

# THE VACCINE ALLIANCE RISK & ASSURANCE REPORT 2016



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## Risk & Assurance Report 2016

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# 1. Introduction

## 1.1. Purpose of this report

Every organisation operates in a dynamic context with uncertain and ever-changing internal and external factors which may impact existing plans and strategies to achieve its goals, either by creating new challenges or opportunities. For Gavi, this is particularly true given the ambitious nature of its mission; the poor and fragile countries in which the Alliance operates; the diversity of stakeholders that make up the Alliance; and its model whereby countries own implementation to enable sustainable development, and partners represent the Alliance and support implementation at country level. By anticipating what might happen and proactively monitoring and managing Gavi's exposures to these potential future events, effective risk management helps the Alliance to deliver on its ambitious mission and to maximise its impact.

Gavi's Risk & Assurance Report sets out the Alliance's current exposure to the critical risks that could potentially impact the ability of the Alliance to achieve its mission and strategic goals. It includes a description of the 15 top risks facing the Alliance – those which have the highest potential impact and are deemed most likely to occur given current mitigation. This first Risk & Assurance Report is based on an extensive cross-cutting exercise at the Secretariat to identify and assess the key risks across the Alliance (including through surveys, workshops, and validation meetings, corroborated by other sources of information and assurance findings). The assessment and segmentation of risks has been validated with partners, and the Secretariat will work with partners going forward to conduct more in-depth analysis and develop more coherent plans to monitor and mitigate each top risk. The report also includes an initial mapping of key sources of assurance on the effectiveness of current mitigation strategies for each top risk, which will be further refined in 2017. Furthermore, it contains an update on progress on the strengthening of risk management capabilities.

This report is prepared annually to provide the basis for an in-depth strategic discussion on Gavi's risk exposures and whether these are within the Board's risk appetite. At this December Board meeting, the Board is asked for its reaction to the report and to share any initial thinking on changes to the risk appetite statement. At the June 2017 Board meeting, the Board will receive a more high-level update on major changes since the last report, and will also review the updated Alliance risk appetite statement, which is particularly timely as this report highlights a number of areas where the current risk appetite statement does not provide sufficient clarity related to the identified top risks.

## 1.2. Gavi's evolving risk profile

Gavi's 2016-2020 strategy has an intensified focus on sustainable coverage and equity of immunisation, which will expose the Alliance to new uncertainties and related risks. Achieving equitable coverage improvements and preparing countries for a sustainable transition out of Gavi support, will require the Alliance to adapt and innovate, including by intensifying engagement with countries (with an increased focus on sub-national levels and areas with the weakest systems), by increasing its investment and bringing new tools to build country capacity, and by delivering new types of support through existing and new partners. During this year, the first cohort of countries has transitioned from Gavi support, and as stronger countries transition, Gavi's investments will become more concentrated in weaker and fragile states, some of which are also approaching transition in the coming years.

Furthermore, over the past year, the external environment has become increasingly uncertain and turbulent. Sluggish growth in advanced economies, slowing growth in developing countries (partly due to low commodity prices), and weak global trade continues to tighten both donors' and implementing countries' fiscal space. This may be compounded by recent and upcoming political events including the UK's decision to leave the European Union, and elections in key G7 economies which account for over half of Gavi's donor support

including Norway, the USA, Germany and France. Moreover, geopolitical tensions and conflict have resulted in record levels of population displacement, and the frequency and impact of natural disasters and infectious disease outbreaks is growing due to long-term trends such as climate change, globalisation and urbanisation.

These developments mean that Gavi's inherent exposure to many risks is increasing. To address this exposure, the Alliance has and will continue to implement a range of mitigation measures to bring and keep Gavi's current levels of risk within its risk appetite.

## 2. Alliance-wide risk exposure

### 2.1. Top risks facing the Alliance

This section discusses the top risks that could potentially impact the ability of the Alliance to achieve its mission and strategic goals. Out of all risks identified, 15 have been assessed as either “high” or “very high” risks. These are current exposures to potential future events which are considered to have the greatest potential impact and highest likelihood of occurrence, taking into account existing mitigation already reducing the risks and addressing issues as they are identified.

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

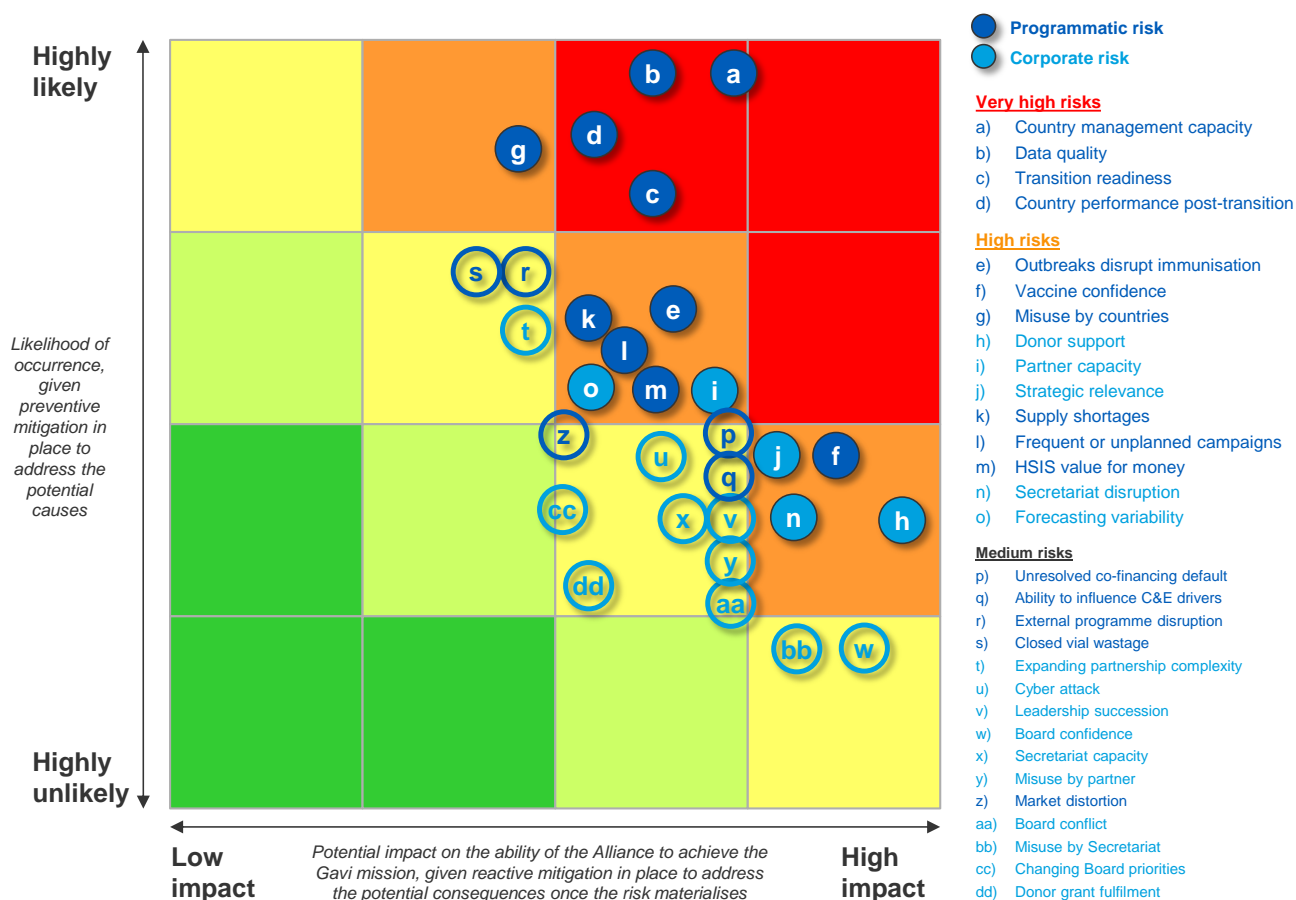
- a) **Country management capacity**  
Some countries (continue to) have insufficient capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity
- b) **Data quality**  
Continued lack of availability and use of quality data for immunisation
- c) **Transition readiness**  
Some countries transition without having built sufficient financial and programmatic capacity to sustain their programmes
- d) **Country performance post-transition**  
Some countries fail to sustain equitable immunisation coverage and introduced vaccines after transition

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

- e) **Outbreaks disrupt immunisation**  
Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries
- f) **Vaccine confidence**  
Significant loss of confidence in vaccine safety and efficacy
- g) **Misuse by countries**  
Deliberate misuse of Gavi funds in some 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 technical support to countries required for the new strategy
- j) **Strategic relevance**  
Gavi becomes less relevant to global development priorities
- k) **Supply shortages**  
Shortages in the global vaccine supply
- l) **Frequent or unplanned campaigns**  
Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services
- m) **HSIS value for money**  
HSIS investments do not materially improve programmatic outcome
- n) **Secretariat disruption**  
Significant disruption of Secretariat operations
- o) **Forecasting variability**  
Gavi forecasting variability driving inappropriate decision-making

# Alliance top risks ranked against likelihood and impact

## Current risk exposure, taking into account existing mitigation



The risk heat map above plots the top risks on two dimensions, taking into account existing mitigation:

- **Likelihood:** probability of the risk occurring given existing mitigation strategies to prevent the risk from occurring
- **Impact:** effect of the risk, if it were to occur, on the Alliance's ability to achieve its mission and implement its strategy given existing strategies to mitigate the impact of the risk

The risks in the red segment are ranked as *very high* and the risks in the orange segment are ranked as *high*. Some of the top risks are ranked high due to a high likelihood of occurring, while others have a relatively lower likelihood but would have a potentially high impact if the risk would materialise. The very high risks have both high likelihood and high 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. It is important to note that risks with high levels of exposure can be perfectly acceptable when the risk appetite is equally high. The next segment of risks in the yellow zone are medium risks (depicted with hollow circles), shown for comparison purposes but not further detailed below.

Many of the Alliance's highest risks are programmatic rather than corporate. This reflects the willingness of the Alliance to take risk in how it pursues its ambitious mission, while accepting a lower level of risk related to the Alliance's processes, systems and people. Furthermore, the very high risks all relate directly to Gavi's strategic goals on coverage and equity and sustainability, for which many mitigation strategies are still in the process of being scaled up. While this risk exposure is not surprising, it highlights the need for rigorous

monitoring and ongoing dialogue on these issues to ensure Gavi can achieve its 2016-20 strategy. For the most part, the high corporate risks are assessed as being unlikely to occur but with very high impact if they were to happen. Given they are less probable, these risks may not always be at the front of people's mind, but they are important to monitor and adequately mitigate given their potential significant impact.

There is a spectrum of risks ranging from more to less easily addressable by the Alliance. The causes of most risks can be directly addressed by the Alliance, at least partially, but for a subset of risks the Alliance has only limited ability to prevent occurrence within its current policies and resourcing. This means the Board either needs to accept risk exposure in these areas as inherent to Gavi's mission, change Gavi's approach to engage more comprehensively in prevention, or invest more in reactive mitigation strategies to reduce the impact to the Alliance when it happens. Most notably, for risk d) *country performance post-transition*, the Board has determined that Gavi should largely end engagement with countries after they transition.

The sections below contain a high-level description of each top risk, and discuss the exposure and potential future evolution of the risk in the context of Gavi's risk appetite (guided by the risk appetite statement where applicable). The appendix contains a more detailed description of each top risk, its causes, consequences and existing mitigation, and identifies the lead team in the Secretariat to manage the risk (recognising that partners also have a critical role in managing most of these risks), and the lead governance body to oversee it. It also contains a summary risk register including the medium risks, the risk universe used to evaluate potential risks in all areas, and a description of the methodology used. The Secretariat maintains a comprehensive risk register, including a broader set of lower risks and their associated mitigation strategies.

## a) Country management capacity

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

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

The Alliance is working with the poorest countries in the world, many of which are fragile states. Naturally, many Gavi countries have weak capacity. Key causes could include a lack of leadership; inadequate management or technical capacity; or insufficient human resources at delivery level. Existing capacity can be disrupted by other risks such as natural disasters, political instability and conflict and disease outbreaks. Joint appraisals, Effective Vaccine Management assessments, Programme Capacity Assessments, Programme Audits and other reviews and evaluations consistently highlight financial, programme, and supply chain management capacity gaps in countries.

Gaps in management capacity could potentially undermine the ability of the Alliance to achieve improvements in coverage and equity, and to prepare countries for a sustainable transition out of Gavi support. Both rely on strong country capacity and capabilities – with an increasing focus on management capacity in addition to a previous focus in many countries on technical capacity. Poor management capacity also increases a number of other risks, such as misuse of Gavi support and poor data quality.





Given the above, engaging and investing in management capacity-building is a key priority for this strategic period. As discussed in the Country Programmes update, Gavi has put in place a number of tools to better assess country capacity e.g. through Joint Appraisals and Programme Capacity Assessments, to better target

Gavi support to build capacity – including exploring new approaches to strengthen leadership, management and coordination (as detailed in the appendix to the Country Programmes update) – and to better monitor results over time. Recognising that capacity-building takes time, current country management capacity could be complemented by embedding partner staff in country systems, disbursing funds through partners where needed, and the use of fiduciary/monitoring agents for high-risk countries. Many of these mitigation strategies are still being scaled up as part of the new strategy and therefore not yet fully effective in mitigating the risk.

It is important to recognise that this risk will remain high, given the level of inherent exposure in many Gavi countries, and will likely grow since Gavi's strategy requires a focus on underserved areas with weaker capacity, and as stronger countries transition leaving the Alliance's investments concentrated in weaker countries. There is a potential trade-off between short-term efforts to mitigate risk (e.g., not using country systems) and long-term efforts to build capacity (which will itself mitigate risk). Although the current risk appetite statement is not explicit, the Alliance will need a high appetite for exposure to this risk in order to achieve its strategic goals in the poorest countries in the world.

## b) Data quality

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

Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
<b>Data quality</b> Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"> <li>• Accurate data not being generated</li> <li>• Generated data not shared with decision-makers</li> <li>• Shared data not used for decision-making</li> <li>• Data being manipulated</li> </ul>				

Many Gavi-supported countries have weak systems and capacity to generate, report and use data. This includes in critical areas such as programme data and disease surveillance. This can be caused by a lack of data collection systems or capacity; inadequate sharing of data with decision-makers; an inability to use data for decision-making; and the possibility of data being deliberately manipulated. Joint appraisals, Data Quality Assessments, Effective Vaccine Management assessments, Programme Capacity Assessments, Programme Audits and other evaluations consistently confirm data quality issues including inadequate data on programme performance, supply chains and disease surveillance, a reliance on inefficient paper-based systems and a lack of trained health workers. Discrepancies often exist between coverage data reported by countries, 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.

Data quality challenges 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.

Improvement in the availability, quality and use of data is a critical enabler for the current strategy, and therefore being addressed by the Data Strategic Focus Area. During the last strategy period, Gavi made significant investments in strengthening data and these are now being accelerated through a more focused and strategic approach. The Secretariat has integrated an enhanced focus on data in its grant management processes and partners in their technical assistance and capacity-building initiatives. 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.



This risk will likely remain high for the foreseeable future, given the level of inherent risk, as current mitigation efforts will take time to meaningfully improve data quality and the Alliance's investment in data is limited. It may increase as stronger countries transition. The current risk appetite statement has a moderate tolerance for risks related to data quality while actively pursuing strategies to assess and improve data systems. The Board should discuss whether current exposure is outside its risk appetite and warrants further investment in mitigation.

### c) Transition readiness

*Some countries transition without having built sufficient financial and programmatic capacity to sustain their programmes*

Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
<b>Transition readiness</b> Some countries transition without having built sufficient financial and programmatic capacity to sustain their programmes	<ul style="list-style-type: none"> <li>• Lack of (subnational) ability/capacity/fiscal space</li> <li>• Poor preparation for transition by Alliance</li> <li>• Insufficient prioritisation of health and immunisation</li> <li>• Overreliance on external support</li> <li>• External programme disruption</li> <li>• Disease outbreaks disrupting immunisation</li> </ul>				

Being time-limited and catalytic, Gavi 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. The Alliance needs to ensure that countries are both financially and programmatically ready for a successful transition out of Gavi support to ensure they make as much progress as possible with Gavi support and are able to sustain progress post-transition. A failed transition can be caused by poor financial, procurement and programme management capabilities; weak systems and capabilities; regulatory hurdles; a lack of fiscal space or subnational financing; or insufficient political will to prioritise health and immunisation. It can also be caused by an overreliance on Gavi or other external support or poor preparation for transition by the Alliance. Readiness can also be disrupted by external events such as natural disasters, political instability and conflict and disease outbreaks.

The first countries to transition under the current policy successfully began self-financing at the beginning of 2016. Another 16 are likely to transition by 2020 and 9 more will have entered the accelerated transition phase by 2020. Most of these countries are on track to transition successfully, but, as described in the Strategy update and Country Programmes update, some are at greater risk of failed transition. For example, Angola and Congo are due to be fully self-financing by 2018 but have been serial defaulters on co-financing, have declining Penta3 coverage and face challenges in terms of political commitment and management capacity. As stronger countries continue to transition out of Gavi support, exposure to this risk will continue to increase with weaker and more fragile states beginning to approach transition. For example, Nigeria is due to enter accelerated transition in 2017 with penta3 coverage which is among the ten lowest in Gavi and the second highest number of under-immunised children globally. It faces a very steep ramp-up in required expenditure from co-financing of US\$ 28.5 million in 2016 to nearly US\$ 200 million for Gavi programmes alone by 2022. Fiscal space in many transitioning countries, including Nigeria, is under pressure due to worsening economic circumstances (partly due to low commodity prices) with GNI falling in several countries which are due to transition. Many of these countries will also be transitioning out of support from other organisations over the coming years. If the cost of transition from Gavi support is conflated with transition out of other programmes – which may impose a higher fiscal burden and so be less sustainable – this would exacerbate the risk for Gavi's programmes.

As a critical strategic goal of the current strategy, the risk that countries are not ready for transition is being addressed by a dedicated Sustainability Strategic Focus Area which emphasises early engagement with every country on sustainability. The Alliance has mainstreamed sustainability into all of its support including through

the new health system and immunisation strengthening (HSIS) framework. For countries approaching transition, transition missions and assessments help identify bottlenecks, which are addressed with transition plans and tailored support to complement HSIS and targeted country assistance (TCA). As described above, the inherent risk is likely to increase over time as weaker countries approach transition. However, this should be balanced by the Alliance's enhanced focus on sustainability.

There is a potential trade-off between short-term efforts to improve coverage and equity (e.g. by introducing vaccines and increasing coverage through campaigns) and mitigate fiduciary risk (e.g., not using country systems), and long-term efforts to build capacity. The current risk appetite statement has a low appetite for strategies putting the sustainability of national immunisation programmes at risk, but is not explicit on how to balance the trade-offs with other risks, and on the tolerance for failed transitions. The Board should discuss whether current exposure is outside its risk appetite and warrants further mitigation.

#### d) Country performance post-transition

*Some countries fail to sustain equitable immunisation coverage and introduced vaccines after transition*

Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
<b>Country performance post-transition</b> Some countries fail to sustain equitable immunisation coverage and introduced vaccines after transition	<ul style="list-style-type: none"> <li>Insufficiently prepared before transition</li> <li>Lack of access to global markets and expertise</li> <li>Reduction in (subnational) ability/capacity/fiscal space</li> <li>Reduction in prioritisation of health and immunisation</li> <li>External programme disruption</li> <li>Disease outbreaks disrupting immunisation</li> </ul>				





At the end of this strategic period, approximately 20 countries will have transitioned out of Gavi support. Even if they are well prepared for transition beforehand (see previous risk), there is a risk that countries still fail after transition. This can be caused by a reduction in capacity, capabilities, fiscal space or prioritisation of health and immunisation after transition. Further causes can be lack of access to global vaccine markets and technical expertise previously provided by Gavi, and external disruptive events such as natural disasters, conflict or socio-political upheaval. Under current policies, the Alliance will not continue to engage with countries post-transition, and will have limited ability to monitor or influence immunisation outcomes.

If countries fail after transition, it will impact health outcomes in that country and diminish the return on Gavi's investments. It may also impact Gavi's reputation and the perceived viability of Gavi's 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.

The Alliance makes every effort to prepare countries for transition and while the Secretariat will not formally engage with transitioned countries, partners continue to do so. Partners monitor post-transition indicators for five years, to assess whether a country is successfully sustaining gains made with Gavi support, and coverage in countries post-transition is one of the strategy indicators. The Secretariat will report on these indicators, and can escalate issues to the Board. However, under current policies, the Alliance will have limited ability to proactively address the risk of failure before it occurs. The current risk appetite statement is not explicit on this risk, but given that the Board has indicated the Alliance should end its engagement with countries post-transition, it will need to accept a high exposure to this risk or modify this policy.

## e) Outbreaks disrupt immunisation

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

Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
<b>Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries	<ul style="list-style-type: none"> <li>• Low population immunity</li> <li>• Lack of capacity/tools to detect, prevent and respond</li> <li>• Population behaviour</li> </ul>				

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. Gavi-eligible countries are particularly vulnerable to outbreaks since they are home to reservoirs for many of these diseases and often have weak public health capacity to prevent, detect and respond to them.





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.

Immunisation has an important role to play in helping countries to prevent, detect and respond to outbreaks. Strong immunisation programmes include key public health capacities to detect outbreaks early (through robust disease surveillance) and respond (including through immunisation campaigns, social mobilisation and contact tracing). Vaccines are often a key tool to prevent outbreaks by building population immunity and to respond to them through immunisation campaigns (for some diseases such as yellow fever, they are the only tool). Through its HSS grants, the Alliance helps countries to strengthen public health capacities and disease surveillance is a key area for the Data Strategic Focus Area. Gavi 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 next Vaccine Investment Strategy). Following an outbreak, the Fragility Policy provides significant flexibility on the support which can be provided to countries to help with recovery.

The current risk appetite statement does not clearly articulate the Alliance's tolerance for this risk. At the April 2016 Board Retreat, the Board agreed that Gavi has a role in helping countries prevent and respond to outbreaks where this links to immunisation but that the Alliance should not have a broader role (e.g., in helping to build core public health capacities beyond immunisation). This implies a moderate risk tolerance for the occurrence of outbreaks where the drivers cannot be addressed through Gavi's core mission.

## f) Vaccine confidence

### *Significant loss of confidence in vaccine safety and efficacy*

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

Adverse events following immunisation (AEFIs) happen, and can undermine confidence in vaccines rapidly. There is no vaccine which is entirely effective and completely risk-free. Beyond the vaccine itself, poor handling, inappropriate vaccine administration, and not disposing of expired vaccines are ongoing issues in some Gavi countries which could lead to AEFIs or the use of impotent vaccines. Moreover, given the scale of immunisation efforts, it is inevitable that some people will have health issues at the same time as, or shortly following, receiving a vaccine. Therefore, while vaccines can directly cause health problems, many AEFIs are coincidental. As more people receive vaccines, AEFIs may increase, and the reduced incidence of disease may make it harder for people to see the impact of vaccines, causing complacency or amplifying scepticism. There are furthermore strong anti-vaccine movements (driven by ideology, religion or false beliefs) in some countries and anti-vaccine sentiment and rumours are moving more quickly across borders due to globalisation and communication technology.

Loss of confidence in vaccines can ultimately have dramatic consequences for immunisation coverage and disease incidence. AEFIs can lead to product recalls and cause programme discontinuations or delays. Furthermore Gavi could become the target of a lawsuit, or 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 efforts to strengthen coverage and equity of immunisation.





To address this risk, the Alliance only procures vaccines which are licensed by a stringent national regulatory authority and WHO prequalified. The Supply Chain Strategy focuses on building supply chain capacity to improve vaccine handling and Gavi supports strengthening of national regulatory authorities through HSIS and PEF. To detect and respond to events, Gavi supports strengthening of safety surveillance and adverse event reporting by countries, and is exploring new approaches to promote demand for and build confidence in immunisation. The Secretariat's Communications department monitors global and national media for reports of vaccine-related incidents and works with Alliance and advocacy partners to strengthen public perception of vaccines. When AEFIs occur in a Gavi-supported country, the Alliance responds rapidly and partners support the government to respond, e.g. with causality assessments and autopsies.

The risk appetite statement expresses a low tolerance for risks to vaccine safety that could negatively affect the health of children in implementing countries, but is not explicit on the wider vaccine confidence risk.



## g) Misuse by countries

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

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

The Alliance works with the poorest countries in the world, many of which have weak systems, low capacity, poor governance and / or prevailing corruption. Gavi seeks to use country systems whenever possible in order to ensure country ownership of programmes and build the capacity of countries to manage those programmes, which is critical for sustainability. Given the weaknesses described above, this exposes the Alliance to the risk of its support being misused. This 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. Several Programme Audits have identified unsupported expenditure, misused funds and weak controls. Vaccines are less prone to theft and diversion, due to a lack of secondary markets. Gavi's exposure to this risk 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 has a financial cost to Gavi and reduces the impact of its investments. Significant or sustained cases of misuse can also 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.

Programme Capacity Assessments assess a country's capacity to manage support and inform Gavi's decision on how to channel cash support. When Gavi has concerns about its funds in a country, Gavi can impose additional controls including use of a fiduciary agent or – when necessary – channelling funds through partners. 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. The Secretariat is also working with partners to clarify accountabilities for detecting and reporting potential misuse. Programme Audits are conducted over a targeted 5-year cycle with higher risk programmes being covered twice in that period. Gavi has also set up an anonymous and confidential whistle-blower hotline to which anyone can report suspected misuse. Gavi has zero tolerance for misuse once it happens and seeks full reimbursement from countries. To date, 99% of reimbursement due (according to the repayment schedule agreed with the respective government) has been repaid to Gavi. After misuse is identified, 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.

The current risk appetite statement states that Gavi will not tolerate misuse of funds, and it will always seek reimbursement for any identified cases. However, although Gavi has zero tolerance for misuse once it happens, it does need an appetite for the risk of misuse, which is inherent to pursuing its mission and building sustainable systems (while actively working to prevent it). There is a potential trade-off between mitigating fiduciary risk (by not using country systems), and long-term efforts to build the capacity of those systems. Mitigation of fiduciary risk can furthermore be costly (e.g. when using fiduciary agents). With more countries approaching transition this strategy period, it will be important to carefully balance this trade-off.

## h) Donor support

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

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

Donor pledges are crucial to sustaining Gavi's currently funded programmes and the Alliance's ability to fund new vaccines. In 2015 total donor funding in the form of direct contributions and proceeds from innovative finance mechanisms amounted to US\$ 1.7 billion. However, sluggish economic growth continues to tighten donors' fiscal space. This may be compounded by recent and upcoming political events including the UK's decision to leave the European Union and elections in key G7 economies which account for over half of Gavi's donor support including Norway, the USA, Germany and France. Political shifts in ideologies and priorities, increasingly hostile media, 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.

To be less dependent on a few large donors, Gavi has been working to significantly widen the donor base. Four new donors (China, Oman, Qatar and Saudi Arabia) made pledges to Gavi for the first time at the 2015 Berlin Replenishment and all BRICS countries have now made pledges to Gavi. Furthermore, contributions are more evenly spread over donors than in the past. The Gavi Secretariat, and especially the resource mobilisation team, invest significant efforts in working closely with donors to ensure their needs are met and that they feel sufficiently engaged in the Alliance. Furthermore, there is increased involvement of the private sector to leverage investments, expertise and innovation. Continuous efforts are made to increase Gavi's public profile (through communications and advocacy organisations) and to engage donors. The fact that the composition of the Board includes key stakeholders in global development helps to ensure continued relevance of Gavi in line with donor priorities.

Although current funding and donor engagement is adequate, this risk is increasing over time given the broader macroeconomic landscape. The risk appetite statement expresses a low risk appetite with regard to raising donor funds in order to safe-guard predictable financing of vaccines. Although the risk is currently well mitigated, a significant increase in the likelihood of this risk materialising may require further Board discussion.

## i) Partner capacity

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

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





Alliance partners play a critical role in the Alliance's ability to deliver on its mission and strategy. Their role is to provide countries with the technical support required to strengthen their immunisation programmes, and they are also the permanent representatives of the Alliance at country level. Partners' capacity to provide the full range of support which countries require is therefore critical. The ambitious goals of the Alliance's 2016-20 strategy will require new and intensified support to countries including assistance in new areas (e.g., implementation support, financial management, building leadership capacity). It will also require that the support is truly country-owned and better coordinated across partners.

The Partners' Engagement Framework, which was launched this year, is aiming at addressing many of these needs and there is progress in developing technical support packages which are based on country needs, creating coherent country technical assistance plans, embedding partner capacity at country level (rather than global or regional level) and engaging a broader set of expanded partners with specific expertise. Nonetheless, there have been delays in recruitment of Gavi-funded staff in partner organisations while the Alliance is still working to find partners with all the required expertise in every geography. The Secretariat and partners are working together to address these challenges and to ensure that countries receive the highest quality of technical assistance in the form of country-driven technical support packages. Implementation of the PEF is being overseen by the PEF Management Team with regular reporting against a pre-defined performance framework, while countries will evaluate the quality of support they receive through a survey later this year. These will be important indicators of whether this risk is being adequately mitigated. Another mitigation strategy is to contract expanded partners and utilise private sector partnerships for new areas of assistance for which the Alliance does not have the expertise and capability. While this may be an effective mitigation strategy for this risk, it does potentially increase transaction costs and challenges to manage an expanded partnership (see medium risk "Expanding partnership complexity").

The current risk appetite statement does not clearly articulate the Alliance's tolerance for this risk. However, it has a high risk appetite for ambitious and innovative strategies to strengthen health systems. This would imply that the Board accepts the risk that there may be some challenges in implementation of the new support model for countries. Nonetheless, since partner capacity is critical to delivering on the strategy, the appetite for this risk overall is likely low.

## j) Strategic relevance

*Gavi becomes less relevant to global development priorities*

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





Gavi was created at the launch of the Millennium Development Goals to drive progress on immunisation – one of the key contributors to the fourth Millennium Development Goal – and also as a new model for development. As one of the most successful and cost-effective health investments, immunisation has remained prominent on the global development agenda, as has the Alliance given the success of its business model and its tangible, substantial impact. However, as the world enters the Sustainable Development Goal (SDG) era, there is a risk that immunisation and Gavi become less relevant. This could be due to competing development priorities, both within the health space (e.g., non-communicable diseases, nutrition) or outside it (e.g., climate change, education). More players are entering an increasingly complex and fragmented global health landscape and a perception may emerge that the job is done due to high coverage of basic vaccines which now reach 86% of children globally. This risk would be exacerbated if Gavi is unsuccessful in securing an ambitious SDG indicator on immunisation. 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 and public 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 highlight the relevance of vaccines to other priorities (e.g., 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 risk is likely to increase given the factors described before. The risk appetite is not explicit on this risk. Although its likelihood is relatively low, its potential impact would be very high. The Board should therefore discuss whether current exposure is outside its risk appetite and warrants further mitigation.

## k) Supply shortages

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

Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
<b>Supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Lack of supply security</li> <li>External disruption</li> </ul>				

Secure and reliable vaccine supply is essential for Gavi-supported immunisation programmes. In the past, supply shortages have delayed introduction of new vaccines such as pneumococcal and rotavirus, while routine introductions of inactivated polio vaccine (IPV) are still being delayed due to supply constraints. Such shortages can also affect outbreak response – efforts to contain the ongoing yellow fever outbreak have had







to use fractional doses in order to cover the target population with the limited vaccine available. The risk of supply shortages is generally decreasing for Gavi's more mature vaccines (e.g., pentavalent) as supply capacity has increased over time and demand is more stable as the pace of vaccine introductions slows. However, it remains a high risk for a number of vaccines (including IPV, yellow fever and measles-rubella) 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 also involve encouraging existing manufacturers to expand capacity or new ones to enter the market. The Alliance secures the 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.

The current risk appetite statement has a low risk appetite for procurement of adequate quantities of vaccines to avoid shortfalls and ensure predictable supply, however it is less clear on the broader global risk and also expressing a high appetite for shaping markets. Existing mitigation is rated as strong as the Alliance attempts to align risk exposure with this risk appetite level, and there are ongoing plans by manufacturers which will increase capacity in most of the markets experiencing supply shortages. However, it is important to note that increasing manufacturing capacity is a long-term process and timelines can be delayed due to unforeseen technical challenges.

## I) 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	Recent evolution	Long-term outlook
<b>Frequent or unplanned campaigns</b> Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>				

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 furthermore often implemented by the same health workers who would otherwise be providing routine services, who typically receive financial "per diems" for participating, potentially creating a perverse incentive. 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.

The Alliance is increasingly exposed to this risk as it has expanded its support for immunisation campaigns, most recently with approval of the new measles and rubella strategy. At the same time, the Secretariat and partners are increasingly working with countries to prevent the 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 new Board-approved 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.

The current risk appetite statement does not clearly articulate the Alliance's appetite for this risk. However, there is an inherent trade-off between the high appetite for achieving equity goals (for which campaigns can be very effective) and the lower risk appetite for misuse of funds and sustainability

#### m) HSIS value for money

*HSIS investments do not materially improve programmatic outcomes*

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

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 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 new HSIS framework brings a much greater focus on ensuring HSIS grants contribute to coverage and equity. 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 Country Engagement Framework, which is currently being developed with a set of early-learning countries. 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.

The risk appetite statement includes a high risk appetite for ambitious and innovative strategies to strengthen health systems but a low risk appetite for misuse. Ongoing efforts should reduce the risk of misuse and of funds being poorly spent, while continuing to support investment in countries and programmes with uncertain – but potentially high-impact – outcomes.

## n) Secretariat disruption

### *Significant disruption of Secretariat operations*

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





The likelihood of a catastrophic event significantly disrupting Secretariat operations is relatively low, were it to occur, it would be highly disruptive and could interrupt the Alliance's operations for a prolonged period of time. Potential causes include a natural or man-made disaster, a substantial security threat to staff, a significant IT systems failure, data loss or data breach, or by 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 historically low reliance on automated systems limits the potential impact of system failures and data loss (although this is changing as the Secretariat is scaling up its investments in knowledge management and rolling out new technology-enabled systems and processes) and the limited confidentiality of data in line with the transparency policy limits the potential impact of data breaches.

To address this risk, the Secretariat is developing a crisis management framework with emergency response plans and recovery arrangements to ensure business continuity during and after a crisis. Over recent years, there has been a particular focus on strengthening travel security. The Secretariat operations team conducts a medical and security risk assessment before an individual travels. Colleagues traveling to high or extreme risk locations are actively tracked, receive regular security alerts, and their accommodation, transportation and security arrangements are reviewed by the operations team. There is also a restriction on the number of key employees allowed to travel on a single flight. IT security is also being strengthened and an IT business continuity and disaster recovery plan is being designed. The crisis management framework will identify other risk areas which require further attention and investment.

The risk appetite statement is not explicit on this risk, but appetite is likely to be low. With the implementation of the planned crisis management framework and the IT business continuity and disaster recovery plan this risk is likely to reduce in the future by strengthening preventive measures and by being better prepared to respond to disruptive situations once they occur.

## o) Forecasting variability

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

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

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. Some of these uncertainties are increasing, e.g., new vaccines represent an increasing share of total spend, and for some expensive vaccines the demand is harder to predict (e.g. HPV). In addition, future expenditure is declining with more countries approaching transition.

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. supply history. Forecasting has also been identified as a future priority for the knowledge management team, which will help design more robust tools and systems. 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.

Although the risk appetite statement includes a low appetite for both supply shortages and insufficient fund-raising to safe-guard predictable financing for vaccines, it is not explicit in its appetite for variability in forecasting. There is a potential trade-off between the need to be ambitious, provide incentives to countries and manufacturers and minimise the risk of funding shortfalls, and efforts to provide a highly accurate point

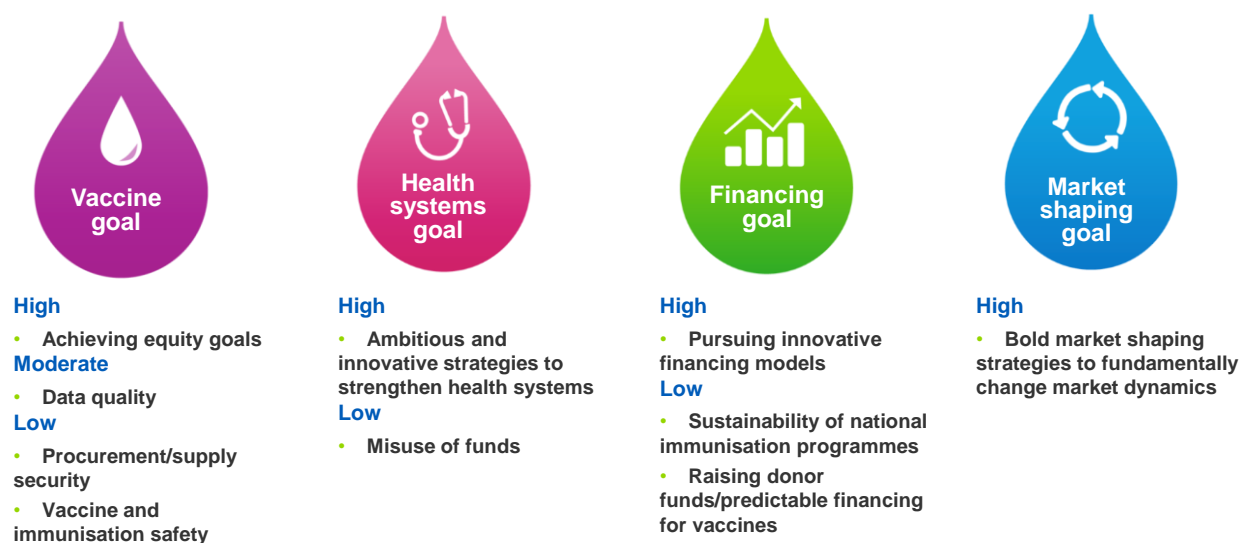


forecast. The Secretariat will continue to work to refine its forecasting while erring towards being conservative on ensuring sufficient supply and funding.

## 2.2. Risk appetite discussion

Some level of risk will always be inherent to Gavi's business, both in its mission to help achieve dramatic progress in immunisation in the world's poorest countries, often with very poor infrastructure, and in its operating model as an Alliance with a lean Secretariat without in-country presence. Some objectives can only be achieved by taking calculated and carefully managed risks, and sometimes the greatest risk is inaction. Moreover, Gavi's ambitious 2016-2020 strategy requires an increased exposure to risks by prioritising efforts to improve sustainable coverage and equity of immunisation, which will require more intensive engagement with countries, greater country capacity-building (including financial capacity), and a deeper focus on weaker and fragile states, poorer urban areas and remote rural locations. A comprehensive and systematic approach to risk management will enable the Alliance to take the right amount of the right type of risks needed to deliver on this ambitious mission and maximise Gavi's impact.

Risk management is therefore not about avoiding or eliminating all risks at all cost, but about taking risks consciously based on informed decisions and prioritising the key risks that are most important to address with limited resources. Potential outcomes are optimised by balancing risk versus reward and the cost of mitigation versus the potential benefit this brings. Gavi's risk appetite statement (see Annex and summary graph below) defines on a broad level the amount of risk the Alliance is willing to accept to achieve its goals, with the belief that if risks were to materialise, the downside is moderate or acceptable in light of the rewards being pursued.



Gavi's current risk appetite statement provides helpful high-level guidance on the Alliance's appetite for broad areas of risk, but is only directly applicable to two of the top risks described above, namely "Data quality" and "Donor support" – and even there more nuanced guidance would help to ensure optimal alignment. The risk that data quality does not improve is currently rated as very high whereas the risk appetite statement expresses a moderate tolerance for risks related to data quality while actively pursuing strategies to assess and improve data systems. A more granular discussion is therefore needed on whether the current risk exposure in this area is outside the Alliance's risk appetite (in which case the Alliance will need to evaluate how to scale-up investment in mitigating this risk or to reduce investment in programmes or countries with the greatest exposure) or whether the risk appetite statement needs to be better nuanced. Similarly for the high "Donor support" risk, the statement expresses a low risk appetite with regard to its core function of raising donor funds in order to safe-guard predictable financing of vaccines. This risk is primarily rated high due to its potential

impact once it occurs, while its likelihood is currently still relatively low (but increasing). More nuanced discussion is therefore needed on how to operationalise a low risk appetite in this context.

For all the other top risks the current risk appetite statement does not provide clear guidance. For some top risks there is also a trade-off whereby a reduction in risk appetite could result in an increase in risk exposure in other areas. To address this, the Secretariat will be developing a more granular risk appetite statement – including specific risk tolerances for each of the identified top risks and a more robust assessment of trade-offs – for consideration by the Board in June 2017.

### 3. Assurance on current risk mitigation

“Assurance” is the outcome of a review process which verifies that risk mitigation actions are operating as designed and thereby confirms that these provide the expected level of control in terms of preventing, detecting, and being ready to respond if a risk occurs. It may also find that this is not the case and identify where improvements might be required. Assurance reviews can also provide additional intelligence and triangulation on the risk level and exposure. When mitigation weaknesses are identified, or when risks have resulted in specific issues by materialising, the Alliance actively works to remediate and monitor these, as well as to strengthen existing or implement new mitigation measures to prevent reoccurrence in the future.

Assurance is provided by several sources, from more subjective self-assessments to more objective evaluations and independent audits (the latter typically being the most robust source of assurance). Key sources of assurance include:

#### Independent assessments:

- Internal Audits assess the effectiveness of processes across the Alliance, both within the Secretariat and beyond.
- Programme Audits assess whether adequate controls are in place in each country and if Gavi support, including cash, vaccines and related supplies, has been used as intended to provide value-for-money.
- Countries are also required to undergo external audits, independent data quality assessments and coverage surveys.
- Donor reviews are an independent source of assurance on the performance of the Alliance and its relevance for donors (although each donor assessment framework is shaped by its own priorities and these entail high transaction costs for the Secretariat).

#### Secretariat assessments:

- Programme Capacity Assessments are a forward-looking review of the programme, financial and vaccine management capacity of an implementer to manage and account for funds received, and to effectively manage programmes and vaccines.
- Transition assessments identify bottlenecks for successful transitions out of Gavi support.
- Evaluations are regularly conducted of Gavi's programmes, policies and performance.

#### Partner assessments:

- Effective Vaccine Management assessments evaluate the strength of vaccine supply chains and help countries to improve supply chain performance.
- WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) contain “grades of confidence” expressing to what extent coverage data is being confirmed with other sources.
- The World Bank conducts Health Financing Systems Assessments, which will include an assessment of immunisation financing in selected Gavi countries.

#### Country assessments:

- Countries self-assess and self-report through different mechanisms including the International Health Regulations self-reporting on surveillance capacities.
- Countries will be asked to provide their feedback on technical assistance provided in a planned PEF TA survey.

The table below provides an initial high-level overview of how each source of assurance maps to the Alliance's top risks. The top risk sheets in the appendix identify all potential sources of assurance available for each risk.

Assurance source	Top risks														
	Country management capacity	Data quality	Transition readiness	Country performance post-transition	Outbreaks disrupt immunisation	Vaccine confidence	Misuse by countries	Donor support	Partner capacity	Strategic relevance	Supply shortages	Frequent or unplanned campaigns	HSIS value for money	Secretariat disruption	Forecasting variability
	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o

#### Independent assessments

Internal audits															
Programme audits															
External government audits															
Data quality assessments / coverage surveys															
Donor reviews of Gavi															

#### Secretariat assessments

Programme Capacity Assessments															
Transition assessments															
Evaluations															

#### Partner assessments

Effective Vaccine Management assessments															
WUENIC Grade of Confidence															
Health Financing System Assessments															

#### Country assessments

Self-assessments / self-reporting															
PEF TA survey															

Existing      Planned      Partial or indirect

The table shows that the highest risks in particular have multiple sources of assurance on the robustness of current mitigation strategies. However, some of the risks rated as “high” have more limited sources of assurance. This is an early mapping based on a high-level review, and will be further refined in 2017 to evaluate whether any top risks currently have inadequate assurance and review the quality and reliability of current assurance (recognising that many are still being scaled up). Upcoming risk assessments will increasingly be informed by the findings from these assurance mechanisms.



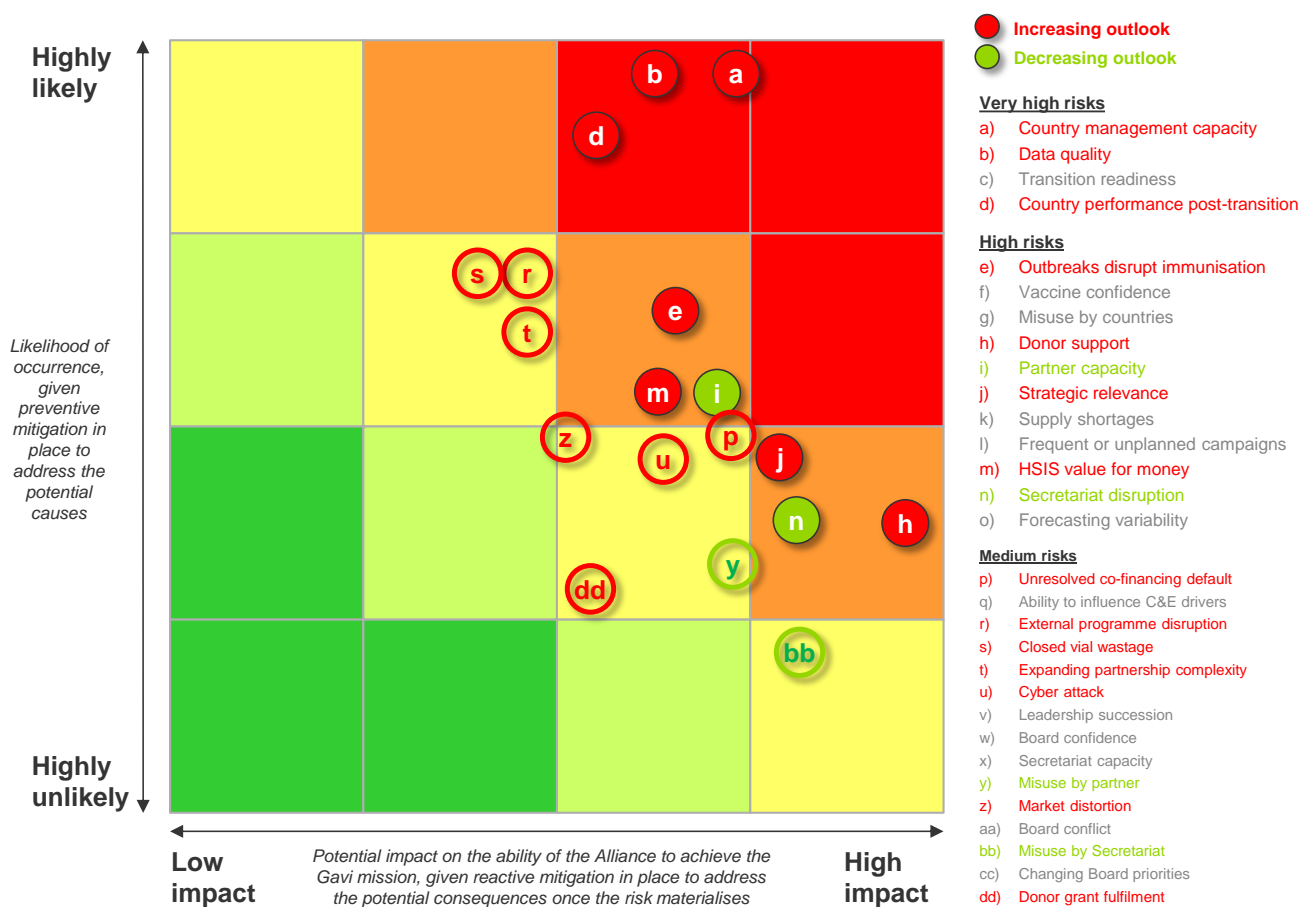
## 4. Continuing the risk management journey

### 4.1. Managing and monitoring identified top risks

Having catalogued and segmented the key risks facing the Alliance, going forward, the Secretariat will work with Alliance partners to conduct more in-depth analysis of these risks and develop more coherent remediation plans to mitigate each top risk. This will be reflected in the next Risk & Assurance Report, which will also seek to assess whether existing remediation plans will appropriately mitigate each risk in line with the Alliance's risk appetite (once implemented as designed) or whether further mitigation actions may be required.

The Secretariat also plans to develop more systematic metrics for monitoring the evolution of each top risk and to capture key developments as they occur. This will enable a more dynamic and objective understanding of how the Alliance's risk exposures may be changing and will inform future analysis for the Risk & Assurance Report. As depicted in the chart below, many of the risks facing the Alliance are evolving with an increasing or decreasing long-term outlook. The ones decreasing may no longer be top risks in the next report, however, a number of medium risks are increasing and may become top risks in the future. The Secretariat will continue to track the evolution of all low, medium and high risks and update the Board on major shifts in June 2017.

## Long-term outlook Evolving and emerging risks



## 4.2. Strengthening risk management capabilities

Gavi's approach to managing risk has evolved over time, driven by a realisation that the original "light-touch" model may not provide sufficient assurance and accountability, and by an increasing risk awareness and reduced risk tolerance among key stakeholders, especially donors. As approved by the Board in December 2014, Gavi is currently implementing a new, comprehensive approach to risk management covering all types of risks: strategic as well as operational, fiduciary and programmatic. The Board approved a Risk Policy<sup>1</sup>, including a risk appetite statement, and the Secretariat launched a new organisational structure in which risk management and assurance functions are structured according to the Three Lines of Defence model<sup>2</sup>. This ensures clear and distinct roles across teams and objective checks, balances and controls. It also included enhanced resourcing in specific functions, the creation of a dedicated Risk function, and the formation of a standing Risk Committee, chaired by the CEO with senior leadership from across the organisation.

In the first line, all new resources against the original plan have been recruited and these are being complemented by additional resources approved by the Board last December. These resources have been allocated in line with levels of fiduciary and programmatic risk in each country, with dedicated Senior Country Managers (SCMs) for the highest risk countries (currently in place for Nigeria, DRC, Pakistan and India). Under the Country Team Approach (rolled out to 16 priority countries), the highest-risk countries have prioritised capacity from staff in other specialist teams (e.g., Grant Performance Monitoring, Legal, Finance). A capability-building programme for existing Country Support staff has been delivered and all new staff will be systematically on-boarded on risk issues. Country Risk Matrices have been rolled out to 34 priority countries and remaining countries will follow by early 2017. The Country Risk Matrix is designed to identify, assess and manage risks in each country, and escalate key risks to management. Cross-cutting risk issues are being discussed in team meetings and quarterly regional review meetings. They will inform how the capacity of Country Programmes staff is allocated, how Gavi engages with countries and will inform key decisions such as grant approval, renewal and reprogramming, disbursements, and provision of technical support. The Programme Finance team has worked on developing key financial and fiduciary risk management tools and approaches (such as budgeting and disbursement reviews, and reporting guidelines).

In the second line of defence, the Programme Capacity Assessment team is now fully staffed and a pool of contractors has been selected to conduct Programme Capacity Assessments (PCAs), based on experience of conducting similar assessments, familiarity with the country, having in country staff, and cost. PCAs evaluate the programme, financial and vaccine management capacity of the structures which oversee the use of Gavi support in each country, and inform country risk assessments, appropriate funding mechanisms, grant agreement conditions, and technical assistance needs. The first wave of PCAs has now been completed and the findings are being integrated into grant management requirements and practices. The PCA tool and preferred contractors are both being refined based on lessons learned from this first wave.

Also in the second line, Grant Performance Frameworks have now been introduced for all countries to enable results-focused management of Gavi's vaccine and health system strengthening grants. These provide a tool to systematically track progress based on metrics and targets agreed with the countries and give an update on how many countries are reporting. Performance-related issues can inform country risk assessments and represent early-warning signals for the need of increased oversight.

The Risk function is coordinating, facilitating and monitoring the implementation of effective risk management practices across the Alliance by providing specialised expertise, promoting a risk-aware culture, and

<sup>1</sup> See <http://www.gavi.org/About/Governance/Programme-policies/Risk-policy/>

<sup>2</sup> See Annex III

establishing risk reporting throughout the organisation. It is now fully operational and is focused on supporting teams to strengthen their risk management practices and enhancing corporate risk management processes including through redesigning the Corporate Risk Register to provide an aggregated top-level view of risks as reported upon in this Risk & Assurance Report.

In the third line of defence, the Audit & Investigations department has in place 12 of the 13 approved positions. Programme Audits assess whether adequate controls are in place in each country and if Gavi support, including cash, vaccines and related supplies, has been used as intended to provide value-for-money. Internal Audits assess the effectiveness of processes across the Alliance, both within the Secretariat and beyond. The 2015 Internal Audit and Programme Audit plans were fully executed. The 2016 Internal Audit and Programme Audit plans were approved by the AFC and execution is ongoing and being routinely reviewed by the AFC. The Investigations function conducts investigations as needed where there is concern as to potential misuse within Gavi and Gavi-supported programmes in-country, following an audit or else triggered by other events. It has undertaken a number of reviews internally and externally and has prepared a fraud-resilience assessment for review by the AFC.

Gavi has largely implemented the changes approved by the Board in December 2014 to strengthen risk management and assurance practices, resulting in significantly enhanced risk management capabilities. Implementation of new tools and processes is now being scaled up and institutionalised in day-to-day management. Once fully scaled up, the Secretariat plans to step back in 2017 to review how well it is functioning and identify potential areas for further improvement. Going forward, the focus will increasingly shift to intensifying work with partners to enhance risk management practices more broadly across the Alliance and at country level.

# ANNEXES

## Annex I – Risk Appetite Statement<sup>3</sup>

### Introduction

Gavi, the Vaccine Alliance, recognises that its ambitious mission, its focus on lower-income countries, its operating principles – including a commitment to aid effectiveness principles – and its business model – with a small-sized secretariat without country presence – come with inherent risks.

While the risk appetite of individual Alliance members may vary, consensus in decision-making is reached through the Gavi Board and guided by the Gavi Strategy, which includes an overall mission, operating principles and goals. Within this strategic framework, Gavi engages in a portfolio of activities, some of which are lower risk and others higher risk. Higher-risk activities will be undertaken only where they offer benefits commensurate with the level of residual risk involved and do not increase risk to an unacceptable level; that is, where an adverse outcome would seriously jeopardise the achievement of the Gavi mission.

### Risk appetite

The following paragraphs articulate risk appetite in relation to Gavi's four strategic goals (SG1-4) and to key functional areas. In addition, tolerance for certain critical risks is expressed. This list is not comprehensive in describing all areas of Gavi's work nor every type of risk; it is intended to give an indication of willingness to accept risk in certain key areas.

- With regard to **accelerating the equitable uptake of vaccines** in lower-income countries (SG1) Gavi has a *higher risk appetite*<sup>4</sup> relative to other areas of work. Achieving rapid access to new, life-saving vaccines is at the heart of Gavi's mission. The Alliance is willing to be bold and take some risk in pursuing this important goal.
  - The Alliance has a *lower risk appetite* in the operational area of **procurement** of adequate quantities of vaccines for national immunisation programmes; it is committed to avoid shortfalls and ensure predictable country supply.
  - The Alliance has a *higher risk appetite* for achieving its **equity** goals, as this implies working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations.
  - The Alliance has *low tolerance* for risks to vaccine and immunisation **safety** that could negatively affect the health of children in implementing countries; it follows the guidance of the World Health Organization on safe and appropriate vaccines.
- The Alliance recognises that working in settings with relatively weak data systems comes with certain risks. It has a *moderate tolerance* for risks related to **data quality** while actively pursuing strategies to assess and improve data systems.
- Gavi has a *higher risk appetite* in relation to **strengthening health systems** (SG2) for better immunisation outcomes; strong health systems are essential for realising the full potential of immunisation and for the sustainability of programmes; the Alliance is willing to pursue ambitious and innovative strategies towards this end, which will come with certain risks.
  - However, the Alliance will *not tolerate* misuse of funds, and it will always seek reimbursement for any identified cases. It will manage **fiduciary risks** through an effective system of controls.
- The Alliance has a *lower appetite* for strategies that put the sustainability of national immunisation programmes at risk (SG3). This is an important limitation to the ambition of achieving SG1.
- Gavi has a *higher risk appetite* when it comes to strategies for **shaping markets** (SG4), for example to reduce vaccine prices, recognizing that in some cases bold steps are needed to fundamentally change market dynamics and sustainably increase access to vaccines in lower income countries.
- Gavi has a *lower risk appetite* with regard to its core function of **raising donor funds** in order to safe-guard predictable financing of vaccines; it has a higher risk appetite in relation to pursuing **innovative financing** models in order to lead innovation in sustainable development financing.

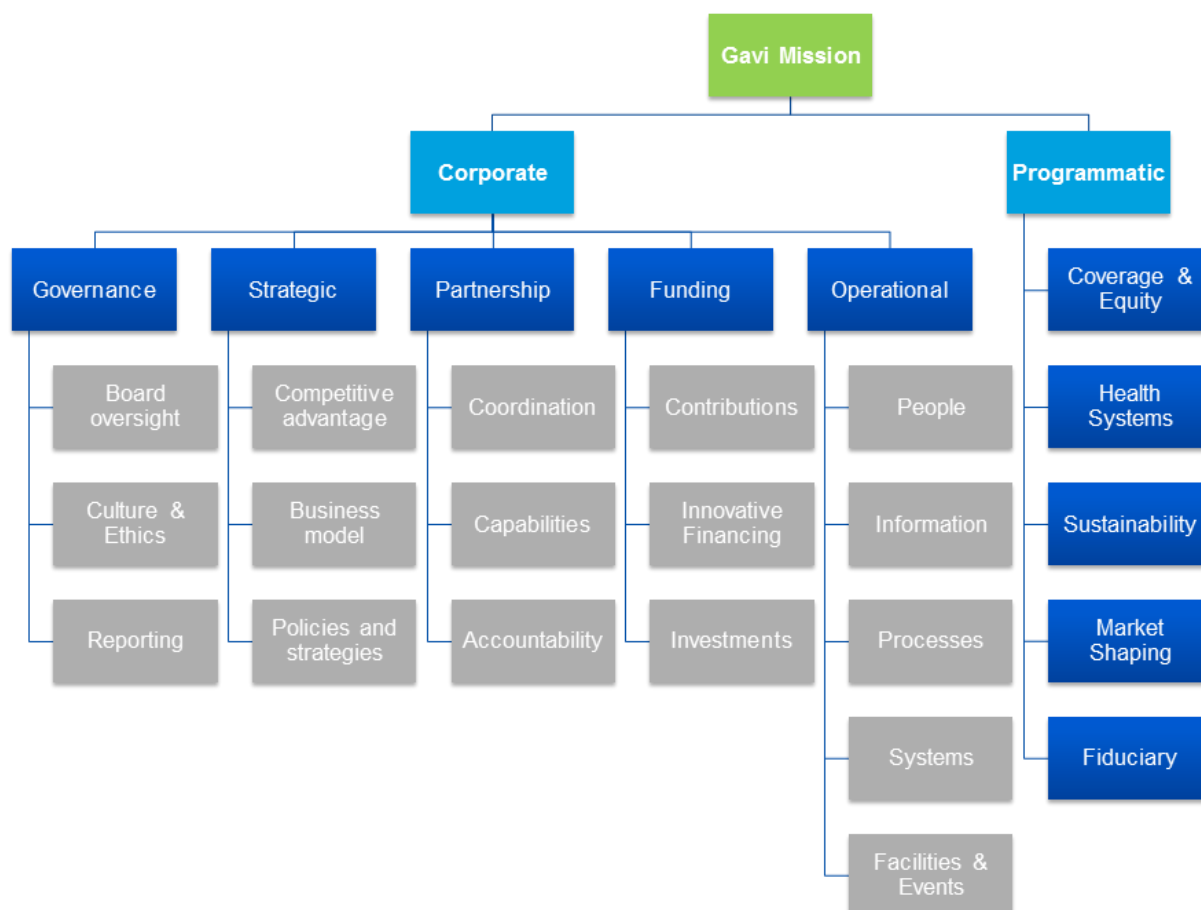
<sup>3</sup> <http://www.gavi.org/library/gavi-documents/policies/risk-appetite-statement/>

<sup>4</sup> A higher risk appetite signals a willingness to accept more risk to achieve certain end goals or benefits with the belief that if risks were to crystallise, the downside is moderate or acceptable in light of the benefits that will accrue.



## Annex II – Methodology and approach

The Risk & Assurance Report is based on an extensive cross-cutting exercise at the Secretariat to identify and assess the key risks across the Alliance (including through surveys, workshops, and validation meetings, corroborated by other sources of information and assurance). The Secretariat maintains a comprehensive risk register, including a broader set of lower risks and their associated mitigation strategies. The graph below depicts the comprehensive risk universe used to evaluate potential risks in all areas.



The assessment and segmentation of risks has furthermore been validated with partners in the Alliance Coordination Team call and the Partners' Engagement Framework Management Team (PEF MT) meeting in September. The Audit and Finance Committee (AFC) has reviewed the full Risk & Assurance Report and the top programmatic risks have been shared with the PPC. Feedback from both AFC and PPC have been incorporated in this final report for the Board.

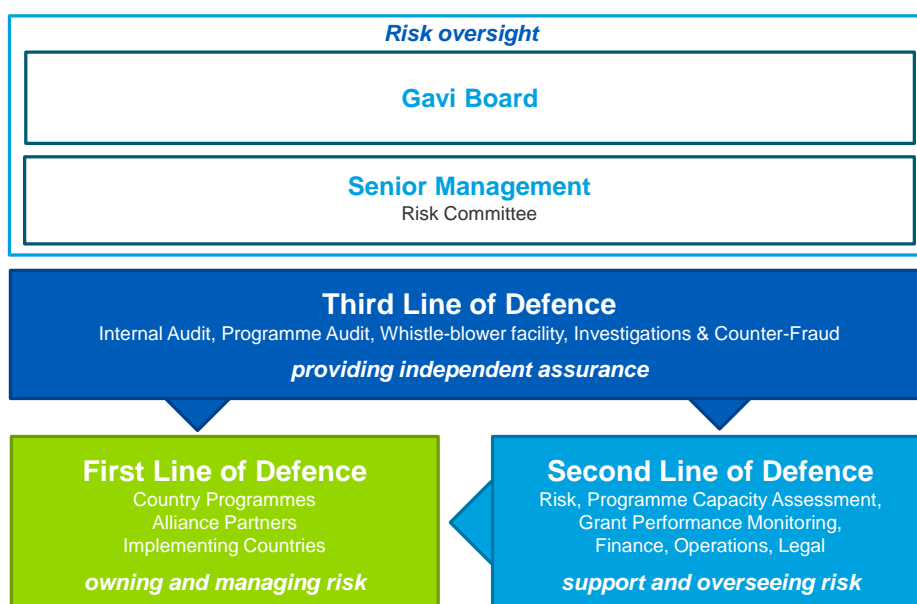
Validating and refining the Alliance's understanding of top risks remains an iterative process and a continuous journey of improvement. After this year's initial phase of cataloguing and segmenting the key risks facing the Alliance, and agreeing on the top risks to prioritise, the Secretariat will work with Alliance partners to conduct more in-depth analysis of these risks and develop more coherent remediation plans to mitigate each top risk. Going forward, the Secretariat also plans to develop more systematic metrics for monitoring the evolution of each top risk and to capture key developments as they occur. As key assurance tools are scaling up and maturing, upcoming risk assessments will also increasingly be informed by the findings of these assurance mechanisms. Over time this iterative process of corroboration using various sources of information, will establish and further refine Gavi's understanding of its risk profile, and its ability to effectively manage critical risks that could potentially impact Gavi's ability to achieve its mission.

## Annex III – Gavi’s Risk Governance 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.

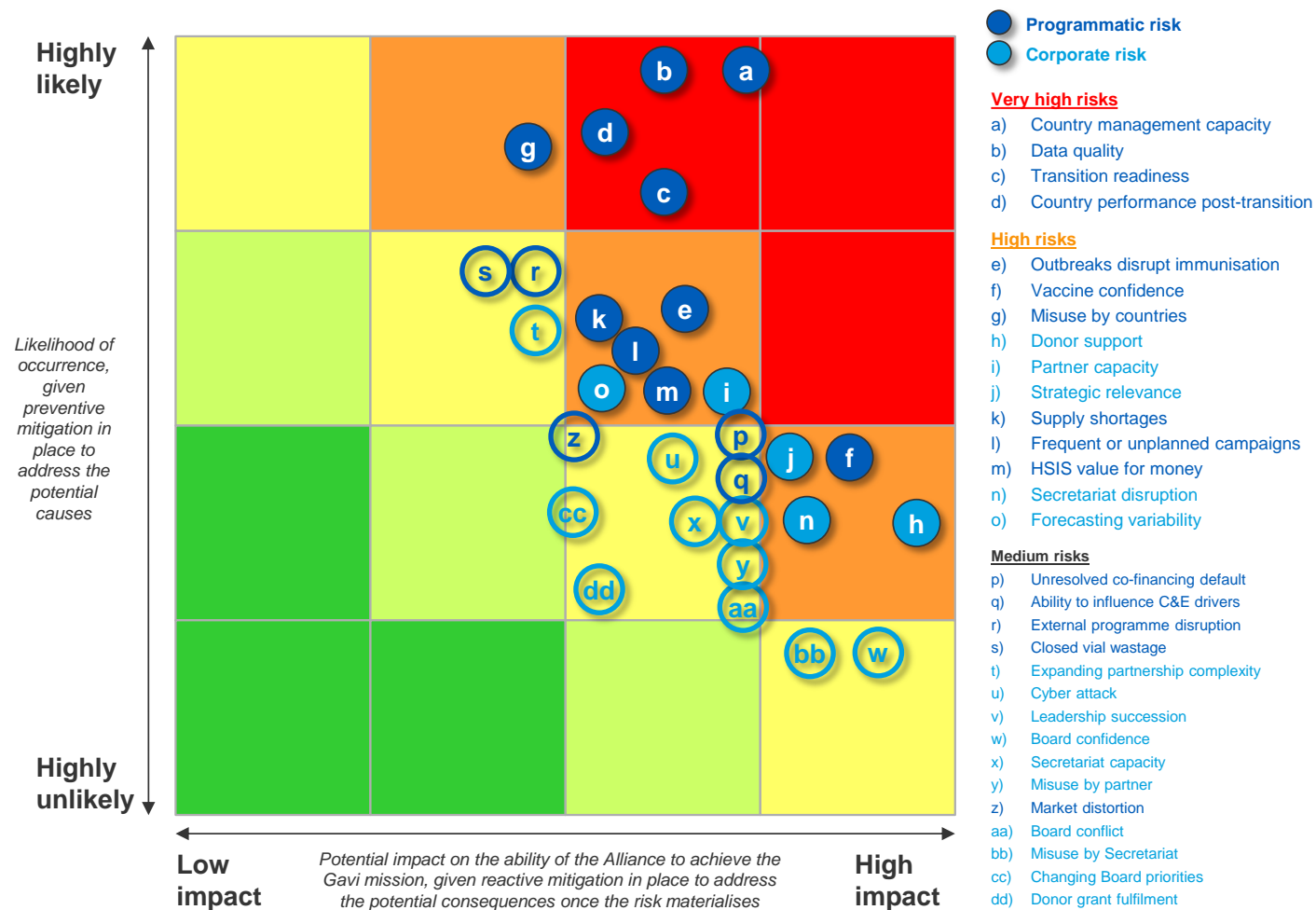


The responsibilities of each of the groups (or “lines”) are:

































- **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 IV – Summary Risk Register





























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



## Alliance-wide top risks summary (1/2)





























Risk				Risk assessment		Risk evolution	
Category		Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
a	Programmatic	<b>Country management capacity</b> Some countries (continue to) have insufficient capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"><li>Weak existing systems and technical capabilities</li><li>Weak management capabilities</li><li>Insufficient human resources</li><li>Insufficient prioritisation of health and immunisation</li><li>Inadequate support from Alliance to build capacity</li><li>External programme disruption</li><li>Disease outbreaks disrupting immunisation</li></ul>				
b	Programmatic	<b>Data quality</b> Continued lack of availability and use of quality data for immunisation	<ul style="list-style-type: none"><li>Accurate data not being generated</li><li>Generated data not shared with decision-makers</li><li>Shared data not used for decision-making</li><li>Data being manipulated</li></ul>				
c	Programmatic	<b>Transition readiness</b> Some countries transition without having built sufficient financial and programmatic capacity to sustain their programmes	<ul style="list-style-type: none"><li>Lack of (subnational) ability/capacity/fiscal space</li><li>Poor preparation for transition by Alliance</li><li>Insufficient prioritisation of health and immunisation</li><li>Overreliance on external support</li><li>External programme disruption</li><li>Disease outbreaks disrupting immunisation</li></ul>				
d	Programmatic	<b>Country performance post-transition</b> Some countries fail to sustain equitable immunisation coverage and introduced vaccines after transition	<ul style="list-style-type: none"><li>Insufficiently prepared before transition</li><li>Lack of access to global markets and expertise</li><li>Reduction in (subnational) ability/capacity/fiscal space</li><li>Reduction in prioritisation of health and immunisation</li><li>External programme disruption</li><li>Disease outbreaks disrupting immunisation</li></ul>				
e	Programmatic	<b>Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries	<ul style="list-style-type: none"><li>Low population immunity</li><li>Lack of capacity/tools to detect, prevent and respond</li><li>Population behaviour</li></ul>				
f	Programmatic	<b>Vaccine confidence</b> Significant loss of confidence in vaccine safety and efficacy	<ul style="list-style-type: none"><li>Major safety issue</li><li>Low vaccine efficacy</li><li>Vaccine scepticism</li></ul>				
g	Programmatic	<b>Misuse by countries</b> Deliberate misuse of Gavi support in some Gavi-supported countries	<ul style="list-style-type: none"><li>Culture of gifts/corruption</li><li>Opportunity for personal gain</li><li>Weak monitoring/deterrence</li><li>Weak institutions</li><li>Weak systems</li></ul>				
h	Corporate	<b>Donor support</b> Significant reduction in donor support to Gavi	<ul style="list-style-type: none"><li>Reduction in development budgets</li><li>Competing priorities in development</li><li>Competing priorities within health</li><li>Loss of donor confidence in Gavi</li></ul>				

## Alliance-wide top risks summary (2/2)

































Risk			Risk assessment		Risk evolution	
Category	Risk description	Potential causes	Current level	Mitigation strength	Recent evolution	Long-term outlook
i Corporate	<b>Partner capacity</b> Sum of comparative advantages of Alliance partners is inadequate to effectively deliver technical support to countries required for the new strategy	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> </ul>				
j Corporate	<b>Strategic relevance</b> Gavi becomes less relevant to global development priorities	<ul style="list-style-type: none"> <li>Prioritisation of other development causes</li> <li>Inability to remain innovative and adapt</li> <li>Reduced faith in Gavi's capacity to deliver</li> <li>Growing portion of unmet immunisation needs outside Gavi countries</li> </ul>				
k Programmatic	<b>Supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Lack of supply security</li> <li>External disruption</li> </ul>				
l Programmatic	<b>Frequent or unplanned campaigns</b> Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>				
m Programmatic	<b>HSIS value for money</b> HSIS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSIS</li> <li>HSIS grants not designed to target key bottlenecks</li> <li>HSIS grants duplicative with other donor funding</li> <li>HSIS grants not large enough to have significant impact</li> <li>HSIS not disbursed in timely fashion</li> <li>Programmes funded by HSIS not well-managed</li> <li>Misuse of HSIS resources</li> </ul>				
n Corporate	<b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>Catastrophic event</li> <li>Security threats and kidnapping</li> <li>Internal or external data breach</li> <li>Systems failure and data loss</li> <li>Departure of large number of key staff</li> </ul>				
o Corporate	<b>Forecasting variability</b> Gavi forecasting variability driving inappropriate decision-making	<ul style="list-style-type: none"> <li>Uncertainty over vaccine demand</li> <li>Financial uncertainties (e.g., prices, FX)</li> <li>Complexity of process</li> <li>Sub-optimal systems</li> </ul>				







## Medium risks summary (1/2)

Risk				Risk assessment		Risk evolution	
Category	Risk description	Potential causes		Current level	Mitigation strength	Recent evolution	Long-term outlook
p	<b>Programmatic</b> <b>Unresolved co-financing default</b> Lasting co-financing default leads to suspension	<ul style="list-style-type: none"> <li>Insufficient partner / Secretariat engagement with countries</li> <li>Growing co-financing obligations as countries introduce more vaccines / enter transition</li> <li>Lack of fiscal space</li> <li>Cash flow / operational budgeting issues in countries</li> <li>Countries do not prioritise immunisation</li> </ul>					
q	<b>Programmatic</b> <b>Ability to influence C&amp;E drivers</b> The Alliance is unable to effectively influence the key drivers of coverage & equity	<ul style="list-style-type: none"> <li>Focusing on the wrong priorities</li> <li>Inadequate design of solutions</li> <li>Limited influence on key drivers (e.g., health budget, recruitment of health workers)</li> </ul>					
r	<b>Programmatic</b> <b>External programme disruption</b> Major external events disrupt programmes in some Gavi-supported countries	<ul style="list-style-type: none"> <li>Political/social instability</li> <li>Conflict</li> <li>Terrorism</li> <li>Major population inflows / outflows</li> <li>Natural disaster</li> </ul>					
s	<b>Programmatic</b> <b>Closed vial wastage</b> Excessive closed vial vaccine wastage	<ul style="list-style-type: none"> <li>Vaccines damaged (broken; exposed to excess heat or frozen)</li> <li>Vaccines expire</li> <li>Vaccines destroyed</li> <li>Vaccines stolen/diverted</li> </ul>					
t	<b>Corporate</b> <b>Expanding partnership complexity</b> Growth in number of new partners (e.g., expanded partners, private sector partners) increases transaction costs and exposure to derived risks	<ul style="list-style-type: none"> <li>Increased administration to coordinate all partners</li> <li>Weak systems among new partners to manage Gavi funding / Gavi-supported programmes</li> <li>Inadequate design of programmes implemented by new partners</li> <li>Lack of oversight / performance management of new partners</li> <li>Major scandal affecting Gavi partner in non-Gavi programme</li> </ul>					
u	<b>Corporate</b> <b>Cyber attack</b> Large cyber attack significantly compromises critical information systems or data	<ul style="list-style-type: none"> <li>Attack by anti-vaccination movement</li> <li>Malware / ransomware attack</li> <li>Deliberate attack to access Gavi data / funds</li> </ul>					
v	<b>Corporate</b> <b>Leadership succession</b> Failure to effectively plan for succession of key leadership at Gavi Board, Secretariat, or Alliance partners	<ul style="list-style-type: none"> <li>Sudden departure of Board Chair and/or CEO</li> <li>Multiple simultaneous end of terms</li> <li>Lack of succession planning</li> </ul>					





## Medium risks summary (2/2)

Risk				Risk assessment		Risk evolution	
Category	Risk description	Potential causes		Current Level	Mitigation strength	Recent evolution	Long-term outlook
w	<b>Corporate</b> <b>Board confidence</b> Board loses confidence in Gavi management	<ul style="list-style-type: none"> <li>Inadequate transparency</li> <li>Poor performance / results</li> <li>Lack of communication</li> <li>Inter-personal conflict</li> </ul>					
x	<b>Corporate</b> <b>Secretariat capacity</b> Secretariat capacity, capabilities and processes are inadequate to deliver on new strategy	<ul style="list-style-type: none"> <li>Insufficient people, turnover and/or burn out</li> <li>Insufficient/inadequate skills</li> <li>Loss of key leadership</li> <li>Inability to adapt processes and systems</li> <li>Inability to adapt mind-set/culture</li> </ul>					
y	<b>Corporate</b> <b>Misuse by partner</b> Deliberate misuse of Gavi funds by partners	<ul style="list-style-type: none"> <li>Inadequate recruitment, capacity, performance management or accountability systems in partner agencies</li> <li>UN single audit principle, no access to audit reports</li> <li>UN auditors may not prioritise Gavi funds</li> </ul>					
z	<b>Programmatic</b> <b>Market distortion</b> Use of financial guarantees and tools creates higher expectations from manufacturers resulting in long-term market distortions	<ul style="list-style-type: none"> <li>Insufficient competition</li> <li>Frequent use of guarantees</li> <li>Manufacturers looking to offset price reductions</li> </ul>					
aa	<b>Corporate</b> <b>Board conflict</b> Irreconcilable disagreement in Alliance Board over key strategic decisions	<ul style="list-style-type: none"> <li>Divergent policy priorities</li> <li>Personality conflicts</li> </ul>					
bb	<b>Corporate</b> <b>Misuse by Secretariat</b> Deliberate misuse of Gavi funds by Secretariat	<ul style="list-style-type: none"> <li>Inadequate recruitment, capacity, performance management or accountability systems</li> <li>Management override of controls/collusion</li> </ul>					
cc	<b>Corporate</b> <b>Changing Board priorities</b> Board turnover results in shifting priorities and/or inconsistent decisions over time	<ul style="list-style-type: none"> <li>Turnover</li> <li>Changing global priorities</li> <li>New Board member brings new views</li> <li>Committee members not authorised to make decisions</li> </ul>					
dd	<b>Corporate</b> <b>Donor grant fulfilment</b> Donors fail to fully pay pledged contributions	<ul style="list-style-type: none"> <li>Reduced budgets</li> <li>Economic downturn</li> <li>Loss of confidence/misuse</li> <li>Change of leadership/prioritisation</li> </ul>					





## a Country management capacity

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Some countries (continue to) have insufficient capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity					HSIS	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Poorest countries in the world with inherent low capacity; large number of Gavi-supported countries classified as fragile</li><li>Gavi capacity-building support limited given scale of need</li><li>Increasing exposure to more remote areas with weaker capacities as part of coverage &amp; equity agenda and as stronger countries transition out of Gavi support</li></ul>	<ul style="list-style-type: none"><li>Weak existing systems and technical capabilities: supply chain and cold chain, data systems/collection/use/reporting</li><li>Weak management capabilities: programme and financial management skills, planning and budgeting, leadership and oversight, performance management</li><li>Insufficient human resources: high staff turnover, low attractiveness of roles (incentives)</li><li>Insufficient political will to prioritise health and immunisation</li><li>Inadequate support from Alliance to build capacity: fragmented, insufficient, misaligned with key needs, poorly implemented, or gap-filling rather than building long-term institutional capacity</li><li>External programme disruption</li><li>Disease outbreaks disrupting immunisation</li></ul>			<ul style="list-style-type: none"><li>Failure to achieve improvement in coverage and equity</li><li>Failure to transition country successfully from Gavi support</li><li>Failure to obtain value for money on Gavi support; enabling environment for misuse of funds in country</li><li>Derived reputational impact</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Programme Capacity Assessments designed to better assess country capacity gaps and inform Gavi support</li><li>Joint Appraisals and Country Engagement Framework designed to ensure Gavi support is better targeted at addressing critical capacity gaps</li><li>Partnership Engagement Framework ensuring targeted technical assistance delivered by in-country staff (embedded vs. consultants/regional staff)</li><li>HSIS framework designed to better build sustainable capacity in key areas, and HSIS investments being scaled up</li><li>Exploring new approaches to strengthen leadership, management and coordination</li><li>Supply Chain Strategy with specific focus on strengthening supply chain managers' capacity</li><li>High-level advocacy being scaled up to increase political commitment to immunisation</li></ul>				<ul style="list-style-type: none"><li>Programme audits and external audits assess strength of country processes and systems</li><li>Internal audits assess whether Alliance processes are adequate to build capacity</li><li>Self-assessment tool for countries to evaluate own capacity being introduced as part of LMC SFA</li><li>Effective Vaccine Management assessments provide periodic assessment of vaccine management capacity</li><li>Programme Capacity Assessments provide periodic assessment of country capacity (including remediation of EVM findings)</li><li>PEF evaluation and TA survey provide assurance on quality of capacity-building support</li><li>Other evaluations (e.g., HSIS grant evaluations, Full Country evaluations) evaluate country capacity and degree to which it has been strengthened</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Partners track country progress on PEF functions 1. Country Planning, Management, and Monitoring; 3. Supply Chain and Vaccine Wastage; and 4. Vaccine Implementation</li><li>Performance monitoring (Grant Performance Frameworks, Country and PEF reporting, WHO/UNICEF Joint Reporting Form)</li><li>Fiduciary/Monitoring Agents oversight</li></ul>		<ul style="list-style-type: none"><li>Requiring to address capacity gaps for grant disbursement</li><li>Channel cash support through partners where country capacity is inadequate</li><li>Tailored approach to help support and build capacity in countries which are classified as fragile (per fragility policy)</li><li>Put fiduciary/monitoring agent in place</li></ul>				

## b Data quality





Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Continued lack of availability and use of quality data for immunisation					M&E/HSIS	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Poorest countries in the world, many of whom have inherently weak data and management systems</li><li>Gavi capacity-building support limited given scale of need</li><li>Increasing exposure as part of coverage &amp; equity agenda and as stronger countries transition out of Gavi support</li></ul>	<ul style="list-style-type: none"><li>Accurate data not being generated: lack of systems, indicators/data points not defined, poor capability</li><li>Generated data not shared with decision-makers: no incentive, lack of reporting systems</li><li>Shared data not used (at global, national, or delivery level) for decision-making: irrelevant, poor culture of data-based decision-making</li><li>Data being manipulated: key data (e.g., population, GNI and immunisation) deliberately altered</li></ul>			<ul style="list-style-type: none"><li>Misallocation of Gavi support</li><li>Reduced efficiency/effectiveness of programme implementation</li><li>Inability to measure and demonstrate impact</li><li>Enabling environment for misuse of funds in country</li><li>Derived reputational impact</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Data SFA strengthening data systems and utilisation for disease surveillance, vaccine safety, health system administrative data, coverage and equity</li><li>Strong data focus in grant approval/renewal phase impacting workplan and performance indicators</li><li>Partnership Engagement Framework ensuring more targeted technical assistance on data capabilities</li><li>Exploring Leadership, Management &amp; Coordination approaches for strengthening capacity for use of data</li><li>Supply Chain Strategy strengthening supply chain and stock data</li><li>WHO and UNICEF conducting workshops on denominators with countries</li><li>Joint initiatives in Global Health (Multi-agency call for action, Health Data Collaborative, streamlining investments with Global Fund in country)</li></ul>				<ul style="list-style-type: none"><li>Programme audits and external audits assess whether country processes and systems are adequate</li><li>Internal audits asses whether Alliance processes are adequate</li><li>International Health Regulations self-reporting by countries on surveillance capacities</li><li>Self-assessment tool for countries to evaluate own capacity being introduced as part of LMC SFA</li><li>WUENIC “Grade Of Confidence” expressing level of supporting evidence for country reported coverage data</li><li>Independent data quality assessments</li><li>Effective Vaccine Management assessments provide periodic assessment of country supply chain and stock data capacity</li><li>Programme Capacity Assessments provide periodic assessment of country capacity (including remediation of EVM findings)</li><li>Other evaluations (e.g., HSIS grant evaluations, Full Country evaluations) evaluate country capacity and degree to which it has been strengthened</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Partners track country progress on PEF function 2. Data</li><li>Performance monitoring (Grant Performance Frameworks, Country and PEF reporting, WHO/UNICEF Joint Reporting Form)</li><li>Triangulation of country population data with UN Population Division data and satellite imagery</li><li>Triangulation of country coverage data with coverage surveys (including for campaigns)</li></ul>		<ul style="list-style-type: none"><li>HSIS reprogramming possible if investments prove to be misallocated</li></ul>				

## c Transition readiness





Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Risk description						
Some countries transition without having built sufficient financial and programmatic capacity to sustain their programmes					IF&S	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>During the 2016-2020 strategy period, the first countries have been transitioning from Gavi support and 16 approach transition</li><li>Increasing exposure as stronger countries, many of whom have been above eligibility threshold for some time, transition out of Gavi support, and more countries who have only recently crossed the eligibility threshold approach transition</li></ul>	<ul style="list-style-type: none"><li>Lack of (subnational) ability/capacity/fiscal space: poor financial, procurement and programme management capabilities, weak systems and capabilities, regulatory hurdles, lack of fiscal space or subnational financing</li><li>Poor preparation for transition by Alliance: lack of capacity for intense engagement required, partners unable to deliver required technical support to countries, late engagement and advocacy</li><li>Insufficient political will to prioritise health and immunisation</li><li>Overreliance on Gavi / other external support / modalities (e.g. HSS, fiduciary agent, data, pre-financing schemes)</li><li>External programme disruption</li><li>Disease outbreaks disrupting immunisation</li></ul>			<ul style="list-style-type: none"><li>Failure to reduce morbidity / mortality before transition</li><li>Country's immunisation performance falls or remains inadequate after transition from Gavi support</li><li>Loss of confidence in Gavi model</li><li>No / limited long-term return on Gavi's investment in countries</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Transition model allows gradual ramp-up in co-financing and active monitoring</li><li>Sustainability SFA is comprehensive approach to integrating sustainability into all Gavi investments, and ensuring early engagement with countries</li><li>Transition missions and assessments identifying bottlenecks to address with transition plans and tailored support</li><li>High level advocacy to struggling countries</li><li>HSIS framework designed to better build sustainable capacity in key areas, and HSIS investments being scaled up</li><li>World Bank support to address financial sustainability bottlenecks</li><li>Global Financing Facility has objective to secure additional financing, particularly domestic resources, for health</li><li>Addis Declaration for Immunisation (ADI) working group on political will in Africa (Gates, UNICEF, WHO)</li></ul>				<ul style="list-style-type: none"><li>Programme audits and external audits assess whether country processes and systems are adequate</li><li>Internal audits assess whether Alliance processes are adequate</li><li>Transition assessments</li><li>World Bank Health Financing System Assessments</li><li>Programme Capacity Assessments provide periodic assessment of country capacity</li><li>Other evaluations (e.g. end-of-grant grant evaluations)</li><li>Post-transition evaluations</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Partners track country progress on PEF function 5 (Countries on track for successful transition)</li><li>Sustainability tracers included in Grant Performance Framework monitor financial sustainability, integration into the health system, and institutional/human capacity</li><li>Strategy indicator monitoring immunisation performance in transitioned countries</li></ul>						







## d Country performance post-transition

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight		
	Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Some countries fail to sustain equitable immunisation coverage and introduced vaccines after transition					IF&S	PPC	
Inherent exposure	Potential causes				Potential consequences		
<ul style="list-style-type: none"><li>• In the 2016-2020 strategic period, a total of 20 countries will have fully transitioned out from Gavi support</li><li>• Increasing exposure as stronger countries have been transitioned out of Gavi support already and weaker ones will follow</li><li>• Under current policies, Gavi will not continue to engage with countries post-transition so have very little ability to monitor or influence immunisation outcomes</li></ul>	<ul style="list-style-type: none"><li>• Insufficiently prepared before transition</li><li>• Lack of access to global vaccine markets and technical expertise</li><li>• Reduction in ability/capacity/fiscal space: poor financial, procurement and programme management capabilities, weak systems and capabilities, regulatory hurdles, lack of fiscal space or subnational financing</li><li>• Reduction in prioritisation of health and immunisation</li><li>• External programme disruption</li><li>• Disease outbreaks disrupting immunisation</li></ul>				<ul style="list-style-type: none"><li>• Increase in morbidity / mortality in transitioned countries</li><li>• Loss of confidence in Gavi model</li><li>• Loss of manufacturer confidence leading to reduced commitment to market and/or raising prices</li><li>• No / limited long-term return on Gavi's investment in countries</li></ul>		
Existing mitigation							
Preventive (addressing causes)					Assurance on effectiveness		
<ul style="list-style-type: none"><li>• Market shaping work to create global healthy markets and secure access to appropriate prices post-transition</li><li>• Continued partner engagement after transition</li><li>• Addis Declaration for Immunisation working group on political will in Africa (Gates, UNICEF, WHO)</li></ul>					<ul style="list-style-type: none"><li>• Post-transition evaluations</li><li>• Very little assurance given the Alliance will not engage with countries post-transition</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)					
<ul style="list-style-type: none"><li>• Ongoing WUENIC coverage data generation by WHO</li><li>• Monitoring coverage in transitioned countries as one of our strategy indicators</li><li>• As part of Sustainability SFA, partners monitor post-transition indicators for five years post transition, to assess whether a country is successful at sustaining gains made during Gavi support. The Secretariat will report on these publicly available indicators.</li></ul>		<ul style="list-style-type: none"><li>• No engagement by Secretariat with transitioned countries</li><li>• Escalation to the Board for discussion if we see a significant reduction in performance post-transition</li></ul>					





## e Outbreaks disrupt immunisation

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight		
	Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries						VI	PPC
Inherent exposure		Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Gavi-supported countries have lower immunisation coverage (for diseases where vaccines exist) and weaker health systems capacity to prevent and respond to outbreaks</li><li>Majority of emerging pathogens have resevoirs in Gavi-supported countries</li><li>Emerging pathogens where no, or insufficient, preventive and curative solutions exist (as per WHO Blueprint for R&amp;D preparedness)</li><li>Increasing exposure due to population growth, globalisation, urbanisation, climate change, population movement and displacement</li></ul>		<ul style="list-style-type: none"><li>Low population immunity: pathogens being transmitted to previously unexposed populations, poor immunisation coverage</li><li>Lack of capacity/tools to prevent, detect and respond: surveillance and programme management capacity, health care workers, financial resources, data collection and sharing, available drugs, diagnosis and vaccines</li><li>Population behaviour: fear of health system, cultural/social norms, stigma on infected people</li></ul>			<ul style="list-style-type: none"><li>Disruption of programmes</li><li>Supply shortage</li><li>Deprioritisation of routine immunisation</li><li>Destablilising neighbouring countries (migration and refugees)</li><li>Inability to engage (inaccessible areas, security issues, inaccessible government)</li><li>Reduced faith in health system and immunisation; increased prioritisation of public health (upside)</li><li>Global impact (e.g. airports shut down)</li></ul>		
Existing mitigation							
Preventive (addressing causes)					Assurance on effectiveness		
<ul style="list-style-type: none"><li>Data SFA strengthening disease surveillance capacity</li><li>HSIS policy designed to better build sustainable capacity in key areas, and HSIS investments being scaled up</li><li>Gavi supports preventive campaigns and routine immunisation for diseases with outbreak potential (Measles, Yellow Fever, Meningitis A)</li><li>Ebola Advance Purchase Commitment towards the development of a vaccine to create a stockpile for future outbreaks and incentivise future manufacturer investments in R&amp;D for diseases with outbreak potential</li><li>Investments in innovation to encourage availability of new products</li></ul>					<ul style="list-style-type: none"><li>Programme audits and external audits assess strength of country processes and systems</li><li>Campaign coverage surveys</li><li>International Health Regulations self-reporting by countries on surveillance capacities</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)					
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Disease surveillance</li><li>Partners supporting countries to monitor outbreaks</li></ul>		<ul style="list-style-type: none"><li>Gavi support for emergency response (vaccine stockpiles for yellow fever, cholera, meningitis, Ebola and measles campaigns)</li><li>HSS/TA to rebuild health systems and catch-up on immunisation</li><li>Rely on partners to engage/access (MSF/Red Cross)</li><li>Fragility policy enables flexible response to countries impacted by major outbreaks (e.g., waiving co-financing, intensified and tailored support, additional doses for countries with refugees from neighbouring countries)</li></ul>					





## f Vaccine confidence

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Significant loss of confidence in vaccine safety and efficacy					VI/COMMS	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>• Risk for adverse events following immunisation inherent to vaccines</li><li>• As more people receive vaccines, increase in AEFIs and reduced incidence of disease making it harder to see impact</li><li>• Strong anti-vaccine movements in some countries and ability to spread stories is growing due to globalisation and technology</li></ul>	<ul style="list-style-type: none"><li>• Major safety issue (e.g., due to expired vaccines, poor handling, inappropriate vaccine administration, allergic reaction)</li><li>• Low vaccine efficacy (e.g., due to expired vaccines, poor handling, use of lower efficacy vaccines such as RTS,S, counterfeit vaccines)</li><li>• Vaccine scepticism (e.g., due to ideological or religious concerns, concerns on key components (e.g. porcine cells, thiomersal), complacency following period of low disease burden)</li></ul>			<ul style="list-style-type: none"><li>• Product recalls, programme discontinuations, other countries delay introductions</li><li>• Loss of public faith in / demand for vaccines leading to reduced coverage</li><li>• Legal risk if Gavi target of lawsuit</li><li>• Safety risk for Alliance staff from extreme anti-vaccine movements</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>• The Alliance only procures vaccines which are licensed by a stringent national regulatory authority and WHO prequalified</li><li>• Supply Chain Strategy with specific focus on building supply chain capacity to improve vaccine handling</li><li>• Gavi supports strengthening of national regulatory authorities through HSIS and TCA</li><li>• Communications and Demand Generation SFA designed to build confidence in vaccines</li></ul>				<ul style="list-style-type: none"><li>• Internal audits assess whether Alliance processes are adequate</li><li>• Effective Vaccine Management assessments provide periodic assessment of country supply chain and stock data capacity</li><li>• Programme Capacity Assessments provide periodic assessment of country capacity (including remediation of EVM findings)</li><li>• Other evaluations (e.g., HSIS grant evaluations, Full Country evaluations) evaluate country capacity and degree to which it has been strengthened</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>• Gavi supports strengthening of safety surveillance and adverse event reporting through HSIS and TCA</li><li>• Secretariat monitors global and national media for reports of vaccine-related incidents</li><li>• WHO pharmacovigilance funded as part of foundational support</li></ul>		<ul style="list-style-type: none"><li>• Intensified engagement with governments by WHO and Secretariat, where required, to respond (e.g., (causality assessment / autopsies)</li><li>• Rapid media and communication handling to respond to every incident</li></ul>				

## g Misuse by countries





Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Deliberate misuse of Gavi support in some Gavi-supported countries					CP	AFC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Poorest countries in the world, frequently with inherent low capacity and corruption issues</li><li>Biggest investments in vaccines, which are less prone to theft than cash</li><li>Increasing exposure due to higher HSIS expenditure 2016-20 than in previous strategic period and intensified focus on weaker countries for C&amp;E agenda / as stronger countries transition</li></ul>	<ul style="list-style-type: none"><li>Culture of gifts/corruption: lack of accountability</li><li>Opportunity for personal gain: large cash transactions, idle money sitting in country, existence of secondary market for vaccines</li><li>Weak monitoring/deterrence: in-country audit capacity, poor laws and legal institutions</li><li>Weak institutions: weak government, unreliable bank, underdeveloped markets</li><li>Weak systems: manual procedures, management override of controls</li></ul>			<ul style="list-style-type: none"><li>Reduced value for money on Gavi investments</li><li>Loss of donor and Board confidence in Gavi</li><li>Failure to build sustainable health systems and government capacity</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Deterrent effect of increasing Secretariat oversight and Programme Audits every 3 years in high risk countries</li><li>Programme Capacity Assessments, which inform financial modalities and capacity building needs</li><li>Supply Chain Strategy enhancing supply chain integrity</li><li>Grant closure policy</li><li>Budget reviews, possibility to reallocate budget to remove riskier elements,</li><li>Disbursements checked against forecasted cash needs</li><li>Channelling funds through UN partners or use fiduciary, monitoring and/or procurement agent for high risk countries</li><li>Increase reporting frequency for high risk countries</li><li>Directly select/contract external auditor and/or increase scope for high risk countries</li></ul>				<ul style="list-style-type: none"><li>Programme audits and external audits assess whether country processes and systems are adequate</li><li>Internal audits assess whether Alliance processes are adequate</li><li>Effective Vaccine Management assessments provide periodic assessment of vaccine management capacity</li><li>Programme Capacity Assessments provide periodic assessment of country capacity (including remediation of EVM findings)</li><li>Other evaluations (e.g., HSIS grant evaluations, Full Country evaluations) evaluate country capacity and degree to which it has been strengthened</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Partners reporting suspected misuse</li><li>Whistleblower hotline</li><li>Analysis of financial performance before annual renewal</li><li>Review of annual and mid-year financial reports</li></ul>		<ul style="list-style-type: none"><li>Investigations and reimbursement</li><li>Reputation management (communications and advocacy)</li></ul>				

## h Donor support





Category: <i>Corporate</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Significant reduction in donor support to Gavi					RM	Full Board
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Inherent political and economic exposure with sovereign donors</li><li>Increasing exposure due to increasing political and economic uncertainties among key donors</li></ul>	<ul style="list-style-type: none"><li>Reduction in development budgets (e.g., due to political shifts, increasingly hostile media)</li><li>Competing priorities in development (e.g. climate change, education)</li><li>Competing priorities within health (e.g., chronic diseases, HIV, TB, malaria)</li><li>Loss of donor confidence in Gavi</li></ul>			<ul style="list-style-type: none"><li>Funding: reduced budget for Gavi programmes leading to disruption of countries' immunisation programmes and reduced health impact</li><li>Increased operating costs: More effort required to mobilise resources / service donors</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Diversifying donor base</li><li>Increased involvement of the private sector to leverage investments, expertise and innovation</li><li>Results highly quantifiable and transparent</li><li>Strategic communications and public engagement to increase Gavi profile and support</li><li>Support from advocacy organisations (One Campaign, Results, Save The Children)</li><li>Board composition includes key stakeholders in global development, which helps to ensure continued relevance</li></ul>				<ul style="list-style-type: none"><li>Internal audits assess whether Alliance processes are adequate</li><li>MOPAN, MAR, and other multilateral reviews</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>Pro-active monitoring of situation and engagement with donors by Resource Mobilisation</li><li>Monitoring peer organisations' replenishments</li></ul>						







## i Partner capacity

Category: <i>Corporate</i>	Risk assessment		Risk evolution		Risk oversight	
Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Sum of comparative advantages of Alliance partners is inadequate to effectively deliver technical support to countries required for the new strategy					CP/S&P	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>• Inherent to partnership model</li><li>• Increasing current exposure due to need for intensified and new forms of technical support to accelerate progress on coverage and equity / sustainability. Will likely require more implementation/management support which will require a broader range of capabilities from partners</li></ul>	<ul style="list-style-type: none"><li>• Lack of government coordination and alignment across partners</li><li>• Lack of capacity / expertise: systems/tools to innovate and support change, people and performance management, prioritisation and leadership to manage change, financial health, ability to transparently implement new type of activities and be accountable for results</li><li>• Lack of availability: limited presence in some countries, inability to find appropriate partners for delivery of new areas of TA</li></ul>			<ul style="list-style-type: none"><li>• Failure to achieve improvement in coverage and equity</li><li>• Failure to strengthen country capacity</li><li>• Reduced value for money on Gavi support</li><li>• Loss of confidence in partnership model</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>• Partnership Engagement Framework clarifying responsibilities and enhancing accountability</li><li>• Enhancing coordination and alignment through Alliance Coordination Team, Alliance Technical Teams, Regional Working Groups, ICC/HSCCs</li><li>• Joint Appraisals and Country Engagement Framework designed to ensure Partner support is better targeted at country needs</li><li>• Exploring Leadership, Management &amp; Coordination approaches to address gaps in comparative advantage of core partners in management support</li><li>• Expanded partners for new type of capabilities</li><li>• Private sector partnerships (INFUSE) planned to deliver broader range of capabilities</li></ul>				<ul style="list-style-type: none"><li>• Programme audits and external audits assess strength of and improvements in country processes and systems</li><li>• Internal audits assess whether Alliance processes are adequate</li><li>• Programme Capacity Assessments provide periodic assessment of country capacity (and indirectly of effectiveness of partner support)</li><li>• Other evaluations (e.g., HSIS grant evaluations, Full Country evaluations) evaluate country capacity and degree to which it has been strengthened</li><li>• Country feedback on partner TA</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>• SCM and Country Team grant oversight</li><li>• Board oversight through accountability Framework performance indicators</li><li>• Performance monitoring (Grant Performance Frameworks, Country and PEF reporting, PEF MT review, WHO/UNICEF Joint Reporting Form, Partners' internal performance monitoring)</li></ul>		<ul style="list-style-type: none"><li>• Possibility to contract new partner from pre-screened expanded partner roster list</li><li>• Escalation of performance issues to partners' senior leadership or to Board</li></ul>				





## j Strategic relevance

Category: <i>Corporate</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Gavi becomes less relevant to global development priorities					PPE/RM	Full Board
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Shifting global development priorities (e.g., climate change, education)</li><li>Gavi's geographic scope increasingly limited as countries transition</li><li>Perception that "job is done" due to high global immunisation coverage and success of introduction agenda for key vaccines (e.g., pneumo, rota)</li></ul>	<ul style="list-style-type: none"><li>Global community increasingly prioritises other development causes</li><li>Inability to remain innovative and adapt the model to new development priorities</li><li>Reduced faith in Gavi's capacity to deliver / value for money</li><li>Growing portion of unmet immunisation needs outside Gavi countries</li></ul>			<ul style="list-style-type: none"><li>Reduced funding</li><li>Lower political commitment to immunisation (global and country level)</li><li>Reduced public support/demand for immunisation</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Periodic strategy/policy reviews to adapt to global priorities and reframe communication</li><li>Board composition includes key stakeholders in global development</li><li>Results highly quantifiable and transparent</li><li>Targeted in-country advocacy to build political will</li><li>Strategic communications and public engagement to increase Gavi profile and support</li><li>Close engagement with donors and influencers, broadening donor base and designing new financial instruments</li><li>Engaging with relevant policy forums, political meetings to stay on the global agenda (e.g., SDGs, G7 / G20) and to highlight relevance of vaccines to other priorities (e.g., global health security, anti-microbial resistance)</li><li>Support from advocacy organisations (One Campaign, Results, Save The Children)</li><li>Engaging champions: global ambassador, first ladies network</li></ul>				<ul style="list-style-type: none"><li>Internal audits assess whether Alliance processes are adequate</li><li>MOPAN, MAR, and other multilateral reviews</li><li>External reports</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>Engagement in global policy fora and monitoring of the global development dialogue</li></ul>		<ul style="list-style-type: none"><li>Escalation to Board for discussion of strategy</li></ul>				





## k Supply shortages

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight		
	Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Shortages in the global vaccine supply affect Gavi-supported countries						MS	PPC
Inherent exposure		Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>• Supply already constrained for some Gavi-supported vaccines (e.g., Yellow Fever, rotavirus, IPV, cholera)</li><li>• Gavi is largest global vaccine procurer (by volume) so challenging to mitigate major supply constraints</li><li>• Gavi / global demand will be scaling up for a number of vaccines over this strategy period</li><li>• Inherent uncertainty in planning supply and demand in 5 years time</li></ul>		<ul style="list-style-type: none"><li>• Manufacturing capacity inadequate to meet demand: manufacturer decision not to invest in manufacturing capacity, manufacturer exits market or decides not to enter (e.g., due to low margins, manufacturer too conservative in capacity planning)</li><li>• Lack of supply security: reliance on small number of manufacturers and one develops production problems</li><li>• External disruption: Gavi deprioritised as part of allocation during global shortage, disrupted global supply chain, increased demand (outbreak, refugees, migration)</li></ul>			<ul style="list-style-type: none"><li>• Disruption of programmes</li><li>• Delayed vaccine introductions</li><li>• Reduced immunisation coverage</li><li>• increased pricing by dominant player after competition exits</li><li>• Loss of confidence in market shaping model</li></ul>		
Existing mitigation							
Preventive (addressing causes)					Assurance on effectiveness		
<ul style="list-style-type: none"><li>• Supply and procurement strategy aims to increase capacity / broaden supplier base in supply constrained-markets</li><li>• Use of innovative tools (e.g., volume guarantees) to incentivise manufacturers to increase capacity and / or secure sufficient supply</li><li>• Intensified engagement with emerging market manufacturers to encourage entry into Gavi market</li><li>• Price and volume forecasts shared with manufacturers to support capacity and production planning</li><li>• Work with WHO to prequalify additional vaccines from other suppliers, in the case of a sole supplier</li></ul>					<ul style="list-style-type: none"><li>• Internal audits assess whether Alliance processes are adequate</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)					
<ul style="list-style-type: none"><li>• Accountability Framework performance indicator</li><li>• Pro-active monitoring of situation and engagement with manufacturers by Market Shaping</li><li>• UNICEF SD who are constantly engaging with manufacturers</li></ul>		<ul style="list-style-type: none"><li>• Preparation of remediation plans with UNICEF</li><li>• Fractional dosing and prioritisation</li><li>• Emergency stockpiles</li><li>• Communication strategy to address shortages</li></ul>					





# I Frequent or unplanned campaigns

Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight	
	Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat
Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services					VI/CS	PPC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Many Gavi countries, especially those with low routine coverage, rely on immunisation campaigns to prevent or respond to disease outbreaks</li><li>Campaigns create intense stress on the capacity of Ministries, EPI programmes and health systems due the sudden upsurge in activity and cash inflows</li><li>Increasing exposure due to growing Gavi investment in campaigns (measles strategy, new vaccines such as JE, stockpiles)</li></ul>	<ul style="list-style-type: none"><li>Periodic very large cash inflows for campaigns</li><li>Front line workers diverted to implement campaigns</li><li>Management capacity diverted to manage campaigns</li><li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li><li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li></ul>			<ul style="list-style-type: none"><li>Disrupts routine immunisation services and reduces coverage</li><li>Creates reliance on campaigns to compensate for low coverage and creates an expectation among health workers of regular per diems to supplement salaries</li><li>Increased risk of misuse of funds</li><li>Derived reputational impact</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>Increasingly integrated disease control strategies (e.g., measles, yellow fever) emphasise improving routine immunisation, reducing number and improving planning of campaigns based on more robust risk assessment</li><li>Encourage delivery of other antigens together with the campaign to increase opportunity to enhance coverage (for example adding Penta and PCV to a measles campaign)</li><li>Require more detailed data on missed children justifying campaigns, have them more targeted/focused, require more lead time of preparation to obtain good quality campaigns if needed</li><li>Secretariat and ICC review operational plans and budgets for campaigns before disbursement</li><li>Disbursement of Gavi operational support for campaigns to partners in high-risk contexts</li><li>Leadership, Management &amp; Coordination SFA to help build management capacity</li><li>HSIS policy requires countries to articulate how they will use operational cost support for campaigns to strengthen RI</li></ul>				<ul style="list-style-type: none"><li>Programme audits review implementation and management of campaigns</li><li>Programme Capacity Assessments provide periodic assessment of country capacity (and indirectly of effectiveness of partner support), including to manage campaigns</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Post-campaign coverage surveys to assess quality and minimise need for repeated campaigns</li><li>Partner monitoring of campaigns</li><li>Audits increasingly reviewing expenditure during campaigns</li></ul>						

## m HSIS value for money





Category: <i>Programmatic</i>	Risk assessment		Risk evolution		Risk oversight		
	Risk description	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
HSIS investments do not materially improve programmatic outcomes						HSIS	PPC
Inherent exposure		Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>Significant barriers to improving coverage and equity and building capacity in most Gavi-eligible countries, many beyond health sector</li><li>HSIS support designed to be catalytic and not sufficient to meet all needs of immunisation programme</li><li>Large number of intermediate steps between disbursement of HSIS funds and improved outcomes, with HSIS contributing not attributing to outcomes and impact.</li></ul>		<ul style="list-style-type: none"><li>Key bottlenecks not addressable by HSIS</li><li>HSIS grants not designed to target key bottlenecks</li><li>HSIS grants duplicative with other donor funding</li><li>HSIS grants not large enough to have significant impact</li><li>HSIS not disbursed in timely fashion</li><li>Programmes funded by HSIS not well-managed</li><li>Misuse of HSIS resources</li></ul>			<ul style="list-style-type: none"><li>Failure to significantly improve coverage and equity and meet Gavi strategy targets</li><li>Failure to build long-term management capacity sufficiently quickly</li><li>Impact on Gavi's reputation as providing value for money and loss of donor confidence in HSIS</li></ul>		
Existing mitigation							
Preventive (addressing causes)					Assurance on effectiveness		
<ul style="list-style-type: none"><li>New HSIS Framework focuses investments on key bottlenecks and enablers of coverage and equity, and seeks to ensure all HSIS grants (not just HSS) contribute to strengthening immunisation programmes</li><li>Alliance enhancing high-level advocacy efforts to address bottlenecks outside health sector</li><li>HSIS budget increased for this strategic period</li><li>Performance-based funding provides incentive for countries to achieve grant targets</li><li>Country engagement Framework designed to improve design of HSIS grants through iterative in-country process with key stakeholders</li><li>Secretariat working to accelerate grant disbursement to country (Alliance KPI for 2016)</li><li>Exploring new approaches to strengthen leadership, management and coordination</li><li>Grant design and budget reviewed by ICC, Secretariat and IRC</li><li>Possibility to channel funds through UN partners or use fiduciary, monitoring and/or procurement agent in high-risk contexts</li></ul>					<ul style="list-style-type: none"><li>Programme audits cover HSIS grants</li><li>Internal audits assess whether Alliance processes are adequate</li><li>Programme Capacity Assessments provide periodic assessment of country capacity</li><li>Thematic and country specific evaluations, e.g. full country evaluations, evaluate performance of HSIS grants</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)					
<ul style="list-style-type: none"><li>SCM and Country Team grant oversight</li><li>Intermediate indicators in place for all HSS grants as part of performance framework</li><li>Surveys to assess grant performance (coverage surveys required as part of HSS grants, post-campaign coverage surveys for operational cost grants, post-introduction evaluations for VIGs)</li><li>HLRP reviews grant progress before extending</li><li>Secretariat monitors disbursement rates and timelines both to and within countries</li></ul>		<ul style="list-style-type: none"><li>Disbursements can be suspended for poorly performing grants or in case of misuse</li></ul>					

## n Secretariat disruption

Category: <i>Corporate</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Significant disruption of Secretariat operations					Ops/KMTS	AFC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>• Secretariat location with few direct threats (e.g., terrorism, natural disaster)</li><li>• Growing profile of Gavi which attracts extremists</li><li>• Transparency policy and limited confidential data</li><li>• Historic reliance on manual processes rather than automated systems</li><li>• Growing use of online and cloud-based systems (outsourced)</li></ul>	<ul style="list-style-type: none"><li>• Catastrophic events (natural disaster, terrorism, fire, disease outbreak)</li><li>• Security threats to staff and kidnapping</li><li>• Internal or external data breach</li><li>• Systems failure and data loss</li><li>• Departure of large number of key staff</li></ul>			<ul style="list-style-type: none"><li>• Inability to coordinate Alliance with consequent effect on partners and countries</li><li>• Data leaks may impact price negotiations or manufacturer trust</li><li>• Inability to complete disbursements to countries or paychecks to employees</li><li>• Loss of building or people</li><li>• Derived reputational impact</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>• Travel security training and country briefings</li><li>• Identity management system, firewalls, anti-virus, increased patching</li></ul>				<ul style="list-style-type: none"><li>• Internal Audits</li><li>• Planning rehearsals of crisis management plans</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>• Travel security monitoring by Control Risk</li><li>• Security alerts and intelligence from authorities and UN</li></ul>		<ul style="list-style-type: none"><li>• Fire evacuation plan</li><li>• Designing a crisis management framework with emergency response plans</li><li>• Designing an IT business continuity and disaster recovery plan</li><li>• D&amp;O liability insurance</li></ul>				



## Forecasting variability

Category: <i>Corporate</i>	Risk assessment		Risk evolution		Risk oversight	
	Current level	Mitigation strength	Recent evolution	Long-term outlook	Secretariat	Board
Gavi forecasting variability driving inappropriate decision-making					VI/MS/Fin	AFC
Inherent exposure	Potential causes			Potential consequences		
<ul style="list-style-type: none"><li>• Inherent uncertainty in forecasting, especially given uncertainty on country introduction decisions, poor target population data and changing vaccine prices</li><li>• New vaccines represent an increasing % of spend (demand for expensive vaccines harder to predict e.g. HPV)</li><li>• Future expenditure declining due to graduating countries</li></ul>	<ul style="list-style-type: none"><li>• Uncertainty over vaccine demand: poor data quality (population, coverage, wastage), changing dates for vaccine introductions</li><li>• Financial uncertainties: price volatility, FX volatility, donor commitments</li><li>• Complexity of process: cross-functional coordination across many countries, partners and Secretariat teams</li><li>• Sub-optimal systems – forecasts developed using multiple spreadsheets</li></ul>			<ul style="list-style-type: none"><li>• Poor resource allocation; insufficient or excess supply from manufacturers; inability to ship doses at right time; large inventory leads to wastage or stock-outs</li><li>• insufficient or excess funding from donors; making commitments not backed with funding</li><li>• Reputational impact based on forecast not achieved</li></ul>		
Existing mitigation						
Preventive (addressing causes)				Assurance on effectiveness		
<ul style="list-style-type: none"><li>• Every forecasting step double checked (two people in parallel)</li><li>• Regular review and update of vaccine introduction expenses</li><li>• Market shaping reducing price volatility</li><li>• Data triangulated with other sources, e.g. supply history</li><li>• Effort to strengthen forecasting with more review and collaboration across teams</li><li>• Programme Finding Policy provides safeguards against misinformed programme funding decisions</li><li>• Hedging Policy in place to reduce FX exposure on non-USD direct contributions</li></ul>				<ul style="list-style-type: none"><li>• Internal audits assess whether Alliance processes are adequate</li></ul>		
Detective (alerting on risk occurrence)		Reactive (addressing consequences)				
<ul style="list-style-type: none"><li>• Quarterly financial updates to SMT</li><li>• Semi-annual financial reporting to the AFC and Board</li><li>• Monitoring if launches are happening on time (Alliance KPI)</li></ul>		<ul style="list-style-type: none"><li>• Engage with manufacturers / donors (as relevant)</li></ul>				