INTERNAL AUDIT REPORT

Vaccine Doses Calculation Process (renewals) Key Controls Audit

September 2018

Gavi
The Vaccine Alliance

Summary

Conclusion

Our audit procedures were designed to provide assurance to management and the Gavi Board on the adequacy and effectiveness of the key controls in the processes related to determining the vaccine dose requirements for Gavi-supported countries during grant renewals.

The process starts with Gavi-supported countries submitting their requests through the country portal. This is followed by analysis of the data for accuracy and consistency using various tools, pre-screening, validation and eventually clarification with countries before final determination of the vaccine dose requirements.

Through our audit procedures, we have confirmed that the process for estimating the vaccine dose requirements is consistent with the current methodology. However, we have identified two medium rated risk issues as summarised below.

Internal Audit Key Issues Summary

Issue Description	Rating	Ref	Page
There is need to enhance understanding of both the methodology and the process of determining vaccine dose requirements	M	2018.01.01	4
Develop and document operating procedures and guidelines for the process of determining vaccine dose requirements	M	2018.01.02	5

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Summary of Findings

Summary of Key Issues Arising

Through our audit procedures, we have identified two medium-rated issues relating to understanding of the methodology and the process and documentation of guidelines and procedures as summarised below.

There is need to enhance understanding of both the methodology and the process of determining vaccine dose requirements

The process of determining the vaccine dose requirements of countries is one of the critical and complex processes in Gavi. There are multiple teams involved, multiple processes have to be managed (internally and externally) and there are multiple non-integrated systems in use (not automated).

Discussions held with management and other internal stakeholders indicated that there is need to clarify the methodology and the process of determining vaccine dose requirements (i.e. vaccine dose calculations). There is limited understanding across the Secretariat of the tools in use (i.e. system that runs the calculations and formulas), the methodology adopted and the process itself because of the technical nature of the subject matter and the lack of simplified documentation and reference material for each of these.

In addition, we noted that there is lack of clarity in Gavi regarding the importance of considering coverage in the process of determining vaccine dose requirements due to the challenges associated with establishing an accurate coverage level and the fact that there is no "single source of truth" on this.

Develop and document operating procedures and guidelines for the process of determining the vaccine dose requirements

We observed that currently the procedures for determining vaccine doses requirements are described in different documents including MS PowerPoint presentations and other materials (e.g. Lessons Learnt documents and management papers).

There is need to prioritise the consolidation of the information in the different documents into one operating procedures manual and/or guideline for ease of reference and institutional knowledge management (the dose calculation is listed within Operational Guidelines (OG), which is still in draft).

Background

Over 75% of Gavi's funding to supported countries is through vaccine support. Since inception to 30 April 2018, Gavi has disbursed around $10 billion for vaccine support (including vaccine operational costs).[1]

During the annual grant renewal, the Gavi-supported countries submit their requests through the country portal, indicating among others, the target, first and last doses for each vaccine, wastage, stock levels and related data for each vaccine.

The process of determining vaccine dose requirements commences in May each year upon submission of the grant renewal requests by the Gavi-supported countries. A data clean-up and high level consistency checks are carried out by the Information Management & Quality Assurance team (IMQA) before the data is transferred into the main tool (VI Track) for calculation of vaccine dose requirements. This is followed by a process of data screening and IMQA coordinates the validation of the vaccine specific issues with the relevant Vaccine Programme Managers, country specific issues with the relevant Senior Country Managers (SCMs), and co-financing issues with the Immunisation Financing and Sustainability team (IF&S). The Monitoring, Data Systems & Strategic Information team (MDS team) may assist in checking for reasonableness and consistency of the country targets (from vaccine to vaccine and year to year), wastage and drop-out based on the country context and previous achievement by the Gavi-supported country. In reviewing the country data, the relevant Secretariat teams compare the data against other independent sources such as WUENIC (for coverage), any surveys carried out in the Gavi-supported-country, UN Population data, actual shipments to Gavi-supported countries (based on UNICEF data) and WHO recommended vaccine wastage rates. Where there are significant differences in coverage rates, discussions on targets occur with the countries, between the SCM and the country EPI manager or Minister of Health.

The discussions from this process are documented in Microsoft OneNote files and issues requiring further

[1] *Figures sourced from the consolidated commitments and disbursements report dated 30 April 2018 from the disbursements by programme year tab.*

Summary of Findings

clarification from the countries are summarised by vaccine and sent to the country (through the SCM) to respond. The communication (through email) also includes a draft Programme Approval Request (PAR) for the country's review and confirmation before finalisation. The countries are given 15 days within which to respond, otherwise consent is assumed. The final volumes of the doses are then locked in VI Track, and used to produce Approval Requests (ARs), the Authorisation Schedule (AS), the Country Notification Letters (CNL) and the final Decision Letters (DLs).

The methodology for determining vaccine dose requirements was revised in 2013[2] to incorporate drop-out between first and last doses, which was previously not considered. Another change in the methodology included consideration of the stock levels in-country and preponed or postponed shipments which are used to adjust the final vaccine dose volumes. The stock adjustments are made when determining the vaccine dose requirements in order to minimise the risk of overstocking or stock-outs in the supported countries.

A Microsoft-Excel based tool (i.e. VI Track) is used to manage the data as well as run the calculations for vaccine doses, including the co-financing obligations for both Gavi and the Gavi-supported countries. The assumptions for each vaccine and other input parameters are in-built into the VI Track.

Audit Objective

Our audit assessed the adequacy and effectiveness of the governance, risk management and internal controls over the key controls in the process of determining the vaccine dose requirements for Gavi-supported countries during grant renewals.

Audit Scope and Approach

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

Our audit approach included interviewing relevant Secretariat teams, reviewing Board and committee reports, reviewing operational and country guidelines, and sample testing evidence of the process of determining vaccine dose requirements. In the course of the audit we also considered the IT systems supporting the processes and the quality of the data available used to determine the vaccine dose requirements.

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; and
- Compliance with relevant policies, procedures, laws, regulations and where applicable, donor agreements.

The scope of this audit covered the key controls in the following key areas in the process of determining vaccine dose requirements for grant renewals for 2017 and 2018:

- Data pre-screening, analysis and validation;
- Robustness of the methodology applied in the process of determining vaccine dose requirements; and
- Adequacy of the tools and systems used in the process.

The following areas were not considered in-scope for this audit:

- New Vaccine Support (NVS) dose requirements; and
- Approval Requests (ARs), Country Notification Letters (CNL) and Decision Letters.

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 all the teams involved in this audit for their on-going assistance.

Head, Internal Audit

[2] The revised methodology was signed off by the Vaccine Implementation Management Team (VIMT), a Board approved technical team consisting of WHO, UNICEF SD, UNICEF PD, PATH, Gates Foundation chaired by the Gavi Secretariat VI Director. However the EO has not signed off on the methodology.

Appendix 1: Detailed Findings and Recommendations

Issue No.	Issue Description	Risk/Implication	Recommended Actions for Management	Management Comments	Action Owner	Target Completion Date	Status
MEDIUM	**There is need to enhance understanding of the methodology and the process of determining vaccine dose requirements across the Secretariat** Over 75% of Gavi's funding to countries is through vaccine support, with $10 billion having been disbursed to countries since inception to 30 April 2018. The process of determining the vaccine dose requirements is therefore one of the critical processes in Gavi and is considered complex by a majority of the stakeholders. Some of internal stakeholders include: Executive Office; Country Programmes; Vaccine and Sustainability; Monitoring, Data Systems & Strategic Information; and Finance teams. It is therefore crucial to ensure that there is a common understanding of the process, including the key activities, methodology and assumptions applied in determining the vaccine doses requirements.						
2018.01.01	The process of determining the vaccine dose requirements of countries is one of the critical and complex processes in Gavi. There are multiple teams involved, multiple processes have to be managed (internally and externally) and there are multiple separate systems in use (not automated). a) However, discussions held with management and other internal stakeholders indicated that there is need to further explain the methodology and the process of determining vaccine dose requirements (i.e. vaccine dose calculations). There is limited understanding across the Secretariat of the tools in use (i.e. system that runs the calculations and the formulas), the methodology adopted and the process because of the technical nature of the subject matter and the	• Lack of effective oversight of the process • The methodology adopted may not be aligned with management expectations	a) The IMQA team should endeavour to bridge the knowledge gap internally on the methodology and the process through targeted one-on-one sessions with key teams and other internal stakeholders.	a) The leadership of VI agrees with this recommended action to further bridge knowledge gap with all stakeholders. IMQA will develop, execute and evaluate the results of a training plan to inform key stakeholders of the methodology associated with doses calculations. IMQA will focus special attention on training for the CS team (in particular the Senior Country Managers) to enable them to effectively carry out their responsibilities. IMQA will conduct one-on-one sessions with the leadership of CS to ensure full understanding and support of the process.	Planning and execution by leadership of IMQA with oversight by VI Director Engagement of CS Director and Region Heads in supporting this training.	Development of a training plan and start of training activities in Q 4 2018; major training objectives, as outlined in the plan, to be completed by beginning of 2019 dose calculation process.	Pending verification by Internal Audit

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	lack of simplified documentation and reference material for each of these. b) In addition, we noted that there is lack of clarity in Gavi regarding the role of coverage in the process of determining vaccine dose requirements due to the challenges associated with establishing an accurate coverage level and the fact that there is no "one source of truth" on this e.g. variances in the administrative data and survey data.		b) The IMQA team should ensure that the methodology adopted is clearly understood, meets senior management expectations and is formally signed off	b) The leadership of VI agrees with this recommendation. The plan referred to above will include a component designed to ensure that the leadership of Gavi is fully briefed on the methodology associated with doses calculations and that this engagement is timed in such a way to enable formal sign-off by the EO per appropriate project timelines. Note that the dose calculation methodology was presented (word and ppt), and signed off in 2013 by the VIMT (a GAVI implementation committee which has evolved into the current monthly meeting called the ACT). Sign off from senior management should be done before approval of renewals AR and Authorisation schedule Sept 29th, 2018 and this will be assisted with expectations being communicated in writing.	Planning and execution by leadership of IMQA with oversight by VI Director	Development of a training plan and start of training activities in Q 4 2018; major training objectives, as outlined in the plan, to be completed by beginning of 2019 dose calculation process. For approvals in 2H 2018, IMQA will organise key activities with the EO to enable timely sign-off.	

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				There is a pending approval for a change in the dose calculation, which was submitted in March & April 2018 (IMQA requested approval to use of average yearly shipments – instead of Country Admin data (for the dose calculation), and is awaiting senior management sign-off or to provide feedback on this request).			
			c) In addition, the IMQA team should consider developing a "Frequently Asked Questions" on the doses estimation process along with answers that can be included on the IMQA team intranet page.	c) The leadership of VI agrees with this recommendation and will incorporate these tactics as part of the training plan referred to above.	Planning and execution by leadership of IMQA with oversight by VI Director	Per training plan described above.	
MEDIUM	**Develop and document operating procedures and guidelines for the process of determining the vaccine dose requirements** Process documentation and standard operating procedures are key control elements in the internal control system of an organisation. The general best practice of process management requires the key processes to be supported by documented process flow maps and procedures and/or guidelines.						
2018.01.02	Through our audit procedures, we observed that the processes and procedures for determining the vaccine dose requirements are disaggregated and not consolidated in a standard	• The process of determining the vaccine dose requirements	a) Document the methodology and the process of determining the vaccine dose requirements in operating procedures and/or operational	a) The leadership of VI agrees with these recommendations and appreciates the specificity of them. The IMQA team will document processes and	Leadership of IMQA with oversight by VI Director. Engagement of internal teams	Initiate activities in Q 4 2018; major objectives as outlined in this document to be completed by	Pending verification by Internal Audit

Appendix 1: Detailed Findings and Recommendations

Issue No.	Issue Description	Risk/Implication	Recommended Actions for Management	Management Comments	Action Owner	Target Completion Date	Status
	operating procedures manual and/or operational guidelines. The processes and procedures are currently described in different documents including Microsoft PowerPoint presentations and other materials (e.g. Lessons Learnt documents and management papers). We are aware that the team is developing process flow maps with the assistance of the Knowledge Management and Technology Solutions team (KMTS) In the case of the dose calculation methodology however, in spite of the lack of documented guidelines, the risk of not applying the methodology consistently is mitigated to some extent (barring any key staff changes), due to the extensive audit trail assembled throughout the Renewals process and the design of the process itself, which requires multiple teams and stakeholders to sign off on the dose allocations through concrete outputs (CS, VI, IF&S and countries sign off on dollar	may not be applied consistently. • Increased risk of organisational knowledge loss, especially when key members of the team leave the organisation	guidelines. Some of the key topics to be addressed in these should among others include: • Background on the methodology used to determine the vaccine doses requirements and the key objectives and risks in the process; • Key teams involved in processes and their respective roles; • The relevant Gavi policies (including Alliance Partners) which relate to the process e.g. buffer, wastage rate and target change of ± 10 % over 2 years (5% p.a.); • Description of the detailed procedures undertaken when determining the doses requirements including: key reconciliations; data analysis and	procedures based on the extensive internal documentation available on this topic dating to VIMT sign-off in 2013 but also including the range of related presentations and documents from other internal sources. IMQA will work with colleagues at Gavi to establish OGs that provide the correct balance between an overview of the process and necessary technical details to ensure that operational staff can execute effectively. The leadership of VI is particularly attuned to the risk of loss of technical knowledge (through turnover in IMQA) and capacity of IMQA to execute on the recommendations in this document and the dose calculations themselves. Given the imminent departure of the Senior Technical Advisor in IMQA, the leadership of V&S has instituted a transition plan to manage knowledge transfer	(e.g. CP for OGs) as required.	beginning of 2019 dose calculation process.	

Appendix 1: Detailed Findings and Recommendations

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	amounts and dose quantities for each programme by approving the PARs, which are used to populate the CNLs and DLs shared with the countries).		comparison, e.g. against WUENIC, UNPOP data and other sources used to check reasonableness of the data provided by the countries; • The process of validating the data and any proposed changes with the relevant teams in Gavi (i.e. VPMs, SCMs, MDS-M&E) and UNICEF-SD and the Gavi supported countries; • The tentative timelines for the key activities within the process; • Reference to the process maps being developed by the KM&TS team; • Reference to other documents (e.g. PAR, Approval Request, Authorisation Schedule, Decision Letters and Country	to the new leadership of IMQA. Capacity of IMQA to execute will continually be assessed and managed. .			

Appendix 1: Detailed Findings and Recommendations

Issue No.	Issue Description	Risk/Implication	Recommended Actions for Management	Management Comments	Action Owner	Target Completion Date	Status
			Notification Letters) that are key in this process; • What key tools are used (e.g. AR extract tool, PAR tool, CTN check tool, DL mail-merge tool, VIPA tool and OneNote) and their role in the process; • Management of VI Track including: access rights; rationale behind the different status assigned to items in the tool, i.e. Active, Inactive and scenario; • The process of review and updating of the VI Track including procedures to ensure security of the system and data; • An annex of the key formulae used to calculate the estimated vaccine doses;				

Appendix 1: Detailed Findings and Recommendations

Issue No.	Issue Description	Risk/Implication	Recommended Actions for Management	Management Comments	Action Owner	Target Completion Date	Status
			• An annex with simplified key column titles of the VI Track from A1 TO DV126 (e.g. "BP68 – Stock Calculation" to "Adjusted stock") and how the columns are used in determining the estimated vaccine doses; • Description of other uses of VI Track such as generation of AR codes for other programmes such as HSS; and • Guidance on how frequently the operating procedures and/or guidelines should be reviewed and the circumstances which would necessitate a review (e.g. changes in relevant policy).				
LOW	**There is need to enhance the process of communicating with countries on the matters arising from review of countries' vaccine dose requests** The Gavi supported countries are required to confirm the estimated vaccine doses before locking in the final volumes in the VI Track. This is done through an email which is sent by the respective SCMs, summarising any issues noted during the process of determining the vaccine dose requirements and the proposed changes. The email includes a table with the following columns: Vaccine/parameter; Issue to be clarified; suggested approach; and country comments/confirmation of suggested approach.						

Appendix 1: Detailed Findings and Recommendations

Issue No.	Issue Description	Risk/Implication	Recommended Actions for Management	Management Comments	Action Owner	Target Completion Date	Status
2018.01.03	We noted that the comments from the Gavi supported countries or lack thereof were sometimes not specific or clear to enable Gavi to understand the supported country's position on the proposed approach (i.e. whether the country agrees or disagrees).	• Gavi-supported countries may not conclusively respond to all the required clarifications. • Risk of significant time being spent on back and forth communication with countries due to the vague nature of responses.	The IMQA team should enhance the structure of the template used to request for responses from the Gavi-supported countries (e.g. add a column to the table included in the email to the Gavi-supported countries with the option of "'Agree or Disagree" with comments to support this position).	The leadership of VI agrees with this recommendation, which can be implemented in the current Renewals cycle. NB: Gavi (IMQA in consultation with leadership) retains the authority to over-ride final dose allocations to countries.	IMQA	30.09.2018	Pending verification by Internal Audit

Appendix 2: Summary of Performance Ratings and Distribution

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 in relation to internal controls, governance and/or risk management that should be resolved as a priority
Medium	Address a control weakness in relation to internal controls, governance and/or risk management that should be resolved within a reasonable period of time
Low	Address a potential improvement opportunity in relation to internal controls, governance and/or risk management

Distribution

Title
Managing Director, Vaccines & Sustainability, Vaccines and Sustainability Management

For Information

Title
Chief Executive Officer
Deputy Chief Executive Officer
Managing Director, Audit & Investigations
Executive Team
Chief of Staff
Managing Director, Country Programmes
Director, Legal
Director, Vaccine Implementation
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Director, Monitoring & Evaluation
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