovative LMC approach is still being scaled up as it takes time to find the right partners able to work at scale with countries. Financial management capacity has not been a major focus until recently but is increasingly a priority given efforts to further mitigate fiduciary risk. The recent evaluation of Alliance technical assistance found that current efforts are primarily focused on short-term gap-filling implementation support with little emphasis on the transfer of knowledge and sustainable capacity building. It also highlighted a need for more technical assistance at the subnational level where there are more prominent and systemic gaps.





Current exposure to this risk remains therefore very high, both in terms of likelihood and potential impact. Many assessments – including Appraisals, Effective Vaccine Management assessments, Programme Capacity Assessments, Programme Audits and evaluations – identify high levels of financial, programme, and supply chain management capacity-related risks and this is reflected in country risk matrices. Inherent risk exposure will likely grow in the longer term since Gavi's strategy requires an increasing focus on underserved areas with weaker capacity, and as stronger countries with lower capacity will transition out of Gavi support.

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. However, it cannot accept the risk that EPI management capacity does not improve across its portfolio, since 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. Moreover, the impact of (continued) weak capacity cuts across all in-country work and can increase a number of risks, such as misuse of Gavi support and poor data quality. This also means that mitigating this risk can reduce many other in-country risks. Current very high risk exposure is therefore outside risk appetite. The Alliance has scaled up its work to build management capacity in 2017 with the launch of an

intensified approach to Leadership, Management & Coordination (LMC). While this will have a positive impact over time, its impact on portfolio risk exposure will be partially offset by the fact that many countries with stronger management capacity are transitioning out of Gavi support. The Secretariat and partners have begun to explore options for a more ambitious approach to build capacity, building on the existing work of the Leadership, Management & Coordination approach. This could require longer-term commitments, increased investment (especially at subnational level and in financial management capacity), embedding more staff funded through the Partners' Engagement Framework in EPI programmes, and cross-Alliance advocacy. Short-term gap-filling efforts to temporarily mitigate immediate consequences of critical capacity gaps may continue to be needed, but these should be balanced with long-term capacity-building to enable sustainable country ownership.

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 Data quality Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"> Data quality not routinely monitored Weaknesses in data and measurement systems Many fragmented initiatives without measurable outcomes Donor-driven activities not country-owned Not planned and implemented to ensure data for action 			OUTSIDE		

Many Gavi-supported countries have weak systems and capacity to generate, report and use data, including in critical areas such as programme data and disease surveillance. Improvements are critical to deliver on all four of Gavi's strategic goals, as well as for strong programme monitoring and evaluation. 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 a number of other risks, such as misuse of Gavi support, closed-vial wastage, disease outbreaks, and vaccine confidence.

During the last strategy period, Gavi made significant investments in strengthening data and these are now being accelerated through the Data Strategic Focus Area. The Secretariat has integrated an enhanced focus on data in its grant management processes and partners have incorporated into their technical assistance and capacity-building initiatives. Alliance partners introduced a coordination forum, developed a theory of change and a partnership framework for strengthening immunisation data for decision-making. Data is triangulated with other sources to improve its reliability. Gavi is also increasing collaboration and alignment of investments with other global health players (e.g., the Global Fund) and increasing engagement with the private sector to help countries access cutting edge data solutions. However, the impact of these mitigation efforts – both building more robust data systems and creating a culture of data use and data-driven decision-making – take time and the Alliance's investment in data is limited compared with the level of inherent risk.

Current exposure to this risk is therefore very high. Joint appraisals, Data Quality Assessments, Effective Vaccine Management assessments, Programme Capacity Assessments, Programme Audits and other evaluations consistently confirm data issues, particularly in countries with weaker health systems, including inadequate quality and use of data on programme performance, supply chains and disease surveillance, a reliance on inefficient paper-based systems and a lack of trained health workers. Discrepancies continue to exist between coverage data reported by countries (e.g., ~20% of countries report over 100% coverage), WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) and household surveys, which is reflected in low "grades of confidence" in the WUENIC estimates for the majority of Gavi countries. This will likely remain a reality for the foreseeable future, and the risk may increase as stronger countries transition.

The Alliance also 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. However, it does not accept the current very high risk that the data availability, quality and use does not improve across its portfolio. Given that immunisation now reaches the vast majority of the population in Gavi countries, achieving our coverage and equity goals increasingly requires a “precision public health” approach – using robust data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. Moreover, 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. Weak data also increases a number of other risks, such as misuse of Gavi support, closed-vial wastage, disease outbreaks, and vaccine confidence. This also means that mitigating this risk can reduce many other risks. Current very high risk exposure is therefore outside risk appetite, and although new approaches as part of the Data SFA are starting to have impact, it is unclear whether this will bring exposure within appetite fast enough, or whether there is a need to accelerate mitigation. The Secretariat and partners are exploring what more could be done to transform the availability and use of robust data in Gavi countries and whether additional investment is required. In the interim, where minimum levels of data quality cannot be achieved, data is increasingly being triangulated with, or based on, alternative data sources. Short-term efforts to overcome current challenges in data quality, or to mitigate other risks resulting from these, should be balanced with the long-term vision of building country capacity and sustaining the quality, availability and use of immunisation data.

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
c Ability to reach the under-immunised The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached	<ul style="list-style-type: none"> Poor data to find and target the unreached Inadequate supply and cold chains into remote areas Insufficient health care workers Lack of demand in underserved communities Lack of political commitment and health budgets 			OUTSIDE		

Gavi’s 2016-2020 strategy has an intensified focus on improving equitable coverage of immunisation in order to reach every child. This will require the extension of immunisation services to reach every community, including building out the service delivery infrastructure, supply chain, and data systems and generating demand in previously underserved communities. For measles second dose and human papillomavirus vaccine (HPV), it will also require platforms to reach older age groups. These are all focus areas for the Alliance’s 2016-20 strategy. The Alliance has focused in particular on the 20 Partner Engagement Framework (PEF) priority countries with the largest number of unvaccinated children and greatest inequities, has worked to enhance its country engagement and support, and has mainstreamed coverage and equity into everything it does.

Nonetheless, current exposure to this risk is very high. While more children were reached with three doses of DTP-containing vaccine than ever before in 2016, the latest WHO/UNICEF Estimates of Immunisation Coverage (WUENIC) suggested no improvement in coverage with three doses of pentavalent vaccine or the first dose of measles (with the increase in number of kids immunised tracking population growth). There is evidence of improvement in some important countries – which is not fully reflected in the most recent WUENIC data highlighting data quality and measurement challenges – and the number of under-immunised children fell between 2015 and 2016 across Gavi countries outside Nigeria. However, as the Alliance has intensified its engagement with countries and risk management efforts, the scale and complexity of barriers to reaching the unreached – such as weak institutional capacity, poor data and inadequate supply chains – have become more apparent. 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. While progress is being made in a number of countries, sustainable change is a long-term process and it is not yet clear that the pace of change is sufficient to secure the Alliance's coverage and equity goals by 2020.

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. The Alliance has mainstreamed coverage and equity into all its processes and introduced new ways of working to improve the speed and impact of its support (e.g., PEF, Joint Appraisals, regular reviews by the High Level Review Panel) over the past two years. While there is some evidence of progress in key countries, it is unclear whether the current rate of change is sufficient to bring risk exposure within appetite fast enough, or whether there is a need to accelerate or for a more ambitious approach to achieve the targets of this strategic period.

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
d Sustainable transition Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> Lack of (subnational) ability/capacity/fiscal space Poor preparation for transition by Alliance Insufficient prioritisation of health and immunisation Overreliance on external support External programme disruption (economic, outbreak) Lack of access to global markets and expertise 			SOMEWHAT OUTSIDE		

Being time-limited and catalytic, Gavi financial support to countries diminishes as their gross national income (GNI) approaches the eligibility threshold, while the share of country co-financing increases until they are fully self-financing. Countries need to be both financially and programmatically ready for a successful transition out of Gavi support to be able to sustain the gains and continue to progress after transition without Gavi financial support. This model will be tested at scale for the first time during the current strategic period with approximately 20 countries projected to transition by the end of 2020. Failure to successfully transition or a regression after transition would diminish the return on Gavi's investments and could impact Gavi's reputation and the perceived viability of the model. Furthermore, it may impact manufacturers' pricing decisions for countries post-transition if they perceive a higher risk that countries will not sustain their programmes.

Gavi's Sustainability Strategic Focus Area emphasises greater and earlier engagement with every country on sustainability. Sustainability tracers are included in Grant Performance Frameworks to monitor financial sustainability, integration into the health system, and institutional/human capacity to guide investments in early phases. Before countries enter the last phase of Gavi support, transition plans are developed based on transition assessments to address bottlenecks with tailored support to complement HSIS and PEF targeted country assistance. All transitioning countries now have a transition plan with active support and monitoring, supported by an increasing number of partners (e.g. UNICEF, World Bank, and CHAI). A forum for transitioning countries has been established which will bilaterally link higher capacity transitioned countries to support lower capacity transitioned countries. Immunisation financing and macro-economic risk analysis is integrated in the Country Risk Matrices to support pre-emptive engagement. The fragility policy also provides flexibilities for fragile countries undergoing transition. The Board will consider at this meeting how it should engage with countries at highest risk for a failed transition and whether Gavi should enhance its post-transition engagement with countries to mitigate the risk of stagnation or decline in performance, including responding to potential political, economic, or natural shocks.

Current exposure to this risk has decreased very slightly since last year as most countries are on track to transition successfully, a further four countries have successfully transitioned and because the Board is actively working to mitigate the highest risk areas – including through the strategies coming for decision at the November 2017 Board meeting. However, the risk remains very high given that with its approach to transition Gavi is a pioneer in the field and a number of higher risk countries are approaching transition including Angola and Congo Republic at the end of this year. In addition, some countries are transitioning with gaps in specific programmatic areas (e.g., capacity of National Immunisation Technical Advisory Groups (NITAGs), National Regulatory Authorities (NRAs) and procurement) and in their vaccine schedule, and performance in transitioned countries could yet be affected by external factors largely outside Gavi’s control (e.g. changes in political will, vulnerable commodity-based economies, or a potential post-transition crisis).

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 (e.g., in countries with inadequate political will or weak institutions beyond immunisation) and needs 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 is willing to consider some 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). Since most countries are currently on track for successful transition, with a few outliers which are actively addressed with tailored approaches, the current very high risk exposure for *some countries* failing sustainable transition is somewhat outside risk appetite.

e) Vaccine confidence

Significant loss of confidence in vaccine safety and efficacy

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
e Vaccine confidence Significant loss of confidence in vaccine safety and efficacy	<ul style="list-style-type: none"> Major safety issue Vaccine hesitancy and scepticism 			SOMEWHAT OUTSIDE		

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), whether coincidental or due to vaccines or their handling and administration, can undermine confidence in vaccines rapidly. 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, or even commercial interests. Loss of confidence in vaccines can adversely impact vaccine introductions and / or coverage, which in turn leads to increased morbidity and mortality and reduced programme impact. Furthermore, Gavi could face reputational challenges and Alliance staff could become the target of extreme anti-vaccine movements. Ultimately, a significant and sustained loss of confidence in vaccines could also reduce support among donor and implementing countries for Gavi’s mission.

To address this risk, the Alliance only procures vaccines that have been licensed by a recognised NRA and pre-qualified by WHO. Gavi provides support for training of healthcare workers on safe immunisation practices and vaccine management, and for strengthening vaccine supply chains and cold chains. Support is also provided to strengthen NRAs and NITAGs, and for global policy and standards for vaccine pharmacovigilance. Alliance partners support AEFI monitoring and risk communications in Gavi countries, as well as AEFI

response and investigations. The Alliance has also developed guidance and provides support through grants and partners for advocacy to build vaccine confidence and generate demand in target populations. The Secretariat monitors global, national and social media and has set up emergency response groups. Finally, the Secretariat is engaged with partners on the emerging risk of fake vaccines and is a member of key fora.

Current exposure to this risk is high mostly in terms of potential impact, but increasing in likelihood with growth in anti-vaccine campaigning most notably in the United States, Europe, and India (but with the potential to spread rapidly to other countries given the speed and cross-border nature of online communication). The threat increasingly comes from political or commercial opportunists, against which traditional vaccine science-based responses are ineffective. Campaigners are seeking to target other countries and although currently the risk seems higher in developed countries, it is difficult to detect when this enters Gavi countries, especially as much of the communication is happening in closed online groups. However, civil society organisations and Ministries of Health have highlighted a perceived growth of anti-vaccine movements in Gavi countries. Vaccine hesitancy issues also contributed to the postponement of a planned measles campaign in Nigeria. While policymakers and mainstream media have so far responded robustly in the US and Europe, institutions or the media in Gavi countries may not be as well-equipped to manage a concerted anti-vaccine campaign. Populations may be particularly susceptible to messages about vaccines with which they are less familiar (e.g. HPV) or for which the disease incidence is becoming rare (e.g. polio). Developing countries are particularly vulnerable where they do not have capacity to respond robustly to AEFIs, especially in terms of communications and social media management. 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 serious AEFIs. Also, an increasing share is consisting of campaigns, which may lead to apparent clustering of AEFIs due to the large number of doses administered in a short period of time.

The Alliance has a low appetite for the risk of a sustained decline in 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, this 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. Such a situation may justify further investments and the Secretariat and Alliance partners have discussed options to improve monitoring of vaccine confidence, to equip stakeholders with a proactive and strong pro-vaccine voice addressing more emotional arguments, and to reinforce programme capacity, e.g. by increasing support to NRAs and NITAGs and further strengthening country capacity to prevent, detect and respond to AEFIs. A more in-depth assessment and additional consultations with Alliance partners are ongoing to inform which further investments are required.

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
f Outbreaks disrupt immunisation Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> Low population immunity Lack of capacity/tools to detect, prevent and respond Population behaviour 			BROADLY WITHIN		

Outbreaks of infectious diseases are occurring with increasing frequency. This trend is driven by factors including climate change – which is increasing the range of disease-transmitting insect vectors such as mosquitoes while climate-related disasters can create the conditions for outbreaks (e.g., cholera) – and urbanisation and population growth, which makes it easier for diseases to spread rapidly and is also increasing human exposure to zoonotic disease reservoirs as cities expand into more rural areas. Globalisation and increased population movement is also enabling diseases to spread further and faster. Disease outbreaks can

be hugely disruptive. They usually require an intense response effort, which can disrupt immunisation programmes. In more serious cases, outbreaks can also cause broader economic and social disruption, interrupt 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 support 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. Gavi also provides vaccine support for many diseases with outbreak potential including measles, polio, yellow fever, meningitis and cholera. For many of these diseases, Gavi supports multiple elements of disease control including routine immunisation, preventive campaigns and outbreak response (including vaccine stockpiles). The Alliance also signed an advance purchase commitment to accelerate availability of Ebola vaccine and may choose in the future to support other vaccines for outbreak response (this will be considered as part of the 2018 Vaccine Investment Strategy). The launch of the Coalition for Epidemic Preparedness Innovations (CEPI) may also increase the availability of vaccines to prevent or respond to outbreaks in future.

Current exposure to this risk remains high. Between 2011 and 2016, WHO reported more than 1,000 epidemics in 168 countries. One-third of Gavi countries had health emergencies in 2016. 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. The 2014 Ebola outbreak in West Africa caused all routine services to be suspended, including immunisation, which made coverage drop by 12% in Guinea, 26% in Liberia and 9% in Sierra Leone. Cholera in Haiti and Yemen in 2016 also significantly impacted routine services, while a number of other countries have suffered outbreaks of Measles, Meningitis, and Yellow fever in 2015 and 2016, requiring intensive immunisation campaigns to address.

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. 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 Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> • Culture of gifts/corruption • Opportunity for personal gain • Weak monitoring/deterrence • Weak institutions • Weak systems 			SOMEWHAT OUTSIDE		

Gavi seeks to use country supply chains for vaccines and to channel funds through country systems whenever possible, in order to ensure country ownership of programmes and to build the sustainable capacity of countries to manage those programmes, which is critical 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 / or prevailing corruption and this exposes the Alliance to the risk of its support being misused.

The inherent risk is particularly high for cash support programmes which account for 20-25% 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. 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 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.

To manage this risk, Programme Capacity Assessments assess a country's capacity to manage support and inform Gavi's decision on how to channel support (supplemented with other risk information including from internal knowledge of the country context and country risk assessments, internal and external audit reports, and risk assessments from partners, donors, or other actors if available). When government systems are insufficiently robust Gavi can require additional controls to ensure strong fiduciary oversight, including potentially channelling funds through alternative channels (e.g., partners or a fiduciary agent) while continuing to strengthen country systems so the Alliance can revert to using them. The Secretariat has strengthened grant oversight, budget and disbursement checks, and financial reporting reviews with the creation of a specialist Programme Finance team and enhanced oversight by Senior Country Managers. It is also working to intensify monitoring of grants (whether by the Secretariat, partners or Monitoring Agents which are being increasingly used especially for immunisation campaigns in higher risk settings). The Secretariat is working with partners to clarify accountabilities for detecting and reporting potential misuse and how partners manage cash grants in weaker countries. Programme Audits are conducted over a targeted 5-year cycle with higher risk programmes being covered twice in that period. The Audit functions of Gavi, UNICEF and WHO are establishing arrangements for collaboration on programme and other audits. Gavi has also set up an anonymous and confidential whistle-blower hotline to which anyone can report suspected misuse, and has a dedicated fraud investigator to follow up on any suspected cases. In case of actual misuse, the Alliance will always require reimbursement as a condition of continued support and no further funding is disbursed through government systems until a clear and credible commitment to reimburse misused funds has been received and Gavi is satisfied that the country's financial systems are sufficiently robust to ensure resources will be managed as required in the future.

Current exposure to this risk is high, mostly in terms of likelihood. Many Gavi countries have weak financial management capacity and many of the newly introduced Programme Audits have identified issues ranging from unsupported expenditure and weak controls to misused funds. To some extent these are symptoms of the light-touch approach of the past (as audits are retrospective), and identification of these weaknesses should help strengthen country systems and fiduciary oversight – and therefore reduce residual risk going forward. Channelling funding away from country systems through Alliance partners may also not adequately mitigate this risk, as Gavi currently has no formal way to assess partners' capacity in country offices to manage additional grants, and does not have full visibility on how their own risk management systems and procedures work and how and when they are applied. Gavi has zero tolerance for misuse once it actually happens and always requires reimbursement as a condition of continued support. To date, 99% of reimbursement due (according to the repayment schedule agreed with the respective government) has been repaid to Gavi. This strong track record significantly mitigates the risk in terms of its potential impact.

The Alliance has a preference to channel support through government systems when these are sufficiently robust and acknowledges 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.

As the recent significant enhancements in fiduciary measures are still scaling up, current exposure is still somewhat outside risk appetite, and it continues to require close monitoring to ensure these will bring exposure within appetite as they take effect.

h) Donor support

Significant reduction in donor support to Gavi

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

Donor support is crucial to enable Gavi to sustain approved programmes and fund new programmes. However, continued sluggish economic growth, shifting political ideologies, increasingly hostile media in some countries, and competing priorities in development and health (such as climate change, education, chronic diseases, HIV, TB, malaria) may lead to a reduction in future donor support to Gavi. The Gavi Board cannot approve or endorse new programmes unless sufficient resources exist to cover expenditures projected for the year in which they are approved and the following two calendar years. Reduced budget for Gavi programmes could therefore 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 widen its donor base and its support is less concentrated from a few large donors than in the past. The Secretariat, and especially the resource mobilisation team, invest significant efforts in engaging donors and ensuring their needs are met. The fact that the Board includes key donors and others stakeholders in global development helps to ensure Gavi's continued relevance to donor priorities. Gavi engages with numerous multilateral reviews and evaluations and 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.

This risk remains high mostly due to its potential impact. Although recent elections in key donor countries were won by centrist candidates, nationalist and populist politicians retain significant support. Gavi also lost many champions due to electoral changes and needs to rebuild high-level champions in UK, France, Italy, Canada and the US. Policies from newly elected governments are still under discussion, and more Gavi donor countries will hold elections in the upcoming months (Italy and Sweden). This uncertainty is exacerbated by recent foreign exchange fluctuations between donor currencies and the US dollar (in which most Gavi expenditure is denominated) as well as uncertainty over the long-term implications of the UK's decision to leave the European Union.

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.

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"> Lack of alignment and coordination Lack of capacity / expertise Lack of availability 			SOMEWHAT OUTSIDE		

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 Alliance's 2016-20 strategy require new and intensified support to countries including assistance in areas that go beyond the traditional comparative advantages of partners (e.g., implementation support, financial management, building leadership capacity, and greater oversight, learning and adaptation to help ensure progress on coverage and equity). It also requires that the support is truly country-owned and better coordinated across partners.

To address this risk, the Partners' Engagement Framework (PEF) has been a fundamental shift in the business model, bringing much more transparency, accountability and new partner capacity at country level through increased funding, including a broader set of expanded partners with specific expertise (currently 48 providers across 45 countries). Most support is, however, still provided by staff from global or regional partners while countries have indicated that local and embedded support is most effective in addressing their needs. Moreover, the recent evaluation of technical assistance found that current support is primarily focused on short-term gap-filling implementation support with little emphasis on the transfer of knowledge and sustainable capacity building. It also highlighted a need for more technical assistance at the subnational level where there are more prominent and systemic gaps, and where support is crucial to achieve equitable coverage improvements.

The current risk exposure is therefore still high, mostly in terms of potential impact. The Alliance has a low appetite for this risk, since partner capacity is critical to delivering on its mission and strategy. As it only has partial ability to directly influence this risk at any individual partner organisation, the Alliance will seek to engage additional partners to fill significant gaps in existing partners' capacity to provide appropriate assistance (e.g., in a specific area or country). As current mitigation is still scaling up, current exposure is still somewhat outside appetite and requires ongoing attention.

j) Secretariat disruption

Significant disruption of Secretariat operations

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
j Secretariat disruption Significant disruption of Secretariat operations	<ul style="list-style-type: none"> Catastrophic event Security threats and kidnapping Internal or external data breach Systems failure and data loss Departure of large number of key staff 			BROADLY WITHIN		

A catastrophic event significantly disrupting Secretariat operations could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and with partners, an inability to complete disbursements to countries or salaries to employees, or an inability to

monitor, analyse and evaluate programmes. This could manifest itself through the loss of access to a Gavi workplace facility, the loss of key IT tools or infrastructure, or the loss of personnel. Potential causes include a natural or man-made disaster, a significant IT systems failure, data loss or data breach, 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 is also increasingly relying on new technology-enabled systems and processes.

The Secretariat has good preventive and detective measures in place, such as building safety and maintenance plans for the facilities; use of firewalls, uninterruptible power supply, cloud based technologies and access management tools for the IT environment; and medical and security risk assessments and travel security measures and monitoring for personnel. To enhance reactive mitigation measures for all areas, the Secretariat is now developing a crisis management framework with emergency response plans and recovery arrangements to ensure business continuity and IT disaster recovery after a crisis.

Current risk exposure has increased temporarily as the Secretariat prepares to move to the Global Health Campus in the summer of 2018. This exposes the Secretariat to potential cost and time overruns on the construction of the new building, disruption during the office move, and could potentially affect productivity and staff engagement due to the new work environment, reduced accessibility or dilution of culture given the colocation with other organisations. Exposure is expected to fall again once the Global Health Campus move is completed. The fact that Gavi has the flexibility of when to move and that this move will be six months after the planned completion date should provide sufficient planning and testing time to mitigate the risk. Once fully implemented, business continuity plans will also address the inherent risk arising from consolidating all the Secretariat's Geneva office space in one location.

The Alliance has a low appetite for risks to Secretariat processes, systems, data, facilities and people, 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. Given the current ongoing mitigation plans and the fact that the current increase due to the move is only temporarily, current exposure is broadly within risk appetite.

k) Strategic relevance

Gavi becomes less relevant to global development priorities

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
k Strategic relevance Gavi becomes less relevant to global development priorities	<ul style="list-style-type: none"> • Prioritisation of other development causes • Inability to remain innovative and adapt • Reduced faith in Gavi's capacity to deliver • Growing portion of unmet immunisation needs outside Gavi countries 			SOMEWHAT OUTSIDE		

Gavi was launched on the eve of the Millennium Development Goal era as a critical new mechanism for achieving the third MDG. Both its mission and its model were highly relevant to global efforts to reduce child mortality and eradicate poverty, and it has continued to evolve its model and policies to reflect new geopolitical trends and priorities. This has been critical to the ability of the Alliance to mobilise resources, engage at the highest political levels with countries and ensure immunisation remains prominent on the international agenda. However, as the world enters the Sustainable Development Goal (SDG) era, there is a risk that immunisation and Gavi become less relevant. There is less global focus on health as a holistic sectoral goal and as an enabler for development. This was apparent in early drafts of the Ministerial Statement leading to this year's High Level Political Forum for the SDGs, where health was not even mentioned despite being one of the 6 goals to be discussed. Gavi's advocacy efforts ensured a health paragraph was included mentioning

immunisation. There are also a number of other competing priorities within the health area (e.g., non-communicable diseases, nutrition). More players are entering an increasingly complex and fragmented global health landscape and there is a risk that progress on immunisation is seen as largely complete given high coverage of basic vaccines (which now reach 86% of children globally) – especially if the global community does not agree on an ambitious SDG indicator which reflects access to new vaccines. Moreover, Gavi’s geographic scope will become increasingly limited as countries transition, and under current policies 70% of under-immunised children globally (based on children receiving three doses of DTP-containing vaccines) will live in countries that are not Gavi-eligible by the middle of the next strategy period. This may lead to reduced funding and political commitment for immunisation globally, and in the remaining Gavi countries specifically.

To address this risk, Gavi periodically reviews its strategy and policies to ensure they are adapted to global priorities. Continuous efforts are made to increase Gavi’s public profile (through communications, advocacy organisations, champions and ambassadors for immunisation). Gavi is also engaging in relevant policy fora to advocate for ambitious goals (including a bold SDG indicator for immunisation) and highlight the relevance of vaccines to other priorities (e.g., universal health coverage, global health security, anti-microbial resistance). The fact that the composition of the Board includes key stakeholders in global development helps to ensure continued relevance of Gavi in line with global development priorities. The Board also has indicated a desire to ensure the Gavi “platform” to shape markets, accelerate adoption of new technologies including new vaccines against priority diseases and advocate for immunisation remains available to a broader set of countries, even as many transition out of financial support.

Current exposure to this risk remains high, mostly in terms of potential impact. In the current geopolitical landscape, challenges such as climate change, migration, gender and socio-economic development appear to be the highest priorities. This exposure is somewhat outside appetite as the Alliance has a low appetite for the risk that it becomes less relevant to global development priorities, and requires ongoing attention to monitor whether it increases in likelihood. In 2018, the Board will begin discussing Gavi’s next strategy in preparation for Replenishment which will enable a fuller discussion of these issues.

1) 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
I Global supply shortages Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> Manufacturing capacity inadequate to meet demand Lack of supply security External disruption 			SOMEWHAT OUTSIDE		

Secure and reliable vaccine supply is essential for immunisation programmes. However, vaccine production is a technically challenging process and there are only a limited number of vaccine manufacturers for any given vaccine. There is also natural volatility in demand, especially for newer vaccines and those with more sporadic use (e.g. with vaccines delivered for campaigns), while increasing manufacturing capacity is a long-term process. The risk of supply shortages is generally decreasing for Gavi’s more mature routine vaccines (e.g., pentavalent) 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 risk may grow if Gavi decides to support additional new vaccines in the future.

One of the key objectives of the Alliance’s Supply and Procurement Strategy is to ensure sufficient and secure supply of vaccines. The Secretariat and Alliance partners work closely with industry to increase production capacity where required to meet demand, including through provision of strategic information and incentives. This can involve encouraging existing manufacturers to expand capacity or new ones to enter the market. The

Alliance secures required supply through long-term agreements with manufacturers. Alliance partners also work closely together to monitor the supply situation and manage supply shortages where they occur – for example, in the case of yellow fever by reallocating available doses from preventive campaigns to outbreak response campaigns and by using fractional doses. However, mitigation of this risk is constrained by the limited ability to affect supplier actions and their own limitations in fixing problems.

Current exposure remains high in some vaccine markets but there are different trends across the portfolio. In particular recent challenges in scaling up supply capacity for human papillomavirus vaccine (HPV) may impact the planned acceleration in scale-up for Gavi’s HPV programme. By contrast, short-term supply constraints for IPV and yellow fever however appear to be easing. Overall risk exposure is currently only somewhat outside the Alliance’s moderately low risk appetite for the risk of supply shortages, but requires ongoing attention.

m) 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
m HSIS value for money HSIS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> Key bottlenecks not addressable by HSIS HSIS grants not designed to target key bottlenecks HSIS grants duplicative with other donor funding HSIS grants not large enough to have significant impact HSIS not disbursed in timely fashion Programmes funded by HSIS not well-managed Misuse of HSIS resources 			BROADLY WITHIN		

HSIS grants are the key financing tool 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 health system strengthening, vaccine introduction and operational support for campaign grants. They represent a significant investment by the Alliance with US\$ 1.3 billion of health system strengthening grants projected between 2016 and 2020. 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 for staff and other health system investments. Some of the key barriers to coverage and equity may not be addressable through HSIS grants (e.g., design of the overall health system). Moreover, the impact of HSIS grants depends on them being well-designed, focused on the key bottlenecks, and well-spent – and given the many factors impacting the performance of immunisation programmes 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. This risk is likely to increase as stronger countries transition out of Gavi support and Gavi’s grant portfolio is more concentrated in countries with weaker systems.





To address this risk, the Partner Engagement Framework (PEF) and the HSIS framework bring a strong focus on ensuring HSIS grants contribute to coverage and equity (and thus to build a platform for universal health coverage by building out the primary healthcare system to reach unserved communities). The HSIS framework includes prioritising critical bottlenecks, evidence-based investments, incorporating sustainability into the grant design, and increasing flexibility to adapt grants according to country progress. The Alliance is also seeking to strengthen the dialogue with countries as they design their HSIS grants including through the revised planning processes piloted under the Country Engagement Framework. The Secretariat is accelerating the process to disburse HSIS grants to countries once they are approved and has begun monitoring disbursements at country level to address bottlenecks as they arise. All HSIS grants now have robust performance frameworks with intermediate indicators measuring direct outputs as well as outcomes. As discussed under the risk on data quality, the Alliance is intensifying support to countries to improve the quality of data reported through these performance frameworks and countries are required to conduct regular coverage surveys to validate the quality

of coverage data. As discussed as part of the risk of misuse, the Alliance has also significantly strengthened its controls to manage risks associated with these grants.

Current risk exposure is high, but 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.

n) Frequent or unplanned campaigns

Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
n	Frequent or unplanned campaigns Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> • Periodic very large cash inflows for campaigns • Front line workers diverted to implement campaigns • Management capacity diverted to manage campaigns • Infrastructure (e.g., supply chain, transport) repurposed for campaigns • Poor planning and management undermine quality of the campaign, resulting in low coverage 			BROADLY WITHIN		

In Gavi's current strategic period, campaigns will account for a higher proportion of Gavi supported activities than in the previous period, 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 (also known as supplementary immunisation activities (SIAs)) help to rapidly increase population immunity and are thus an important tool for both preventing and responding to disease outbreaks. At the same time, frequent or unplanned mass vaccination campaigns can disrupt routine immunisation programmes and health systems. Campaigns are often implemented by the same health workers who would otherwise be providing routine services, who typically receive financial "per diems" for participating, potentially creating perverse incentives. Similarly, managers are often engaged to supervise campaigns, and key infrastructure such as supply chain can be repurposed to support a campaign. This can undermine routine immunisation, especially when repeated campaigns occur in a short period. The quality of implementation can vary significantly and some countries have to frequently repeat campaigns due to a failure to achieve sufficient coverage among the target population. They are also expensive (with per diems typically a major cost driver), resulting in large sums of money being disbursed in a short period of time. This can be a challenge for the implementing entity to manage and increases the risk of misuse. Some countries rely heavily on campaigns, often to compensate for poor routine immunisation coverage. While justified under certain circumstances, such reliance on campaigns is not sustainable given their cost and disruptive impact. Nonetheless, well-planned targeted campaigns, as part of a comprehensive immunisation delivery strategy, remain valuable and necessary to raise the profile of immunisation, vaccinate missed children, and mitigate risks of outbreaks. All members of the Alliance are expected to work with countries to ensure that campaigns are planned and executed in a manner that protects – and ideally strengthens – the broader immunisation programme.

The Gavi Secretariat and partners are increasingly working with countries to prevent this risk from occurring – by developing more integrated control strategies which emphasise high routine immunisation coverage as the primary strategy, and by strengthening planning and implementation of campaigns. 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, and encourages countries to invest operational grants in longer-term health systems strengthening. The Alliance also now requires that all campaigns include a coverage survey to evaluate the quality of implementation and identify unreached populations (for more targeted follow-up campaigns). The Secretariat is also intensifying its

review of campaign budgets before disbursing funds and ensuring funds are disbursed to partners where countries' systems are seen as inadequate to manage the funds. Expenditure is increasingly becoming subject to audit as the Programme Audit team has been expanded.

Given these measures, current exposure is still high but expected to decrease, and therefore broadly within appetite. Exposure will also likely decrease further if global polio eradication is achieved since polio campaigns have been particularly intense in some countries (although this may reduce the capacity to implement high-quality campaigns in some countries). The Alliance has a low appetite for the risk of immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of emergency campaigns responding to disease outbreaks.

o) Forecasting variability

Gavi forecasting variability driving inappropriate decision-making

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<p>o Forecasting variability Gavi forecasting variability driving inappropriate decision-making</p>	<ul style="list-style-type: none"> • Uncertainty over vaccine demand • Financial uncertainties (e.g., prices, FX) • Complexity of process • Sub-optimal systems 			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 estimates of population and immunisation coverage in each country; projected vaccine introduction dates and uptake; wastage estimates (depending on product presentations); countries' projected Gross National Income (GNI) (defining their co-financing share and transition date); vaccine price forecasts; projections of expenditure on cash-based programmes, Partner and Secretariat operating costs; and resource inflows (donor contributions, innovative financing proceeds, and investment income). 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, 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 been strengthening its forecasting processes and workflows with more 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 in to the process and data is reviewed and triangulated with other sources, e.g. shipment history and stock levels. 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.

Forecasting of the mature and routine vaccine portfolio (pentavalent, pneumococcal and rotavirus) has improved with variances in this year's projected expenditure due largely to reductions in pricing and better management of vaccine stocks. However, risk exposure remains high 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 however 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.

Polio transition

Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations

Not ranked pending further information becoming available to accurately assess exposure

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 such as micro-planning, programme management and population tracking, which could be beneficial if mainstreamed into routine immunisation programmes. With eradication coming closer and GPEI closure to occur following the certification of polio eradication, GPEI has begun to ramp down its financial support for activities in countries that have eliminated polio and has initiated planning with countries to map polio assets and determine the functions that can be repurposed to support broader health goals. While some GPEI-funded staff and assets, particularly those related specifically to conducting oral polio vaccine mass campaigns, can be let go with likely minimal impact on broader immunisation programmes, the loss of others, particularly related to disease surveillance, outbreak response and programme management, could have a larger impact on immunisation programmes. If the transition of immunisation-critical assets is not well-managed, public health capacity may be lost in some countries that would adversely impact national immunisation programmes including efforts to improve coverage and equity and conduct high-quality campaigns. Polio transition may also adversely impact WHO's capacity to support countries, particularly in sub-Saharan Africa, where its country offices and programmes are highly dependent on polio staff and funding.

In order to understand the contribution of polio assets to routine immunisation programmes and to determine where gaps will arise if those activities cease, polio asset mapping exercises are being undertaken by countries facilitated by GPEI. As more detailed asset mapping becomes available, 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. 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. However, progress to ensure full country ownership of polio transition planning is mixed and no country has finalised its plan with detailed budgets and potential funding sources for assets to be maintained. GPEI is under considerable financial pressure due to the difficulties of eliminating polio from the last three polio-endemic countries, Afghanistan, Pakistan, and

Nigeria, so it may soon need to accelerate its reductions in support for work in countries that have eliminated polio, including very fragile states such as Somalia and South Sudan.

Gavi's actual exposure to this risk varies by country, but could exist particularly in a small number of fragile countries where the footprint of GPEI is relatively large and national systems are very weak. In most other countries, routine immunisation programmes are less reliant on polio assets, but polio transition may impact specific capacities, particularly in disease surveillance and programme monitoring and evaluation. However, there is currently not sufficient information available in most countries to accurately assess the specific likelihood and potential impact of this risk on Gavi. It therefore is not prioritised as a top risk in this year's report, but as further information becomes available and understanding improves of how much risk this actually poses to Gavi, this may or may not appear as a top risk in next year's report.