INTERNAL AUDIT REPORT

Examination of Country Support team Oversight of Vaccine Programme Management In-Country AUGUST 2016





Conclusion

Gavi is currently going through a significant transformation to ensure it is structured to be able to deliver on the new 2016-2020 strategic objectives focused on coverage, equity and sustainability as well as strengthening its risk management and fiduciary oversight in accordance with stakeholders reduced risk tolerance.

Vaccine Programme Management is one of the key processes in the grant management cycle and therefore effective oversight of this process is critical as it enhances proactive identification, reporting and mitigation of risks related to management and use of Gavi investments in supported countries. Country Support is one of the teams in the wider Country Programmes department tasked with carrying out specific oversight roles of vaccine programme management in-country. There are other teams in Country Programmes and the Gavi Secretariat that undertake various oversight roles of this process. In addition, the Alliance Partners provide the first line of oversight in-country.

The audit of oversight of vaccine programme management in-country will be undertaken in two phases, with the first being the examination of the role of the Country Support team. The overall conclusion on the operating efficacy of Gavi's oversight of vaccine management across the Alliance will only be concluded when the second phase of this audit is completed. Our audit procedures for this first phase of the audit were designed to provide assurance to management and the Gavi Board on the effectiveness of the oversight provided specifically by Country Support team of vaccine programme management in-country.

The Country Support team has achieved much in the last eighteen months in improving Gavi's stewardship of funds and management of fiduciary risk. In addition, further initiatives are still being developed and implemented.

Given this state of transition, existing processes have not been sufficiently formalised or implemented for a long enough period of time for us to provide overall assurance on their operating effectiveness. Consequently, this audit has focused on reviewing the current initiatives underway, with the intention of our providing feedback to management on the changes in-progress considering both their design, and execution. It is intended that a further follow-up audit be undertaken, targeted for the next 12-18 months, when many of these initiatives will be complete and in-place, better to gauge the final state of implementation.

Internal Audit Issue Summary

Issue Description	Rating	Ref	Page						
Audit Issues Relating to the Design of Planned Changes									
Roles & Responsibilities	Medium	2015-02.01	6						
Resources & Capacity	Medium	2015-02.02	7						
Risk-Based Oversight Approach	Medium	2015-02.03	8						
Audit Issues Relating to the Execution of Planned Changes									
Change Management Process	Medium	2015-02.04	10						
Guidelines, Tools & Systems	Medium	2015-02.05	10						
Monitoring & Follow-Up of Recommendations	Medium	2015-02.06	12						
Access to Stock and Cold Chain Management Data & Reports	Medium	2015-02.07	13						
Recent Cases Concerning Vaccine Management In-Country	Medium	2015-02.08	14						





Summary Performance Ratings on Areas Reviewed

For ease of follow up and to enable management to focus effectively in addressing the issues in our report, we have classified the issues arising from our review in order of significance: High, Medium and Low.

In ranking the issues between 'High', 'Medium' and 'Low', we have considered the relative importance of each matter, taken in the context of both quantitative and qualitative factors, such as the relative magnitude and the nature and effect on the subject matter. This is in accordance with the Committee of Sponsoring Organisations of the Treadway Committee (COSO) guidance and the Institute of Internal Auditors standards.

Rating	Implication
High	Address a fundamental control weakness or significant operational issue that should be resolved as a priority
Medium	Address a control weakness or operational issue that should be resolved within a reasonable period of time
Low	Address a potential improvement opportunity in operational efficiency/effectiveness

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Distribution

Title
Managing Director, Country Programmes
Director, Health Systems & Immunisation Strengthening (HSIS)
Director, Vaccine Implementation
Regional Heads, Country Support

For Information

Title
Chief Executive Officer
Deputy Chief Executive Officer
Managing Director, Audit & Investigations
Executive Team
Director, Legal
Head, Risk



Audit Objective

Our audit assessed the design and operating effectiveness, where possible, of the key controls related to Country Support team's oversight of Vaccine Programme Management In-Country.

Audit Scope

Country Support is one of the teams in the wider Country Programmes department tasked with carrying out specific oversight roles of vaccine programme management in-country. The Country Programmes department are the stewards of Gavi-funded programmes and are key participants in the process of fiduciary oversight for vaccine programmes. There are other teams in Country Programmes and the Gavi Secretariat that undertake various oversight roles of this process including Vaccine Implementation, Health Systems & **Immunisation** Strengthening, Programme **Immunisation** Financing Finance. Sustainability, Grant Performance Monitoring & Evaluation and Programme Capacity Assessment. In addition, the Alliance Partners provide the first line of oversight in-country. The scope of this audit was limited to examination of oversight of vaccine programme management in-country by the Country Support team. This audit specifically did not cover the oversight roles of other teams in Country Programmes and the Secretariat and the role played by Alliance Partners even though all these teams play a complementary role in providing oversight in-country. In addition, it should be noted that this audit focused on the period from January 2015 to March 2016. This is because oversight of vaccine programme management was an area that was until one and a half to two years ago not within the direct remit of the Secretariat or Country Support (Senior Country Managers), rather the agreed Gavi approach was that Alliance Partners were entirely responsible for Therefore the findings recommendations set out in the summary and appendix 1 relate to only one sub-process of an entire oversight process that is still work in progress and should be read and understood in this context. It is anticipated that examination of the oversight roles of other Country Programmes & Secretariat teams and the Alliance Partners will be covered in phase 2 of

this audit later in the year and a separate report issued (part 2).

Audit Approach

We adopted a risk-based audit approach informed by our assessment of the system of internal controls.

This audit was designed to assess the:

- Design and operating effectiveness, where possible, of the key controls;
- Economy and efficiency of the utilisation of resources;
- Quality of implemented governance and risk management practices;
- Compliance with relevant policies, procedures, laws, regulations and where applicable, donor agreements.

We carried out the following audit procedures during fieldwork:

- Obtaining relevant documentation in relation to the key risks and mitigating controls:
- Conducting an anonymous survey of SCMs (between 2 & 29 February 2016) and Regional Heads and face to face interviews;
- Understanding the key processes and controls by conducting process walkthroughs with process owners;
- Assessing the design of the key controls that manage the key inherent risks;
- Substantive testing (on a sample basis) the operating effectiveness of these key controls; and
- Assessing the quality of the implemented governance and risk management process throughout the audit.

Background

The majority of Gavi's investments in eligible countries relate to new and underused vaccine support (NVS) programmes.

Since inception, Gavi has disbursed US\$ 8.7 billion in funding and US\$ 6.8 billion (78%) of this has been for the purpose of accelerating the introduction and uptake of new and underused vaccines. In 2014 and 2015, Gavi disbursed US\$ 2.8 billion and US\$ 2.3 billion respectively (average 79%) related to NVS programmes. From 2010 to 2015, 45%



(US\$ 2.4 billion) of NVS funding went towards pneumococcal programmes and 37% (US\$ 1.9 billion) to pentavalent programmes1.

Historically, Gavi's business model was designed based on Gavi's adoption of a 'light touch' model with emphasis on country ownership, use of national systems and partner oversight. Oversight of vaccine programme management by the Secretariat was an area until one and a half to two years ago not within the direct province of the Secretariat, rather the agreed Gavi approach was that partners were entirely responsible for it. It is only after it was realised that this was not sufficient and that there was a push toward more proactive grant management by the Gavi Secretariat and SCMs, that the intent to play a role in this area came in, together with the Secretariat overall move from 'light touch' to 'right touch'.

The mismanagement and/or misuse of vaccines has generally been seen as lower risk because of the low value per dose, centrally managed procurement, successful routine immunisation provided free by government reducing likelihood of a secondary demand, and the need to transport vaccines through a cold chain and deliver through a medical facility/appropriately trained staff.

However, there is a prospect of a changing profile of risk due to newer, higher-cost vaccines, vaccines taken up on a discretionary basis (e.g. HPV) and the challenge of reaching the 5th child. More recently, the Gavi Board has placed an increasing emphasis on strenathenina Gavi's risk management approach, and particularly building the accountability and capabilities Secretariat. At the same time, risk tolerance is declining, with donors in particular.

In addition, Gavi has just commenced a new strategic period. The 2016-2020 strategy shifts Gavi's focus from vaccine introductions to improving the coverage, equity and sustainability of vaccine programmes. This strategy will require more intensive engagement with countries, greater country

capacity-building (including financial capacity) and a deeper focus on weaker and fragile states, as well as enhanced proactive management of programmatic and financial risks.

Therefore, in order to achieve the 2016-2020 strategy and respond to the enhanced emphasis on risk management, Gavi is making a number of strategic changes to its structures, processes and ways of working, including:

- Institutionalising enhanced and systematic risk management processes in accordance with the three lines of defence risk management model;
- Rolling out new tools, systems and training;
- Increasing resourcing and implementing a risk-based allocation of the country profile;
- Implementing a country team approach;
- Implementing a country-centric approach in which interventions are tailored to the country context and needs;
- Strengthening key processes and functions at country level;
- Enhancing engagement and accountability of partners for risk management in-country.

As the stewards of Gavi-funded programmes, the Country Support team together with other teams within the Country Programmes department (Health Systems Immunisation & Strengthening team and Vaccine Implementation team) are responsible for implementing a number of these strategic changes. The HSIS team provides important support to the Country Support team including capacity building and analysis on vaccine stock data which SCMs use during the course of grant implementation to avoid stock outs and wastage of vaccines. This analysis in turn relies on timely access to the right data (and quality of that data) where Alliance partners play a key role. The HSIS team also monitors and assesses cold chain equipment to ensure compliance with Effective Management criteria. The VI team (Information Management and Quality Assurance subteam) tracks the vaccine grants, provides tools

¹ Figures sourced from the Consolidated Commitments, Approvals, and Disbursements report produced by Finance as at 31 December 2015



and works with SCMs to help assess the appropriate quantity of vaccines to be supplied to countries at the time of grant renewal versus their need, and to help minimise over/understock of vaccines. Therefore these teams are at the front line of Gavi's work with countries, collaborating closely with partners, and are key participants in the process of fiduciary oversight for both cash and vaccine programmes.

Conclusion

Our audit procedures were designed to provide assurance to management and the Gavi Board on the effectiveness of the Country Support team's oversight of vaccine programme management in-country.

The oversight of vaccine programme management is critical and it enhances proactive identification, reporting and mitigation of risks related to management and use of Gavi investments in supported countries.

The Country Programmes team and other Secretariat teams have achieved much in the last eighteen months in improving Gavi's stewardship of funds and management of fiduciary risk, including implementation of an effective three lines of defence risk management model and particularly the strengthening of the first line of defence with an increased focus on fiduciary oversight. This has been communicated to governance forums and donors, and there has been consistent and continuous progress reported.

A significant number of changes have already been implemented by Country Programmes including:

- Improvement of the hiring process and tools;
- Recruitment of additional staff;
- Reallocation of the country portfolio among SCMs based on risk;
- Development and piloting of the country risk matrix;
- Development and piloting of the country team approach;
- Development and implementation of nine operational guidelines to date;
- Implementation of a capability building programme;

- Roll out of the PEF Targeted Country Assistance, including new accountability framework and reporting on vaccine management; and
- Piloting and roll out of PCAs, which includes a vaccine management review component.

Further initiatives are still in development and will be implemented including the full implementation and operationalisation of the country team approach and country risk matrices, the recruiting of additional staff, the further allocation of country portfolio to ensure Regional Heads are not responsible for individual countries, and the developing of additional tools and systems to assist the Country Support team in providing effective oversight. All of these will have a bearing on the development of the vaccine management oversight processes.

Given this state of transition, existing not been processes have sufficiently formalised or implemented for a long enough period of time for us to provide overall assurance on their operating effectiveness. Consequently, this audit has focused on reviewing the current initiatives underway, with the intention of our providing feedback to management on the changes in-progress considering both their design, and execution. It is intended that a further follow-up audit be undertaken, targeted for the next 12-18 months, when many of these initiatives will be complete and in-place, better to gauge the final state of implementation.

Summary of Issues Arising

It is clear that expectations around risk management generally, and risk management specifically have shifted significantly and given the increased demands of the 2016-20 strategy, significant change is happening. Gavi is in the early stages of implementing and operationalising these changes, the vision is well-developed but there is need for greater clarity on implementation. We have identified recommendations for improvement in the design, and implementation of certain of the Country Support team's processes and tools which are in development and roll-out.



Our audit identified eight (8) medium-rated issues. A summary of the issues identified is provided below:

Design of the Planned Changes

Roles and Responsibilities

Historically, Gavi's business model was designed based on Gavi's adoption of a 'light touch' model with emphasis on country ownership, use of national systems and partner oversight.

Oversight of vaccine programme management by the Secretariat was an area until 18 to 24 months ago not within the direct province of the Secretariat, rather the agreed Gavi approach was that partners were entirely responsible for it.

This 'light touch' model is not fully aligned to donors' declining risk tolerance, and the increased focus on risk management. Therefore it is only after it was realised that this was not sufficient and that there was a push toward more proactive grant management by the Gavi Secretariat and SCMs, that the intent to play a role in this area came in, together with the Secretariat overall move from 'light touch' to 'right touch'. As a result, Gavi is in the process of implementing a three lines of defence management model risk increasing its focus on proactive grant management and fiduciary risk management. Although, the transition from 'light touch' to 'right touch' model has been ongoing for the past 18 to 24 four months, there appears to be lack of clarity among most SCMs about the new model and the specific implications of this on their roles and responsibilities.

In order to ensure there is a clear understanding within the Country Support team of both their own roles and responsibilities, and the accountabilities of other teams, management will clearly define and communicate the roles and responsibilities of each team.

Resources & Capacity

In order for Gavi to be able to drive the strategic outcomes (coverage, equity and sustainability) while increasing the management of programmatic and financial risks, the roles and resources of the Country Programmes and other Secretariat teams have been enhanced.

This includes hiring additional implementing a holistic capability-building programme, reallocating country portfolios based on risk, developing a model to determine the workload per country based on inherent factors (e.g. country risk, number of grants, TA intensity, status with respect to transition) to appropriately allocate SCMs and POs to regions and countries, and developing a country team approach. Under this approach, the HSIS team provides important support to the Country Support team including capacity building and analysis on vaccine stock data. The HSIS team also monitors and assesses cold chain equipment to ensure compliance with EVM criteria. The VI team (IMQA subteam) tracks the vaccine grants, provides tools and works with SCMs to help assess the appropriate quantity of vaccines to be supplied to countries at the time of grant renewal versus their need, and to help minimise over/understock of vaccines.

Even so, we noted that the Country Support team members surveyed and/or interviewed from 2nd – 29th February 2016 do not feel they have adequate resources and capacity to effectively undertake oversight of vaccine programme management in-country.

In order to ensure that the expectations on the Country Support staff are realistic and achievable, management should conduct a bottom-up review of how much time is required in addition to other assigned roles to CP and other Secretariat teams to conduct effective risk management and oversight. This may vary from one country to another depending on total Gavi investment, implementing partner capacity, fiduciary weaknesses, health system weaknesses and political or economic complexity/instability.

In addition, we are aware that management has started to reallocate countries so that Regional Heads are not responsible for individual countries. We think this is a good initiative and is expected to be completed by end of 2016.

Risk-Based Oversight Approach

Gavi has limited resources with which to achieve its strategic objectives while effectively managing risks, therefore, it is critical that



resources are allocated on a risk-based approach, and that higher risks are effectively managed. The Country Support team has developed a country risk matrix tool to support systematic, consistent risk identification and assessments, as well as enable risk-based informed decisions such as allocations of staff/time and process differentiation.

We noted that management has not defined how the risk matrices will be updated, reviewed and consolidated.

In order to ensure that the country risk matrices are effectively implemented and used to drive the right risk actions, management has provided training to the Country Support staff in completing and using the risk matrices. In addition, management is working on ensuring Regional Heads drive the routine use by SCMs and country teams of the country risk matrix as a tool to discuss and decide on risk mitigation actions, then follow them up / monitor them over time.

Execution of the Planned Changes

Change Management Process

There are currently multiple significant initiatives underway that either the Country Support team is leading or is a key stakeholder in including rolling out new tools, bolstering resourcing and staff allocation, systems and training including holistic capacity-building programme for staff, strengthening key processes and functions at country level, institutionalising enhanced and systematic risk management processes, implementing a country team approach across the Secretariat, and enhancing engagement and accountability of partners for risk management in-country.

We noted that no assessment has been done to determine the resources required to successfully implement these changes and the impact on the Country Support team members who are actively involved in managing and progressing the majority of these initiatives in addition to their day-to-day operational responsibilities.

In addition, there is no central project plan or summary document that covers all key initiatives and that provides guidance on which changes should be prioritised for implementation.

Management will implement this plan in order to ensure the current resourcing model is appropriate to support the sustainable delivery of the initiatives and as a basis of prioritising implementation.

Guidelines, Tools and Systems

The Country Programmes department is in the process of developing and implementing a set of Operational Guidelines to outline the way Gavi manages different activities and steps of the grant management cycle. However, there is currently not an Operational Guideline in place covering the on-going oversight of vaccine programme management in-country to ensure responsibilities are fully defined and applied consistently across programmes.

The Country Support team has drafted a guidance document on proactive grant management and has certain checklists in place for planning and carrying out country visits. In order to ensure that the expectations and minimum requirements of the Country Support team in relation to oversight of vaccine programme management in-country are well defined and understood, management will supplement the existing documents. In addition, management will clarify in what situations formal memos are required to be approved for exceptions or where there is room for interpretation (i.e. where/when/which type of flexibility could be applied).

Monitoring & Follow-Up of Recommendations

There are various reports received and reviews undertaken as part of Gavi's oversight of vaccine programme management in-country. In particular, Effective Vaccine Management Assessments are commissioned by countries, and there are a number of Gavi-led reviews including programme audits (cash and vaccines), programme capacity assessments, monitoring reviews, etc.

Although we understand that the Country Support team follows-up on the recommendations and issues arising from these reports, we were unable to verify independently whether this is being done formally and consistently across countries apart from the Joint Appraisal review process



where EVMs progress is discussed and reported on – and subsequently reviewed by the HLRP.

In order to ensure consistency of approach, management should consider implementing an issue/recommendations tracking tool for use by Country Support. In addition, management should provide clear guidance on the process and approach for following-up on the issues and recommendations from the JAs and the different Gavi-led country visits, reviews and audits.

Access to Vaccine Stock Management and Cold Chain Management Data and Reports

As the stewards of Gavi-funded programmes, the Country Support team together with other within the Country Programmes department (Health Systems Immunisation & Strengthening team and Vaccine Implementation team) are responsible for oversight² of vaccine programme management in-country. The HSIS team provides important support to the Country Support team including capacity building and analysis on vaccine stock data which SCMs use during the course of grant implementation to avoid stock outs and wastage of vaccines. This analysis in turn relies on timely access to the right data (and quality of that data) where Alliance partners play a key role. The HSIS team also monitors and assesses cold chain equipment to ensure Effective compliance with Management criteria. The VI team (Information Management and Quality Assurance subteam) tracks the vaccine grants, provides tools and works with SCMs to help assess the appropriate quantity of vaccines to be supplied to countries at the time of grant renewal versus their need, and to help minimise over/understock of vaccines. These teams are at the front line of Gavi's work with countries, collaborating closely with partners, and are the primary owners of fiduciary oversight for both cash and váccine programmes.

In carrying out this responsibility, the Country Support and other teams within CP visit

countries on a periodic basis as well as receiving and reviewing various reports and data.

Through survey and interviews of SCMs, Regional Heads and the Supply Chain team (within HSIS), we confirmed that about half of them do not have access to the countries' stock management system (including stock analysis reports) and came to the same conclusion as CP that having access would enhance their oversight role.

We also noted that there is no consistent approach by the Country Support team regarding the level of monitoring of vaccine stock management and cold chain equipment management and how the team utilises the various reports and data submitted by Alliance Partners and countries to provide oversight. It is acknowledged that some of the differences in the approach and level of monitoring is due to the different country contexts, robustness of the stock management tool in use, skills level and current abilities.

In order to have a consistent and effective approach of oversight of this process, Country Support will define the level of access to vaccine stock and cold chain management data and reports expected and the oversight role of implementing partners in this. In addition, EPI managers will be required to analyse their vaccine stocks every month and share this data with the SCM and Alliance partners. Countries will also be urged to report, twice per year, their actual stocks. Once management has defined an effective approach of vaccine management oversight, other modalities to ensuring risk reduction other than giving additional responsibilities to SCM's could be considered. For example, a specialised vaccine management team (first line of vaccine management defence) comprising of staff who have expertise in drug/vaccine management that focus on stock analysis and reporting may be an option.

Strengthening Risk and Fiduciary Oversight Paper - 24 October 2014

GAVI Risk Policy, Risk Management and Fiduciary Oversight – Report to the Board (10-11 December 2014)

² GAVI'S Approach To Managing Risk and Fiduciary Oversight Paper— 30 July 2014





Review of Recent Cases Concerning Vaccine Management In-Country

Recent cases concerning vaccine management in-country were noted through our review of governance reports, stock management tool analyses (performed by the Supply Chain Management team), and interviews with SCMs. In addition, the Programme Audit team completed a number of country programme audits in 2015 and a number of themes have emerged from these in relation to vaccine management and supply chain management. In particular, for each of the programme audits undertaken in 2015, the stock records maintained were inadequate and vaccines were not distributed in accordance with the principle of Earliest-Expiry-First-Out (EEFO). As a consequence certain cases of expired or near-expired vaccines were identified.

In order to enhance visibility of cases of vaccine mismanagement in-country. Gavi. The Alliance needs to define mismanagement in the context of Gavi's programmes, and the actions that are required to be taken when a case of vaccine mismanagement is identified. In addition, Gavi will implement a more structured process for recording, reporting and analysing cases of vaccine mismanagement to identify root causes, trends and actions required to prevent reoccurrence and/or occurrence in other Gavi eligible countries.

We will continue to work with management to ensure that these audit issues are adequately addressed and required actions undertaken.

We take this opportunity to thank the Country Programmes team for their assistance during this audit.

Head of Internal Audit



	Issue Description	Risk/Implication	Recommended Actions	Management		Target	Status
No. Rating				Comments	Action Owner	Completion	
						Date	

Roles & Responsibilities

The Country Programmes team has gone through significant re-organisation since 2011 to emphasise their stewardship role and ensure there is greater focus on results as well as programme and financial accountability. There has been a significant increase in resources within the Country Programmes team with a near tripling of headcount between the end of 2010 and 2014. Over the last eighteen months, the entire Country Support recruitment approach, tools, and job descriptions have been redesigned for all core positions.

Historically, Gavi's business model was designed based on Gavi's adoption of a 'light touch' model with emphasis on country ownership, use of national systems and partner oversight. Oversight of vaccine programme management by the Secretariat was an area until eighteen to twenty four months ago not within the direct province of the Secretariat, rather the agreed Gavi approach was that partners were entirely responsible for it. This 'light touch' model is not fully aligned to the declining risk tolerance of donors, and their increased focus on risk management. Therefore it is only after it was realised that this was not sufficient and that there was a push toward more proactive grant management by the Gavi Secretariat and SCMs, that the intent to play a role in this area came in, together with the Secretariat overall move from 'light touch' to 'right touch'. As a result, Gavi is in the process of implementing a three lines of defence risk management model and increasing its focus on proactive grant management and fiduciary risk management.

02.01

- 2015- **Medium** a) We confirmed through an anonymous survey of SCMs and Regional Heads from 2-29 February 2016 and face to face interviews thereafter that 77% felt there isn't adequate clarity of their roles and responsibilities in relation to oversight of vaccine programme management.
 - b) In addition, less than 40% of SCMs and Regional Heads felt they have a clear understanding of the role of other teams (excluding Country Support) in relation to oversight of vaccine programme management in-country.
 - c) We also confirmed that 64% of SCMs interviewed feel that there is no defined accountability of other teams involved in the oversight of vaccine programmes.

In our opinion, these findings are indicative of some of the challenges related to the implementation plan (including communication) of transition from a 'light touch' model to a model with increased focus on proactive grant and risk management. Although, the transition from 'light touch' to 'right touch' model has been ongoing for the past eighteen to twenty four months, there appears to be lack of clarity among most

SCMs may have different understanding of their role and responsibilities leading to different oversight activities being performed and some oversightrelated risks not being fully addressed.

- 1. Clarify and document the accountabilities of the different Country Programmes teams in relation to oversight of vaccine programme management under the new model: and
- 2. Clearly define and communicate the roles and responsibilities of each team.

In order to ensure a clear understanding within CS team of both staff roles and responsibilities, and the accountabilities of other teams, we will clearly define and communicate the roles and responsibilities of each team.

Q1 2017

MD, CP

Open



	Issue Rating	Issue Description	Risk/Implication	Recommended Actions	 ET Member/ Action Owner	 Status
•		SCMs about the new model and the specific implications of this on their roles and responsibilities.				

Resources & Capacity

In order for Gavi to be able to drive the strategic outcomes (coverage, equity and sustainability) while increasing the management of programmatic and financial risks, the roles and resources of the Country Programmes department have been enhanced. Additional SCMs and Programme Officers (POs) have been appointed including setting up of Programme Finance and Supply Chain teams with recruitment still on-going for some roles. In addition, the recruitment process and tools have been improved to enable an enhanced approach to recruiting appropriate levels of skills and experience.

A holistic capability-building programme has been developed and is being delivered by management to ensure that country-facing staff are equipped with the necessary knowledge and skills for effective, consistent management of grants, risk and stakeholders. A leading consultant has been engaged to assist in the development and facilitation of the programme, and the structure of the programme has been based on an initial needs assessment.

The country portfolios allocated to the SCMs and POs have also been reviewed by management and a risk-based reallocation of the countries has been implemented. A model has been developed to determine the workload per country based on inherent factors (e.g. country risk, number of grants, TA intensity, status with respect to transition) to appropriately allocate SCMs to regions and countries. In particular, dedicated SCMs and POs have been allocated to some of the most complex and highest risk countries. The remaining countries have been allocated to SCMs and POs based on a consideration of the risk and as new SCMs and POs are appointed the number of countries each SCM is managing is decreasing.

A country team approach has been developed by management and is currently being piloted for selected higher risk countries. Under this approach, priority countries will benefit from having a defined cross-Secretariat team to pool skills and capacity across the organisation for more effective oversight and management of grants e.g. the HSIS team provides important support to the Country Support team including capacity building and analysis on vaccine stock data which SCMs use during the course of grant implementation to avoid stock outs and wastage of vaccines. This analysis in turn relies on timely access to the right data (and quality of that data) where Alliance partners play a key role. The HSIS team also monitors and assesses cold chain equipment to ensure compliance with Effective Vaccine Management criteria. The VI team (Information Management and Quality Assurance sub-team) tracks the vaccine grants, provides tools and works with SCMs to help assess the appropriate quantity of vaccines to be supplied to countries at the time of grant renewal versus their need, and to help minimise over/under-stock of vaccines. It is intended that the country team approach will be rolled out to all priority countries using a phased approach.

915- <mark>Medium</mark> 9.02	a) Through an anonymous survey of SCMs and Regional Heads, we confirmed that 100% felt they did not have the adequate time, resources and capacity to effectively undertake oversight of vaccine programme management in-country.	SCMs may not be dedicating adequate time to oversight of vaccine programme	Conduct a bottom-up review of how much time is required in addition to other assigned roles to CS and other Secretariat teams to carry out effective risk	The increase in SCM number is recent and the ratio of countries per SCM still quite high, therefore not allowing sufficient time	MD, CP	Q1 2017	Open
	b) We were unable to determine the effectiveness of the model that is used to allocate SCMs and POs to regions and countries. This is evidenced by the results of an anonymous survey of SCMs and Regional Heads in which they indicated that they do	management. SCMs may not have the resources to proactively identify, report and manage	management and oversight of a country's grants. This may vary from one country to another depending on total Gavi investment, implementing partner capacity, fiduciary weaknesses, health systems	for SCM to look at all elements of oversight, notably as neither partners nor countries report on vaccines regularly. With new recruitment ongoing, there is a model to			



Issue No.	Issue Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
		not feel like they have adequate time, resources and capacity to provide effective oversight.	issues and risks related to vaccine programmes.	weaknesses and political or economic complexity/instability. 2. Consider aligning the current resourcing plans with this analysis.	allocate POs and SCM according to the risk identified (risk matrix, CPA and PCA)			
		c) Regional Heads are currently responsible for individual countries in addition to their management and regional responsibilities. It is acknowledged that management have identified this as a risk and are working to appoint additional resources in order to reallocate these countries by the end of 2016.	Regional Heads may not have the capacity to effectively manage a country's grants while undertaking their additional management and regional responsibilities	3. Consider prioritising the reallocation of country portfolios to ensure that Regional Heads do not have individual country responsibilities so that they can focus more on strategic leadership and support, cross-cutting issues, risk management and performance of teams.	This is already planned, but can only happen once we have recruited the full set of new SCMs and POs for 2017 and those have joined.	MD, CP	Q1 2017	Open
		d) We confirmed through our interviews with SCMs that 91% (10 out of 11) felt that the capability building programme could be improved to ensure more practical training and tools are provided. In our opinion, this issue is related to the points raised above on the lack of tools and operational guidelines to enable the SCMs to effectively undertake their oversight role. It is difficult for some of the training modules to deliver tools if these tools are not available, or the detailed processes have not yet been defined.	SCMs may not have the adequate training and skills to effectively undertake oversight of vaccine programme management incountry	4. Review the current capability building programme and identify modules that can provide further practical training and tools based on SCMs' needs.	The issue is not much training than tools. Tools are being developed by HSIS and VI (within their limited bandwidth), as well as OGs that will clearly specify roles and responsibilities in all areas of grant management. The second element is country team approach that is progressively implemented, but also relies on staffing. The third element is PEF, to engage partners in	MD, CP	Q2 2017	Open



ls:	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
				proactive risk management	•		

Risk-Based Oversight

Strong risk management and fiduciary oversight is even more important in next strategic period given the reduced risk tolerance among stakeholders. Gavi has limited resources with which to achieve its strategic objectives while effectively managing risks. Therefore, it is critical that resources are allocated taking into account the level of risk, and that higher risks are effectively managed.

The Country Support team has developed a country risk matrix tool to support systematic, consistent risk identification and assessments. The risk matrix provides a tool to systematically assess and monitor the risk of a given country as relates to Gavi support, and will enable risk-based informed decisions such as allocations of staff/time and process differentiation. The country risk matrix was piloted across a range of countries in 2015, and formally rolled out across all countries in February 2016.

15- <mark>Medium</mark>	The country risk matrix was not formally	The country risk	1. Provide training to SCMs	Training has been	MD, CP	1.Q3 2016	Closed
	rolled out during the audit period, however	matrices may	on how to use the country	provided to CS staff in			
	the matrix has been piloted in a sample of	not be correctly	risk matrix, particularly on	completing and using			
	countries.	completed or used, leading to	how the risk matrix should inform decisions and actions	the risk matrices. In addition, Regional			
	a) Through SCM interviews, we confirmed	an inconsistent	illionii decisions and actions	Heads will drive the			
	that 64% (7 out of 11) were not able to demonstrate that the prioritisation of	approach to		routine use by SCMs			
	oversight activities was aligned to the	identifying and		and country teams of			
	underlying risks in-country.	managing risk,	2. Formalise how the country	the country risk matrix		2. Q1 2017	Open
	b) In addition, we confirmed that 82% (9 out	and a lack of	risk matrices will be updated, reviewed and consolidated,	as a tool to discuss			
	of 11) of the SCMs were aware of the country	alignment between the	as well as how issues and	and decide on risk mitigation actions,			
	risk matrix but were generally unclear on the	level of risk and	findings from other reviews	then follow them up /			
	use, ownership, timing for implementation,	the monitoring	will inform and be	monitor them over			
	link to actions, process for updating and	activities	incorporated into the risk	time. The risk matrix is			
	consolidation of risks across countries and teams.	undertaken	matrix (e.g. Monitoring	being revised to be			
	teams.		Reviews, Programme Audits	more aligned with			
			and Programme Capacity Assessments (PCAs) and	grant management			
			Refresher PCAs)	and mitigation actions			



Issue Issue	e Issue Description	Risk/Implication	Recommended Actions	Management	ET Member/	Target	Status
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Change Management Process

There are currently multiple significant initiatives underway that either the Country Support team is leading or is a key stakeholder in. The initiatives include rolling out new tools, bolstering resourcing and staff allocation, systems and training including holistic capacity-building programme for staff, strengthening key processes and functions at country level, institutionalising enhanced and systematic risk management processes, implementing a country team approach across the Secretariat, and enhancing engagement and accountability of partners for risk management in-country.

Currently, the majority of these initiatives are managed and progressed by members of the Country Support team on top of their day-to-day operational responsibilities. For the majority of the initiatives there is no dedicated project management resource to make sure the changes are managed, implemented and monitored effectively.

2015- Medium 02.04	a) During the review, we noted that no assessment has been done to determine the resources required to successfully implement initiatives/changes in Country Support and the impact on the team members who are actively involved in managing and progressing majority of these initiatives in addition to their day-to-day operational responsibilities.	The current resources may not be adequate to effectively implement all the initiatives and changes within the envisaged timeframes	1. Consider whether the current resourcing model is appropriate to support the sustainable delivery of all the initiatives. This exercise should be preceded by an assessment of the resources required to successfully implement all the initiatives.	Additional headcount has been approved to allow better implementation of new initiatives. Recruitment is ongoing to align risks and staffing in CS. In addition the HSIS	MD, CP	Q2 2017	Open
	b) In addition, there seems to be no central project plan or summary document that covers all key initiatives and that provides guidance on which changes should be prioritised for implementation.	24 P+	2. Develop a central project plan covering all key initiatives for the Country Support team, as well as clear prioritisation of the initiatives.	team is being strengthened to better support SCMs through country team approach. A new staff dedicated to OG will help centralize all guidance and tools.			

Guidelines, Tools & Systems

The Country Programmes team is in the process of developing and implementing a set of Operational Guidelines (OGs) to outline the way Gavi manages different activities and steps of the grant management cycle – from grant submission to graduation and grant closure. It is intended that the OGs will eventually be merged into an Operational Manual that will cover each step of the grant management cycle.

The Country Support team has developed the following documents to assist Senior Country Managers (SCMs) in fulfilling their oversight role: a) Country Visit List of Consideration and Questions; b) Country Visit Preparation Checklist; and c) Monitoring Visit Template.

In addition, the Country Support team is currently drafting a guidance document for SCMs on Delivering Coverage, Equity and Sustainability Goals through Pro-Active Grant and Risk Management. This guidance document aims to outline and ensure a common understanding of what is broadly expected in terms of pro-active grant and risk management along the grant management cycle. The document is not intended to be an Operational Guideline, but rather provide a holistic framework for coverage, equity and sustainability from a grant management perspective. The document contains key actions to consider and strategic questions to ask along the key steps of the life of a grant.



Issue No.	Issue Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
2015-02.05		a) We noted during the review that there is currently no Operational Guideline or similar document that defines and outlines the role of the Country Support team in overseeing vaccine programme management in-country to ensure responsibilities are fully defined and applied consistently across programmes. In our opinion, this guideline is critical and should be prioritised. We confirmed through an anonymous survey of SCMs and Regional Heads and face-to-face interviews, that 85% felt the Country Programmes oversight role in relation to vaccine programme management is not well documented or understood. We understand that the oversight required is based on the specific country context, however we believe that there are consistent actions and activities that take place across all countries (such as; the Effective Vaccine Management Assessment and the improvement plan that is developed thereafter, Programme Capacity Assessments(PCA), Programme Audits, (PA) Monitoring Reviews(MR) and etc.).	Risks and issues relating to vaccine programmes may not be consistently identified and addressed.	1. Develop and implement OGs (or similar documents) that clearly define and outline how the Country Support team oversees vaccine programme management in- country, including minimum requirements and best practices	12 OGs to date have been developed. Some will need revisions, but a new staff is being recruited to be dedicated to development and update of OGs covering the entire field of grant management	MD, CP	Q1 2017	Open
	interviewed (8 out of 11) do not feel they vaccine value adequate tools (templates, checklists programmes pand systems) to fulfil their role. The majority of the SCMs interviewed were inconsistent and a	2. Identify the key tools that would enable the SCMs to provide effective oversight of vaccine programmes, and assess whether these can be developed/updated	HSIS and VI (IMQA) are developing tools to assist SCM in this area. The most critical element however is lack of information regularly communicated to the Secretariat by countries and partners, and an official communication to the countries has	MD, CP	Q2 2017	Open		



Issue No.	Issue Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
					been made in June by the MD of CP to request monthly review at country level of stock management, and bi-annual submission of stock data to the Secretariat			
		c) We confirmed through interviews with SCMs that for situations where there is no guidance/policy, where the guidance/policy is unclear or where there is an exception to a policy, a formal memo is prepared and approved by the Managing Director, Country Programmes or the Executive Officer.	Where there is room for interpretation, inconsistent decisions may be made.	3. Consider having documented guidance to clarify in what situations a formal memo is required to support a certain decision or course of action, and who is authorised to approve these	This will be developed as part of the OG and operational procedures, with an effort at documenting current practices	MD, CP	Q2 2017	Open
		However, we were unable to effectively review this process for purposes of this audit given that there is no documented guidance as to when a formal memo is required, and who should approve the memo, etc.		memos. 4. Implement a process to review these decisions and provide clear guidance for repeated situations.				

Monitoring & Follow-Up

There are various reports received from countries and Alliance Partners and reviews undertaken as part of Gavi's grant oversight of vaccine programme management in-country. In particular, for vaccine programmes, an Effective Vaccine Management Assessment (EVMA) should be commissioned by the country every 3-5 years to assess the quality and sufficiency of the country's supply chain. There are also a number of Gavi-led reviews including programme audits (cash and vaccines), programme capacity assessments and refreshers, monitoring reviews etc.

2015- <mark>I</mark>	Medium	According to an anonymous survey of SCMs	EVMA	1. Develop clear guidance on	EVMs progress is	MD, CP	1. Q1 2017	Open
02.06		and Regional Heads, 92% are aware of an	recommendation	the SCMs role in the follow	discussed, reported			
		EVMA being completed for their countries	s may not be	up of the EVMA	on and subsequently			
		within the last five years, and the same	implemented on	recommendations.	reviewed by the High			
		number believe the EVMA added value.	a timely basis or	2. There should be a clear	Level Review Panel.			
		a) We confirmed through the same	at all leading to	link between other forms of	It is the role of		2. Q3 2017	
		anonymous survey that 23% of the SCMs	weaknesses and	Gavi support to countries	Alliance partners to			
		and Regional Heads do not formally follow up	bottlenecks in	(such as health system	ensure EVM			
		on the implementation of the EVMA	the country's	strengthening grants) and the	recommendations are			
		recommendations while 31% play no role in	supply chain		implemented and has			



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Issue Is No. R	ssue Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
		the follow-up of the implementation of the EVMA recommendations. In addition, of the proportion of respondents that do follow up on the implementation of the EVMA recommendations, only 62% maintain evidence of this oversight exercise. In our opinion this may be partly due to the lack of clear guidance on how Gavi should be supporting the implementation of the EVMA recommendations (e.g. cash grants). Therefore there is no consistent expectations as to the SCMs involvement in following up on the EVMA recommendations.	ultimately impacting Gavi supported vaccine programmes	EVMA recommendations and improvement plan.	been included in their PEF deliverables.			
		b) We were unable to evidence a consistent and formalised approach of follow-up of issues and recommendations from Gavi-led reviews (e.g. country visits, Programme Audits, Monitoring Reviews, Programme Capacity Assessments, Refresher PCAs, etc.) c) We noted that formal management letters are sent to some countries after country visits but this was not consistently applied across the countries.	Risks and issues raised may not be adequately addressed on a timely basis and therefore may impact Gavi supported vaccine programmes	 Clarify the process and approach of follow-up of issues and recommendations from different Gavi-led country visits, reviews and audits. Consider implementing a tool that works as a central repository of all issues and recommendations and that facilitates tracking Ensure formal management letters are sent to countries after country visits and to follow up on outstanding actions. 	Agreed. Such a tracking tool would indeed be useful, should be a single tool to track all recommendations across different sources (dependent on KMTS). Follow up is improving with the increase in staff time dedicated to each country. Staffing increase ongoing.	MD, CP Director, KMTS	Q3 2017	Open



Open

Appendix 1: Detailed Findings and Recommendations

Issue Issue	Issue Description	Risk/Implication	Recommended Actions	Management	ET Member/	Target	Status
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As the stewards of Gavi-funded programmes, the Country Support team together with other teams within the Country Programmes department (Health Systems Immunisation & Strengthening team and Vaccine Implementation team) are responsible for oversight³ of vaccine programme management in-country. The HSIS team provides important support to the Country Support team including capacity building and analysis on vaccine stock data which SCMs use during the course of grant implementation to avoid stock outs and wastage of vaccines. This analysis in turn relies on timely access to the right data (and quality of that data) where Alliance partners play a key role. The HSIS team also monitors and assesses cold chain equipment to ensure compliance with Effective Vaccine Management criteria. The VI team (Information Management and Quality Assurance sub-team) tracks the vaccine grants, provides tools and works with SCMs to help assess the appropriate quantity of vaccines to be supplied to countries at the time of grant renewal versus their need, and to help minimise over/under-stock of vaccines. These teams are at the front line of Gavi's work with countries, collaborating closely with partners, and are the primary owners of fiduciary oversight for both cash and vaccine programmes.

In carrying out this responsibility, the CS and other teams within CP visit countries on a periodic basis as well as receiving and reviewing various reports and data.

The monitoring activities undertaken by the SCMs in particular in relation to the vaccine programmes may include (amongst other activities) visiting warehouses, sample checking the quality of the vaccines, reviewing the stock management records, inspecting the quality of the cold chain equipment and visiting health centres.

02.07

2015- **Medium** a) Through the anonymous survey of SCMs and Regional Heads and interviews with the Supply Chain team (within HSIS), we confirmed that 46% do not have access to the country's stock management system (including stock analysis reports), and 85% do not believe their access to the stock management system is adequate for the purpose of providing oversight (and believe that having access would enhance their oversight role).

> We confirmed through interviews of SCMs and the supply chain manager that only certain countries and/or partners provide access to the stock management records and/or share analysis of the vaccine stocks.

Vaccine stock management and cold chain equipment issues may not be identified and resolved on a timely basis to mitigate potential exposure of Gavi investments

1. Provide clear quidance on what level of oversight is expected of SCMs regarding vaccine stock management and cold chain equipment management vis-à-vis that of implementing partners. In addition, there will be a need to define the level of access vaccine stock management and cold equipment to support the expected oversight.

In order to have a MD. CP Q3 2017 consistent and effective approach of oversight of this process, Country Support will define the level of access to vaccine stock and cold chain management data and reports expected and the oversight role of implementing partners in this. In addition, a letter was sent to all EPI managers on 2 June 2016 requiring them to analyse their vaccine stocks every month and share this data with the SCM and Alliance partners. Countries have also

³ GAVI'S Approach To Managing Risk and Fiduciary Oversight Paper – 30 July 2014 Strengthening Risk and Fiduciary Oversight Paper-24 October 2014 GAVI Risk Policy, Risk Management and Fiduciary Oversight - Report to the Board (10-11 December 2014)



Issue No.	Issue Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
					been urged to report, twice per year, their actual stocks.			
		b) We confirmed through SCM interviews that there isn't a consistent approach of carrying out oversight of vaccine stock management and cold chain equipment management i.e. what and how. In our opinion, this inconsistency is partly due to lack of clear guidance regarding what level of 1st line oversight is expected of SCMs and how this should be done.	Vaccine programme issues/risks may not be identified and responded to on a timely basis	2. Build the capacity of SCMs to be able to effectively carry out 1 st line oversight of vaccine stock management and cold chain equipment management.	Once we have defined an effective approach of vaccine management oversight, other modalities to ensuring risk reduction other than giving additional responsibilities to SCM's could be considered. For example, a specialised vaccine management team (first line of vaccine management defence) comprising of staff who have expertise in drug/vaccine management that focus on stock analysis and reporting may be an option: IMQA is already involved in this aspect of stock analysis whenever data is available	MD, CP	Q4 2017	Open

Review of Recent Cases Concerning Vaccine management in-country

Recent cases concerning vaccine management in-country were noted through our review of governance reports, stock management tool analyses (performed by the Supply Chain Management team), and interviews with SCMs. These cases covered various regions and related to fires in warehouses, vaccine expiry, lack of storage capacity, unaccounted for vaccines and non-functioning cold chain equipment. In addition, through an anonymous survey of the SCMs and Regional Heads, we confirmed that 54% were aware of cases concerning vaccine management in their countries.



Issue Issue	Issue Description	Risk/Implication	Recommended Actions	Management	ET Member/	Target	Status
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The Programme Audit team completed a number of country programme audits in 2015 with a widened scope to review vaccine stock and supply chain management. These audits have not yet been finalised but a number themes have emerged from these reviews in relation to stock records and supply chain management. In particular, for each of the programme audits undertaken in 2015, the stock records maintained were inadequate and vaccines were not distributed in accordance with the principle of Earliest-Expiry-First-Out (EEFO). As a consequence certain cases of expired or near-expired vaccines were identified. These trends have also been confirmed by the findings from the country Joint Appraisal processes and the Stock Management Tool review by the Supply Chain Management team.

2015- Mediun 02.08	a) There seems to be no clear definition of what constitutes vaccine mismanagement, and the actions required of countries and Gavi (both Partners and the Secretariat) if a significant case of vaccine mismanagement is identified.	Cases of vaccine mismanagement may not be identified or reported, and if they are, actions taken may not be consistently applied	1. Define what vaccine mismanagement is in the context of Gavi's programmes, and the actions to be taken when a case of vaccine mismanagement is identified	Agreed. This should be defined within the Alliance, involving partners and Secretariat teams (CP and A&I)	MD, CP	Q2 2017	Open
	b) Currently countries are not required to report vaccine mismanagement issues in the Annual Progress Reports. In addition, we were unable to evidence a systematic way of identifying and reporting cases of vaccine mismanagement from countries and partners to Gavi. We confirmed through SCM interviews that cases of vaccine mismanagement are generally either identified by the Country Programmes staff during visits, or reported by countries only when they significantly impact Gavi programmes e.g. stock-outs, fires, lack of storage capacity, adverse events following immunisation (AEFIs).	Some cases of vaccine mismanagement impacting programmes may not be reported to Gavi by the countries or partners	2. Implement a process for countries and partners to report significant cases of vaccine mismanagement to Gavi once vaccine mismanagement has been defined	Once vaccines mismanagement is clearly defined, countries and partners will be requested to report. It should be noted that reporting from countries is notoriously weak, for example AEFI are not reported in the majority of countries (lack of capacity at periphery level, absence of clear procedures to address AEFIs and lack of staff at central level to	MD, CP	Q3 2017	Open



Issue Issue No. Rating	Issue Description	Risk/Implication	Recommended Actions	Management Comments	ET Member/ Action Owner	Target Completion Date	Status
				analyse and follow up AEFI			
	c) We noted that there is no formal process to record cases of vaccine mismanagement identified/reported, root causes, analysis of trends and actions taken/required to prevent reoccurrence and/or occurrence in other Gavi eligible countries. d) In addition, we were unable to evidence how trends across jurisdictions/regions are analysed and lessons learnt from previous cases of mismanagement are shared and used to inform and improve Gavi's processes.	Cases of vaccine mismanagement may be on the increase due to lack of a structured process to analyse trends, determine root causes and actions needed to prevent reoccurrence	3. GAVI, The Alliance should implement a process for recording, reporting and analysing cases of vaccine mismanagement to identify root causes, trends and actions required to prevent reoccurrence	Agreed. Once vaccines mismanagement has been defined, an agreement will have to be arrived at with partners to report (PEF should be used for this)	MD, CP	Q3 2017	Open