SUBJECT:	**GAVI'S SUPPORT FOR EMERGENCY VACCINE STOCKPILES**
Agenda item:	13
Category:	For Decision
Authored by:	Aurelia Nguyen, Wilson Mok, Melissa Ko, Patience Musanhu, Stephen Sosler

1. Executive Summary

1.1 Rationale

(a) Disease outbreaks in Gavi-supported countries are a growing concern, two recent examples being Ebola and yellow fever. Outbreaks are often symptoms of weaknesses in routine immunisation and health systems. For diseases with limited vaccine supply, maintaining stockpiles facilitates rapid and equitable access to vaccines in an outbreak situation.

(b) Gavi currently supports three emergency vaccine stockpiles: yellow fever, meningitis and cholera.[1] Each stockpile is managed by an International Coordinating Group (ICG) [2] which makes annual decisions on stockpile size and determines how doses should be allocated in response to country requests. The ICG is supported by a Secretariat at WHO. Gavi provides funding for: (1) vaccine costs; (2) operational costs; and (3) WHO staff to support the ICGs and serve as disease focal points. From 2006-2015, Gavi has disbursed approximately US$ 90 million in vaccine and operatonal cost support for the three stockpiles, making available over 70 million doses of vaccine.

(c) Emergency vaccine stockpiles have been an essential and effective mechanism to support countries in responding to outbreaks. However, Gavi's investments have been made incrementally and without a systematic approach to design, implementation and accountability. Through this review, opportunities have been identified for Gavi to enhance the impact of its stockpile investments through a more consistent approach which is aligned to broader disease control

[1] Gavi has also committed to fund a future stockpile of Ebola vaccines; this was beyond the scope of the review and the applicability of the recommendations to Ebola will be assessed at the time of future investment decision-making.

[2] The ICG is composed of a representative from four member organisations: International Federation of Red Cross and Red Crescent Societies (IFRC); Medecins Sans Frontieres (MSF); UNICEF; and WHO. For cholera, the ICG only manages the emergency component of the stockpile, while non-emergency use is coordinated through the Global Task Force on Cholera Contol (GTFCC), of which the Gavi Secretariat is a member.

strategies; better harnessing the comparative advantage of Alliance partners in implementation; and strengthening transparency and accountability.

1.2 Purpose

(d) This report seeks Board approval of a set of principles to strengthen how Gavi manages its investment in emergency vaccine stockpiles. The PPC recommended these principles to the Board at its meeting on 25-26 October 2016, emphasising that these should be seen as conditions for future Gavi support of vaccine stockpiles. The PPC also noted financial implications of US$ 86 million associated with the new approach. [3] This amount excluded incremental funding for the meningitis stockpile for 2017 as the Board had already allocated funding at its June 2016 meeting. To align our approach across all stockpiles, an additional US$ 2 million is required to align the operational costs of the meningitis stockpile in 2017 with the other programmes, which is presented to the Board for approval as part of the programme funding request (Doc 02f).

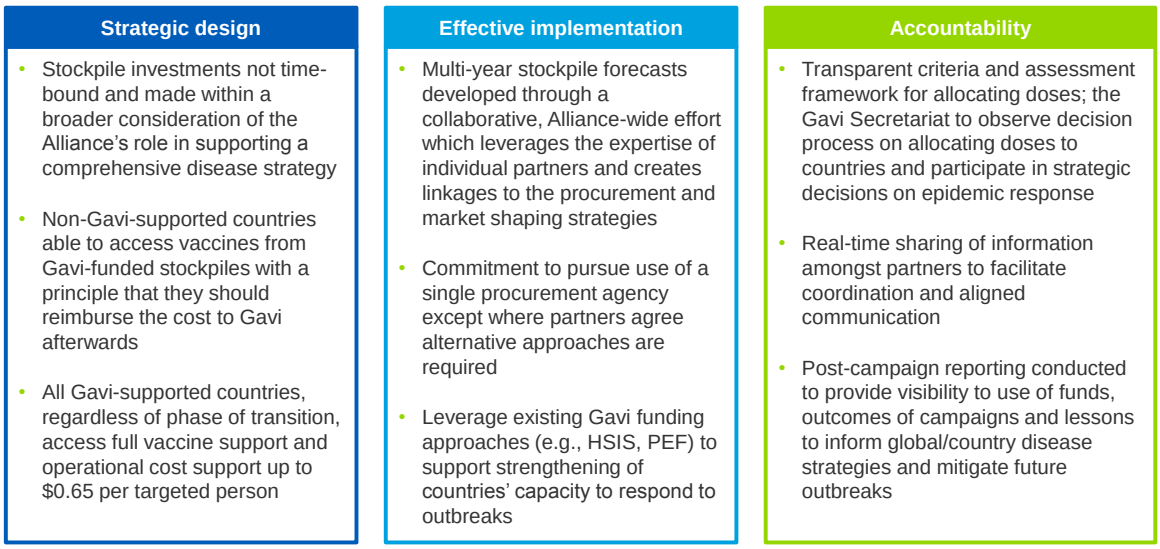
(e) The Audit and Finance Committee at its meeting on 21 October 2016 noted that it had reviewed the financial implications of these and other potential funding decisions that may be considered by the Board and concluded that these decisions could be approved by the Board in accordance with the Programme Funding Policy.

1.3 Salient features

(f) The proposed principles for Gavi's engagement in emergency vaccine stockpiles, updated to address feedback from the PPC at its October 2016 meeting, are summarised in Figure 1 and described further below.

[3] This consists of US$ 47 million for meningitis from 2018-2020 and US$ 39 million for the emergency component of the cholera stockpile for 2019-2020, inclusive of vaccine and operational costs. The projection for cholera is only for emergency use and was developed by the Gavi Secretariat while a long-term forecast agreed by Alliance partners is still under development.

Figure 1. Principles of future Gavi support for emergency vaccine stockpiles



Strategic design

(g) Gavi's emergency stockpile investments have been made incrementally over time and lack a systematic approach. They have typically been time limited and standalone, rather than integrated into a comprehensive, long-term disease control strategy (e.g., nine separate funding decisions related to the yellow fever vaccine stockpile have been taken over a 12 year period). This creates uncertainty for partners, countries and manufacturers and limits the the ability of the Alliance to make linkages across programmatic approaches as well as to pursue market shaping efforts. Moreover, key policies have been unclear or inconsistent – especially on which countries are eligible for support, the level of operational cost support and the decision-making process to approve emergency support when unforeseen needs arise. The PPC has recommended three principles for the design of Gavi's stockpile investments going forward:

(i) Emergency stockpile investments will not be time bound and will be part of a comprehensive disease control strategy, which would typically have a primary focus on strengthened routine immunisation complemented by preventative campaigns and outbreak response as required. In line with other programmes, stockpile funding will be managed within the Programme Funding Envelope, which provides a defined process for Gavi to rapidly approve funding when unforeseen needs arise.[4]

[4] Through Gavi CEO allotment of funds from the Board-approved annual funding envelope based on a technical recommendation (with subsequent reporting to the Board on the use of funds).

(ii) Non-Gavi-supported countries will have access to vaccines from Gavi-funded emergency stockpiles (through ICG-approved requests), with a principle that they are required to reimburse the cost.[5] In-country Alliance partners will engage with countries to facilitate timely reimbursement and Gavi would take on the financial risk of non-repayment.[6] The PPC recommended against automatically restricting countries' future access to the stockpile in case of a failure to reimburse.

(iii) To enable a rapid response to outbreaks and ensure that funding is not diverted from routine immunisation, all Gavi-supported countries (including those in accelerated transition) will have access to support for vaccines and operational costs without co-financing. Gavi will provide operational cost support of up to US$ 0.65 per targeted person, consistent with other Gavi support for immunisation campaigns.[7] Countries will be required to provide expenditure data as part of their post-campaign reporting.

Effective implementation

(h) The current processes to implement emergency vaccine stockpiles have not systematically harnessed the comparative advantage of all Alliance partners, or facilitated strong collaboration – especially in the areas of market shaping and country capacity building. Currently, stockpile demand forecasts are developed only for a single year, lack a structured approach with documented assumptions and do not reflect broader Alliance perspectives. In addition, multiple channels have been used to procure stockpile vaccines. This makes it challenging to have an integrated approach to demand forecasting, procurement and market shaping for a given vaccine, or clear and coherent engagement with manufacturers. In some cases, a lack of country capacity to rapidly detect and confirm cases, prepare requests or implement campaigns has also hindered the speed and effectiveness of their response (for example in 2013, the time from laboratory diagnosis of the first case of yellow fever to the initiation of immunisation with vaccine from the stockpile varied from 23 to 201 days). The PPC has recommended three principles for the implementation of Gavi's stockpile investments going forward:

(i) Stockpile demand forecasts will cover multiple years and be linked to broader Alliance demand forecasting including demand

[5] The second principle under "Strategic design" has been updated based on feedback from the PPC at the 25-26 October 2016 meeting that there may be circumstances based on public health considerations where a country in default may not be excluded from further access to the stockpiles.
[6] Since Gavi commenced funding emergency vaccine stockpiles in 2002, only three non-Gavi-supported countries have accessed Gavi-funded stockpile vaccine and all have reimbursed the cost of vaccine or replenished the stockpile.
[7] For cholera, up to US$ 0.65 per targeted person *per vaccination round* is exceptionally provided as per the June 2016 Board decision.

for routine immunisation and campaigns. UNICEF and the Secretariat will both provide input into these forecasts and will take part in the closed session of ICG annual meetings where stockpile needs are established. In determining stockpile size, forecasts will include more explicit consideration of risk (both of not having enough vaccine and of having unused vaccine) and use of trade-off analyses.[8] All of the Alliance's stockpile investments will be included in comprehensive market shaping strategies ("roadmaps") developed by the Secretariat, in line with the Supply and Procurement Strategy approved by the Board in June 2016.[9] These enhancements will facilitate a clearer perspective on when and how risk sharing in contracting should be utilised.

(ii) UNICEF will be the sole procurement agency for stockpiles unless the ICG, UNICEF and the Gavi Secretariat jointly agree that ad hoc procurement through another channel is necessary.

(iii) Gavi will encourage countries to use HSIS and PEF support to strengthen planning and implementation of emergency immunisation campaigns and to build longer-term response capacity, including surveillance and laboratory capacity.

Accountability

(i) There has been insufficient transparency on emergency stockpile-related decisions and on the use of stockpile vaccines. The ICG's approach to allocating doses in response to country requests is not clearly defined and there is limited transparency on allocation decisions. Moreover, the Alliance has not clearly defined performance indicators or reporting mechanisms for stockpile investments, country post-campaign reporting is often incomplete and there is little post-campaign evaluation. This impairs coordination and the ability of the Alliance to communicate with one voice, and limits visibility on the use and impact of Gavi support. It also hinders the Alliance's ability to learn from each outbreak to strengthen disease control interventions including strengthening of routine immunisation. The review proposes three principles to strengthen accountability of Gavi's stockpile investments going forward.

(i) The terms of reference of the ICG will be updated to include detailed and objective decision-making criteria and an associated assessment framework. The PPC further requested

[8] The forecast should include an indication of the probability of different scenarios of vaccine need and an explicit assumption on the risk appetite (e.g., stockpile estimated to cover needs in x% of scenarios).

[9] Previously, the scope of Gavi's market shaping activities implicitly excluded vaccines procured only for stockpiles such as meningitis polysaccharide vaccines. The Supply and Procurement Strategy 2016-2020 clarified that all vaccines which Gavi funds, including only for stockpiles, are in scope.

that the Gavi Secretariat be an observer to the ICG decision-making process on individual requests, which will enhance transparency and coordination. This would be a particularly important condition for continued Gavi support and the PPC agreed that clarity on whether the Gavi Secretariat could observe ICG decisions would be required for the Gavi Board before its meeting in December 2016.[10,11] In cases where decisions are more strategic and complex than just allocating doses (for example, the decisions on use of fractional dosing and pre-emptive campaigns to respond to yellow fever outbreaks taken this year), decisions will be made through cross-Alliance discussion, including the Gavi Secretariat.

(ii) WHO and UNICEF will routinely provide information to each other and the Secretariat on their stockpile activities and programmatic developments in-country, including through a real-time dashboard. They will also develop consistent communication materials to publicly explain the rationale for vaccine stockpiles, how they operate and provide up-to-date information on the response during the course of an outbreak.

(iii) Monitoring and evaluation will be strengthened through a more comprehensive set of performance metrics for partners, supported by regular performance reviews. Countries will be required to submit post-campaign reports on programmatic, technical and financial outcomes, including a plan for how to mitigate future outbreaks.

2. Recommendations

2.1 The Gavi Alliance Programme and Policy Committee recommended to the Gavi Alliance Board that it:

(a) **Approve** the principles set out in Figure 1 of Doc 13 for Gavi's support for emergency stockpiles of Gavi-supported vaccines as an integral part of integrated disease control strategies, as amended by discussions at the PPC, overriding previous Board decisions on Gavi's support for emergency stockpiles; and

[10] As of the finalisation of this paper, WHO has not confirmed the ability of the Gavi Secretariat to observe ICG decision-making and is still engaging with other ICG member organisations on this matter. An update will be provided at the Board meeting.

[11] The PPC requested the Gavi Secretariat have observer status on ICG decision-making pending finalisation of the ICG TORs. The process to update TORs would be coordinated by the ICG Secretariat and include input of all relevant stakeholders including ICG members, UNICEF and the Gavi Secretariat. The ICG has proposed an independent evaluation of the ICG mechanism to include updating the ICG TORs by the first quarter 2017. Should this timeline change, the prompt implementation of the principles from this review including the update to the ICG TORs should nevertheless proceed given continued Gavi stockpile funding would be contingent on them.

(b) **Note** that additional funding associated with the adoption of the principles for the period 2017-2020 amount to approximately US$ 86 million for meningitis and cholera.

Attachment

Appendix 1: Gavi's support for emergency vaccine stockpiles: Report to the PPC, 25-26 October 2016, Doc 08

Report to the Programme and Policy Committee
25-26 October 2016

SUBJECT:	**GAVI'S SUPPORT FOR EMERGENCY VACCINE STOCKPILES**
Agenda item:	08
Category:	For Decision
Authored by:	Aurelia Nguyen, Wilson Mok, Melissa Ko, Patience Musanhu, Stephen Sosler

Section A: Overview

1. Purpose of this report

1.1. Disease outbreaks in Gavi-supported countries are a growing concern, two recent examples being the Ebola epidemic and the yellow fever outbreaks in central Africa. Outbreaks are often symptoms of weaknesses in routine immunisation and health systems. For diseases with limited vaccine supply, emergency stockpiles facilitate rapid and equitable access of vaccines in an outbreak situation. Currently there are 3 vaccines for which Gavi-supported stockpiles are maintained: yellow fever, meningitis and cholera. Ebola would be the fourth to be stockpiled for emergency use with Gavi funding.

1.2. International Coordinating Groups (ICGs) facilitate and coordinate the use of the three existing stockpiles and serve as an independent dose allocation decision-making body. While existing stockpile mechanisms have been essential in supporting countries to respond to outbreaks, there remains ample scope for improvement. For instance, Gavi's stockpile investments have been short-term and siloed, not well aligned to other investments in routine immunisation and preventative campaigns and lacking in clarity and consistency on country eligibility to access vaccine and operational support. There is also room to better define partners' roles and responsibilities and leverage each other's comparative advantage with a view to strengthening coordination at both global and country level and ensuring accountability.

1.3. Given the above, this report seeks a PPC recommendation on a more systematic approach to Gavi's support for emergency vaccine stockpiles. This is based on three key elements:

(a) Taking a more strategic approach to stockpile investments, whereby they are integrated into a broader disease control strategy and with clearly defined eligibility policies.

(b) Strengthening implementation and cross-Alliance collaboration, particularly in the areas of long-term demand forecasting, procurement and country capacity-building.

(c) Ensuring greater transparency in decision-making and accountability for performance including evaluation of outbreak campaigns.

Section B: Content

2. Background on Gavi's investment in vaccine stockpiles

2.1. Gavi commenced funding an emergency vaccine stockpile for yellow fever in 2002, meningitis in 2009 and cholera in 2014, and in 2014 also committed to fund a future stockpile of Ebola vaccine once a vaccine is licensed, prequalified and WHO-recommended. Each of the existing stockpiles is managed by an International Coordinating Group which makes dose allocation decisions based on country requests and is supported by a Secretariat at WHO. Gavi provides funding for (1) vaccine procurement; (2) operational costs of emergency campaigns in Gavi-supported countries; and (3) funding through the Partners' Engagement Framework (PEF) for staff at WHO, to support the ICGs and serve as disease focal points.

2.2. For yellow fever and meningitis, Gavi's stockpile investment is in addition to support for routine immunisation and mass preventative campaigns[1]. For cholera, Gavi does not currently have a country support window for routine use or preventative campaigns; however, Gavi has provided support to strengthen the evidence base for the use of planned, preventative cholera vaccination in endemic settings to facilitate reconsideration of this strategy in the next Vaccine Investment Strategy (VIS) process planned for 2018. Table 1 summarises Gavi's disbursements in these three diseases[2].

Table 1. Gavi disbursements 2006-2015: yellow fever, meningitis, cholera

	Stockpile disburse-ments: vaccines (US$ M)	Stockpile disburse-ments: operational costs (US$ M)	Total stockpile disburse-ments (US$ M)	Total disease disburse-ments* (US$ M)	Stockpile disburse-ments as % of disease disburse-ments	Disease disburse-ments as % of total Gavi disburse-ments
Yellow Fever	$30	$7	$37	$278	10%	3%
Meningitis	$39	$5	$44	$375	16%	4%
Cholera	$8	-	$8	$8	100%	<1%
Total – 3 diseases	**$77**	**$12**	**$89**	**$661**	**13%**	**8%**

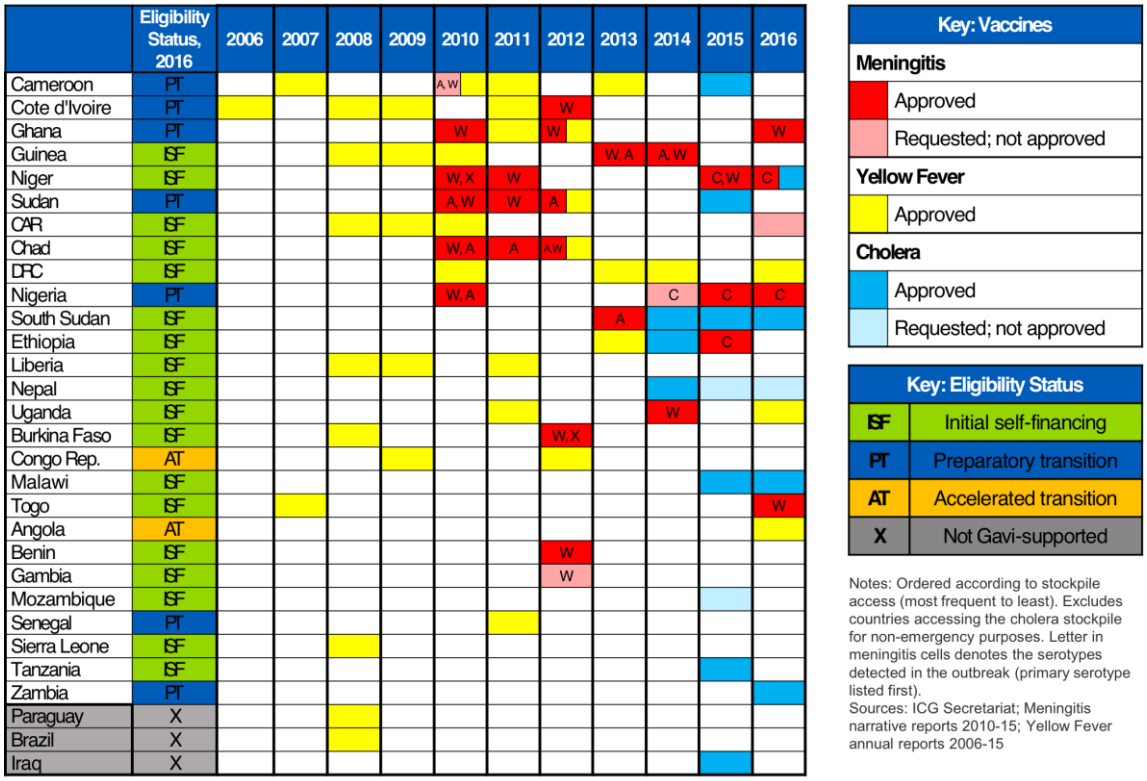
* Includes routine immunisation, mass preventative campaigns and stockpile

[1] For meningitis, routine immunisation and mass preventative campaign support is only for Meningococcal serotype A.

[2] Given the integration of mass preventative campaign and emergency campaign funding within the investment cases, operational cost disbursements are not reported in a disaggregated manner. Estimates are based on partner reporting of annual approved stockpile doses and may underestimate total Gavi disbursements made to partners.

2.3. Since 2006, 72 million doses from these three stockpiles have been made available to 30 countries through 113 approved requests for emergency response (Fig. 1). 90% of these countries have been Gavi-supported[3], with two-thirds of these still in the initial self-financing phase of transition. Some of these countries have made frequent applications for stockpile vaccines with 6 countries having accessed the stockpiles 5 times[4].

Figure 1. Country vaccine requests for the yellow fever, meningitis and cholera stockpiles from 2006 through July 2016



3. Overview of stakeholder perspectives and recommendations

3.1. The Gavi Secretariat held consultations with implementing partners, industry, implementing countries and other relevant stakeholders regarding *whether* and *how* the Alliance should be engaged in the stockpiles (Annex A). Key perspectives from these discussions include:

(a) The Alliance should continue to support emergency vaccine stockpiles as it is now the primary source of donor funding for immunisation and stockpiles play an essential role in addressing disease outbreaks.

(b) The Alliance's engagement in stockpiles should be part of a broader disease control strategy that focuses on routine immunisation, supported as needed by preventative and reactive campaigns. Beyond

[3] The remaining was funded either by separate donors (specifically for cholera) or through the ICG Revolving Fund (whose funding is primarily from past reimbursement by Gavi-supported countries).
[4] In some instances multiple stockpile requests have been necessary to manage supply through sequenced vaccination of different target populations, particularly for cholera.

providing funding and supporting market shaping, a key role for the Alliance is to bring a comprehensive immunisation lens including a focus on routine immunisation and coverage and equity. These efforts should be coordinated with other components of disease control outside the Alliance's core mandate (e.g. International Health Regulations).

(c) Flexibility and rapid decision-making are required to respond to outbreaks, and it is important to ensure the Alliance's policies and procedures enable an equitable and swift response.

(d) Accountability and transparency of stockpile processes is critical and should be enhanced, particularly in the context of increasing scrutiny on the effectiveness of the global community's response to outbreaks.

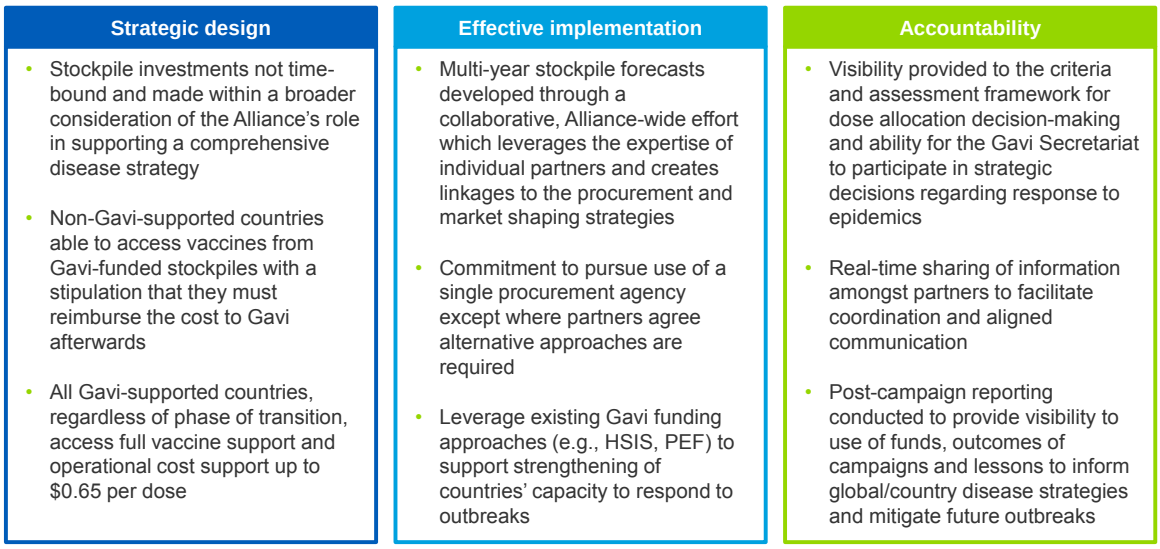
(e) Given the unpredictability of outbreaks and fast-moving dynamics, the Alliance must be comfortable with a higher degree of both financial and operational risk compared to that of routine immunisation.

3.2. Additional lessons learned were drawn from recent reviews including a 2014 analysis of the yellow fever and meningitis stockpiles (Annex B); a 2016 assessment of meningitis outbreak response (Annex C); Gavi Secretariat analyses and stakeholder discussions across all three stockpiles (Annex D); and the review of Gavi's investments in yellow fever (Doc 09).

3.3. Overall reviews and consultations have highlighted that the ICG plays an essential role as an independent and rapid decision-making body and the stockpiles have been critical in supporting countries in their response to outbreaks. However, the outbreak response landscape has evolved with more stakeholders engaged, increasing focus on linkage with broader disease strategies and enhanced requirements for scrutiny and risk assurance of donor-funded programmes. In this context, the level of coordination and communication between the ICG and other partners, as well as visibility and accountability of decision-making have not evolved sufficiently, contributing to challenges in implementation. Enhanced engagement by the Gavi Secretariat in the ICG mechanism and strategic decision-making was identified as important to address these challenges, including participating in the closed session of the annual ICG meetings. It should be noted that an independent evaluation of the ICG mechanism by WHO is still planned. While this evaluation may identify additional challenges and opportunities for enhancement, the recommendation from this review is to move forward promptly with implementation of the principles outlined in the following section.

4. Proposed Principles for Gavi's support for emergency stockpiles of Gavi-supported vaccines

Figure 2. Principles for Gavi's support for emergency stockpiles of Gavi-supported vaccines



4.1. Based on the above reviews and stakeholder consultations, the Secretariat is proposing a more systematic approach to its stockpile investments, grounded in a set of principles (Figure 2). While Gavi recognises the unique characteristics of each individual disease/stockpile, all future Gavi support for stockpiles will be contingent on these high-level principles.

4.2. The following sections describes the rationale for and detail of each of these principles.

5. Strategic design

5.1. *Stockpile investments*

5.2. Gavi stockpile investments have often been short-term and piecemeal. For yellow fever, nine separate funding decisions related to the stockpile have been taken over a 12 year period. This has not provided clarity on Gavi's long-term engagement, reducing incentives for manufacturers to make long-term investments in vaccine supply and creating uncertainty with partners and countries. In addition, these investments have rarely been integrated within a comprehensive disease strategy, undermining the ability to make linkages across interventions. For example, there has been limited analysis of the causes of outbreaks for which stockpiled vaccines were needed, which could help direct future investments to prevent their recurrence, such as through routine immunisation strengthening. Finally, there is no pre-defined process for Gavi to rapidly approve additional funding when unforeseen needs arise, which has necessitated *ad hoc* approaches, as with the response to yellow fever outbreaks this year. If unaddressed, in the future this could potentially delay the response to an outbreak.

5.3. Going forward, Gavi will make future stockpile investment decisions in the context of a comprehensive disease control strategy rather than as standalone investments. Such investments will no longer be time-bound but managed within the Programme Funding Envelope and reported to the Board through regular reporting mechanisms in line with other Gavi programmes[5]. This principle will be systematically applied to Gavi's existing stockpiles as follows:

(a) Yellow fever: The revised approach to Alliance investment in yellow fever, being reviewed by the PPC at this meeting (Doc 09), presents a comprehensive approach to disease control including investments in routine immunisation, mass preventive campaigns and the emergency stockpile.

(b) Cholera: the original stockpile investment decision was made in the context of the broader disease strategy. The emergency stockpile will be extended so that it is no longer time-limited through 2018. As planned, the next VIS will consider the need to expand Gavi's investment in a comprehensive disease control strategy, for example with preventative campaigns or vaccination in endemic settings.

(c) Meningitis: Gavi stockpile funding will be extended beyond 2017, as currently approved (Annex E). A full review of Gavi's investments in meningitis will be conducted as part of the next VIS, including reviewing changes in epidemiology and potential support for multivalent conjugate vaccines in routine immunisation or mass preventative campaigns.

5.4. *Non-Gavi supported countries' access to vaccine stockpiles*

5.5. There is no consistent policy on non-Gavi-supported countries' access to Gavi-funded stockpiles. Consultations indicated that restricting access to only countries that are supported by Gavi is inefficient.

5.6. Therefore, in future non-Gavi-supported countries will have access to vaccines from Gavi-funded stockpiles (through ICG-approved requests) if they commit to reimburse the cost of vaccines to Gavi (either from their own budgets or non-Gavi donor funding). To mitigate financial risk and set appropriate expectations, those countries in default on their reimbursement would not be able to further access the stockpile until arrears are paid or they provide upfront funding for that vaccine request. In-country Alliance partners will engage with countries on a sustained basis to facilitate timely reimbursement and obviate the need to invoke penal provisions.

5.7. *Gavi support to eligible countries*

5.8. Current policies defining countries' level of, and eligibility for, Gavi stockpile support are not clearly defined nor always consistent. In particular:

[5] Through Gavi CEO allotment of funds from the Gavi Board approved annual funding envelope based on a technical recommendation.

(a) The level of operational cost support for yellow fever and meningitis emergency campaigns (i.e. US$ 0.25 per dose) differs from what is provided for non-emergency campaigns for these two diseases as well as what is provided for cholera (i.e., up to US$ 0.65 per dose). Limited expenditure data from meningitis and cholera emergency campaigns shows that total costs can be US$ 1.00 or higher per dose[6]. And country feedback indicates that for yellow fever and meningitis, limited operational cost support has been a barrier to conducting timely and high-quality campaigns.

(b) There is no formalised approach to the level of Gavi support available to countries in accelerated transition.

5.9. Going forward, operational cost support for yellow fever and meningitis emergency campaigns will be set at up to US$ 0.65 per dose, consistent with other Gavi campaign support. Based on a review of a country's budget, the approved level of operational support could be less than US$ 0.65 per dose. To address the lack of robust data on operational costs, countries will be required to provide post-campaign reporting including on expenditure. Additional data could provide the basis for future adjustments to the policy[7]. Under exceptional circumstances there may be a need for flexibility to provide additional operational cost support[8]. The Gavi CEO would have authority to approve additional support based on a recommendation from technical partners, with a timely report back to the Board.

5.10. All Gavi-supported countries, including those in accelerated transition, will have access to support for vaccines and operational costs. No co-financing or reimbursement will be required and the level of support will be the same for all Gavi-supported countries including those in accelerated transition. This approach has the benefit of (1) simplicity and consistency with Gavi's support for preventative campaigns, where no co-financing is required; (2) facilitating timely implementation of campaigns and rapid interruption of transmission; and (3) focusing country efforts on conducting high-quality campaigns as opposed to mobilising resources during an emergency. Requiring country co-financing may carry the risk of countries diverting funding from routine immunisation.

6. Effective implementation

6.1. *Forecasting, procurement and market shaping*

6.2. Assessment of past experiences highlighted opportunities to enhance coordination, clarify roles and responsibilities and take a longer-term, more strategic approach:

[6] Based on analysis of two cholera emergency campaigns in Guinea and evaluation of meningitis emergency campaigns in Niger and Nigeria.
[7] This would be integrated within future reviews of Gavi's Health Systems and Immunisation Strengthening (HSIS) support to bring a holistic view to operational cost support.
[8] For example, to address additional cold chain requirements as with Ebola vaccines that must be stored at -70C. This may be provided in an emergency situation as per the Fragility and Emergencies Policy (see Doc 07).

(a) The ICG demand forecast is short-term (only annual), limiting the ability to signal long-term needs to manufacturers and effectively shape markets. In addition, stakeholders using the forecast, including the procurement agency, have insufficient visibility on the underlying assumptions, which results in less informed and effective procurement.

(b) Establishment of stockpile size and composition lacks a structured approach to weigh trade-offs and risks and does not currently reflect broader Alliance perspectives.

6.3. In future, multi-year stockpile demand forecasts will be developed, linked to broader Alliance demand forecasting and market shaping efforts. This will facilitate more effective engagement with manufacturers and enable potential multi-year procurement to improve affordability and supply security. The forecasting process will include more explicit consideration of risk (both of not having enough vaccine and of having unused vaccine) and use of trade-off analyses to determine the stockpile size and vaccine composition[9]. While the ICG will continue to lead development of the recommendation, it will reflect Alliance-wide input including from UNICEF Supply Division (SD) on manufacturer offers and contracting modalities and the Gavi Secretariat on market shaping strategy and financial implications[10]. The Gavi Secretariat will lead on broader demand forecasting and market shaping efforts (including for routine immunisation and mass preventative campaigns) in coordination with other stakeholders, in particular the ICG (assessment of epidemiological need); UNICEF SD (linkage to the procurement strategy); and other experts (contributing understanding of disease epidemiology, including through modelling).

6.4. *Procurement agency*

6.5. For meningitis specifically, the existence of an ICG revolving fund[11] and lack of alignment across stakeholders has resulted in multiple procurement channels, creating confusion with manufacturers and inefficiency. Moreover, the approach to market shaping has not been coordinated. The

[9] This is particularly important for meningitis, where there are both conjugate and polysaccharide vaccines covering different serotypes. The epidemiological forecast should give an indication of the likelihood/probability of different scenarios of vaccine need and an explicit assumption should be made regarding the risk appetite (e.g., stockpile level estimated to cover needs in x% of scenarios).
[10] As part of facilitating this coordinated decision-making, both UNICEF SD and the Gavi Secretariat will participate in the closed session of the annual ICG meetings where forecasting is discussed. Should procurement not fully meet the ICG's recommendation, UNICEF SD, the Gavi Secretariat and the ICG would jointly consider implications and mitigation approaches.
[11] The ICG revolving fund provides a separate source of funding which the ICG has utilised to procure vaccine on behalf of Gavi-supported countries via WHO procurement. The objectives of the ICG revolving fund are to (1) provide longer-term financing for the vaccine stockpile should Gavi not extend its time-limited investment, and (2) provide a source of financing for non-Gavi supported countries. There has not been clarity historically on which countries need to reimburse stockpile funding. In the past, Gavi-supported countries (or donors on their behalf) had reimbursed the cost of vaccines to the ICG revolving fund, but since 2015 it has been clarified that they need not reimburse.

Alliance Supply and Procurement Strategy ("roadmap") for meningitis includes only meningococcal A conjugate vaccine and not other meningococcal vaccines procured for the stockpile.

6.6. Going forward, the Alliance will also ensure that all its stockpile investments are included in comprehensive market shaping strategies ("roadmaps") in line with the updated Gavi Supply and Procurement Strategy approved by the Board in June 2016[12].

6.7. To enhance procurement efficiency and align engagement with manufacturers, in future UNICEF SD will be the sole procurement agency for stockpiles. If *ad hoc* procurement through another channel becomes necessary, this would be agreed by the ICG, UNICEF SD and the Gavi Secretariat. With this approach and Gavi's commitment to long-term stockpile investments, there appears less need for an ICG revolving fund, but it may still be useful as a contingency mechanism particularly as Gavi's new approach is implemented. Partners will jointly define the criteria, timeframe and process to reduce the scope or redefine the revolving fund.

6.8. *Country capacity to respond to outbreaks*

6.9. Capacity constraints can impact the speed and effectiveness of countries' response to outbreaks. Countries may not have the ability or resources to rapidly detect and confirm cases; prepare requests; prepare their response; or implement campaigns. This can be exacerbated by a lack of operational funding and in some cases delays in receiving funds. These challenges can all contribute to slow response times. For yellow fever, the time from laboratory diagnosis of the first case to the initiation of vaccination can vary widely and be significant (e.g., 23 to 201 days in 2013)[13].

6.10. The Alliance will intensify support for countries to plan and implement campaigns and build longer term response capacity, including surveillance and laboratory capacity. This could include supporting countries more systematically to harness HSIS grants, operational cost support and technical support through PEF to address capacity gaps. One potential model for such support is the Global Task Force for Cholera Control (GTFCC), of which Gavi is a member. The GTFCC provides a forum for technical exchange, awareness building and coordination, and facilitates the strengthening of countries' capacity through dissemination of guidance and technical assistance[14].

[12] Previously, the scope of Gavi's market shaping activities had been unclear. The Gavi Supply and Procurement Strategy 2016-2020, approved by the Gavi Board in June 2016, clarified that all vaccines for which Gavi funds procurement, including only for emergency stockpiles, are in scope.
[13] "Yellow Fever Control: Gavi's Investment and its Impact", July 2015, KL Cairns
[14] The applicability of such a model and use of existing platforms to be leveraged would need to be further explored by partners.

7. Accountability

7.1. *Dose allocation*

7.2. Currently, the criteria and approach to ICG dose allocation decisions on individual country requests are not clearly defined and communicated, which can create confusion. Furthermore, experiences this year have highlighted that in some cases, broader strategic decision-making is needed to determine how best to address epidemics that span multiple countries and formalised, coordinated approaches are lacking. Specifically, in addressing the yellow fever outbreaks in central Africa, there has been a lack of clarity and alignment on the definition of a "pre-emptive" campaign (which can target areas where there are no confirmed cases, but high risk) and whether they qualify as emergency campaigns (ICG decision pathway) or non-emergency campaigns (Independent Review Committee decision pathway). This has necessitated *ad hoc* discussions and decision-making amongst partners.

7.3. To address these challenges, terms of reference (TORs) will be developed/updated for each stockpile specifying the profile of ICG representatives, the criteria by which country requests are reviewed and the assessment framework applied[15]. This includes clarifying the criteria for emergency use of each stockpile. To ensure alignment, these TORs will be reviewed and agreed upon by all stakeholders[16]. The dose allocation decisions should remain with the ICG, given the importance of independence and neutrality in decision-making. In cases where broader strategies are required, such as when severe outbreaks put at risk multiple countries or regions and exceptional approaches must be considered (e.g., fractional dosing), all partners including the Gavi Secretariat will be engaged in decision-making.

7.4. *Information sharing and coordination*

7.5. Existing mechanisms are inadequate to provide stakeholders with a common fact base on stockpile allocation and countries' outbreak response activities, impairing coordination and the ability to communicate with one voice. For example, countries often reach out to the Gavi Secretariat when their requests have not been approved, but the Secretariat lacks information regarding the decision and thus cannot support countries in addressing issues in their request.

7.6. In future, the ICG Secretariat and UNICEF SD will maintain a "dashboard" of up to date information on their respective activities and programmatic information from countries. This will be shared with all partners to provide a single source of information for aligned communication and coordination (for example to give Secretariat Senior Country Managers the information

[15] The criteria and assessment framework encompass establishing epidemic thresholds and defining differences between what qualifies as an emergency vs. non-emergency campaign.
[16] Including ICG members, WHO, UNICEF SD and the Gavi Secretariat. The process to update TORs would be coordinated by the ICG Secretariat and completed by the end of the first quarter of 2017.

needed to follow-up with countries on their requests or post-campaign reports). Country requests and summaries of ICG decisions including the rationale will also be shared with the Secretariat in real-time.

7.7. *Annual and post-campaign reporting*

7.8. The Alliance has not clearly defined performance indicators or reporting mechanisms for stockpile investments. Moreover, country post-campaign reporting is often incomplete and there is little post-campaign evaluation. This limits the Alliance's transparency on impact and its ability to learn from experiences and adapt long-term approaches.

7.9. Monitoring and evaluation of stockpile investments will be strengthened through a more comprehensive set of performance metrics and application of a more systematic and consistent reporting template for partners to report annually. Countries will also be required to submit post-campaign reports on programmatic, technical and financial outcomes, including a plan for how the country could mitigate future outbreaks[17]. This will be the basis for discussion with the Secretariat and Alliance partners on how to leverage other types of support, such as HSIS grants or technical support under PEF, to strengthen outbreak prevention and response efforts. In addition, there will be a greater focus on synthesising learnings from outbreaks and making linkages with other programmes (e.g., adapting disease control strategies).

Section C: Recommendations

8. The Gavi Alliance Programme and Policy Committee is requested to recommend to the Gavi Alliance Board that it:

(a) **Approve**, subject to confirmation by the Audit and Finance Committee that sufficient funding is available, the principles set out in Figure 2 of Doc 08 for Gavi's support for emergency stockpiles of Gavi-supported vaccines as an integral part of integrated disease control strategies, overriding previous Board decisions on Gavi's support for emergency stockpiles; and

(b) **Note** that additional funding associated with the adoption of the principles for the period 2017-2020 amount to approximately US$ 86 million for meningitis and cholera (the financial implications for yellow fever are addressed in the yellow fever strategy paper (Doc 09)).

Section D: Risk implication and mitigation and Financial implications

9. Risks and mitigation

9.1. There is a risk that in implementation of the principles there is *insufficient movement from the status quo and challenges with accountability,*

[17] Specific country reporting requirements would be developed by technical partners in consultation with the Gavi Secretariat.

coordination and information sharing persist. The Gavi Secretariat, together with implementing partners, will define performance indicators which would be the basis of ongoing review of the implementation of the principles and inform continued programmatic and PEF funding.

9.2. By moving away from capped, time-bound investments, there is a risk of *Gavi's investment in stockpile funding increasing from historical levels*. By bringing stockpile funding within the overall disease envelope and enhancing the integration with the overall immunisation strategy, there will be greater focus on reducing the risk of outbreaks through strengthening of routine immunisation and mass preventative campaigns, and thereby reducing the long-term need for stockpiles.

9.3. There is a risk that not requiring co-financing or reimbursement will *undermine the ownership and commitment of Gavi-supported countries to reduce the likelihood of outbreaks*. Given the potential public health and economic impact of outbreaks, including to other countries, countries should be motivated to take steps to minimise the occurrence of outbreaks. Within the requirement for post-campaign reports, countries must develop plans to mitigate the risk of future outbreaks.

9.4. There is risk that *non-Gavi supported countries fail to reimburse the cost of stockpile vaccine, for which Gavi holds financial liability*. In the medium-term, the overall magnitude of this risk is relatively limited[18]. To mitigate this risk, future access to the stockpile will be restricted until reimbursement is made or upfront funding is provided. The Gavi Secretariat will work with partners to identify additional risk mitigation approaches during implementation of this policy[19].

9.5. Implementing the policy of restricting future access to the stockpile for defaulting countries creates *a public health risk should access to vaccine to address an outbreak be delayed*. If faced with such a situation, all partners including the Gavi Secretariat and ICG would engage to consider contingency mechanisms or an exceptional decision.

9.6. There is a risk of *misuse of operational cost support*, exacerbated by the increase in funding level. This will be mitigated through reviews of country budgets in advance of approval of support and requirements for countries to report on their use of funds following the emergency campaign.

9.7. There is a risk that *increased requirements regarding transparency and information sharing hamper the ability to respond rapidly*. To mitigate this risk, an emphasis will be placed on prioritising only the most critical information and having tools in place to streamline the reporting process.

[18] Only three non-Gavi supported countries have accessed the stockpiles since 2006, with no instances of default, and over that period only two of the Gavi-supported countries that have accessed the stockpile are projected to fully transition out of Gavi support within the next five years.
[19] Two concepts proposed are (1) to require non-Gavi supported countries to establish an emergencies budget line before being able to access the stockpile and (2) proactively identifying other sources of donor funding to help non-Gavi-supported countries with reimbursement.

For countries, the requirements are isolated to post-campaign reports, which would not impact the immediate response.

9.8. There is a risk that *countries do not meet expectations on post-campaign reporting*, given past experience with such reporting not being prioritised and the limited leverage partners have to enforce it. Other stakeholders, including the Gavi Secretariat, will also engage with countries to support post-campaign reporting and reporting will be integrated within broader evaluation mechanisms (e.g., joint appraisals) to reinforce country accountability. Across programmes, there is ongoing work within the Gavi Secretariat to define potential consequences for countries not providing programmatic and financial reporting, which when defined could be applied to post-campaign reporting.

9.9. There is a risk that *Gavi-funded stockpile vaccine goes unused*. For those vaccines which have other uses, this risk is mitigated by taking an integrated immunisation approach whereby overall vaccine supply is managed across different purposes. For example, manufacturers can rotate vaccines through the stockpile for use in routine immunisation to avoid expiry of stocks. For vaccines limited to emergency use, the structured approach to setting the stockpile size and composition which is recommended will better take into account the risk of unused vaccine. For such vaccines, it should be noted that the risk of unused vaccine is inherent and needs to be accepted given the uncertainty regarding when outbreaks will occur, and that the supply constrained markets necessitate Gavi sharing some of the risk with manufacturers.

10. Financial implications

10.1. The proposed principles would add approximately US$ 86 million to the forecasted expenditure presented to the December 2015 Board for 2016-2020. This consists of US$ 47 million for meningitis and US$ 39 million for cholera, inclusive of vaccine and operational costs[20].

10.2. Yellow fever funding for the period 2017-2020, inclusive of the stockpile, is described in the yellow fever strategy paper (Doc 09).

[20] The projection for cholera is only for emergency use for the stockpile and was developed by the Gavi Secretariat while a long-term forecast agreed by Alliance partners is still under development. Future investment decisions on the disease control strategy for cholera taken as part of the VIS in 2018 would supersede this projection.

Appendix: Implications

11. Impact on countries

11.1. Countries should benefit from improved visibility of stockpile decision-making, increased operational cost support for yellow fever and meningitis campaigns and potentially additional support for capacity building. However, there will be increased requirements to report on the use of vaccine and operational funding and increased expectations on commitment to mitigate the risk of outbreaks and improve systems to better respond. The importance of this commitment was strongly highlighted by the Board at its 2016 retreat.

12. Impact on implementing partners

12.1. Implementing partners have increased accountability regarding management of the stockpile and Gavi funds, including responsibility for providing greater visibility into decision-making and outcomes and more extensive and frequent sharing of information.

13. Impact on Secretariat

13.1. With the new principles, there is a greater emphasis on the Gavi Secretariat facilitating linkages between the stockpile and other programmes such as enhancing coverage and equity in routine immunisation and supporting systems strengthening. The expectations for programme monitoring and management are increased and greater engagement on stockpile forecasting, procurement and market shaping is required.

14. Legal and governance implications

14.1. Subject to the PPC recommending to the Board the approval of the new principles, appropriate legal arrangements will be made with relevant partner organisations to implement them.

15. Consultation

15.1. The Gavi Secretariat consulted with over 35 individuals – including partners, industry and country representatives – through individual and small group discussions to understand how Gavi should engage going forward and areas for improvement (Annex A). Separately, a stakeholder consultation meeting was held on 31 August 2016 with expert representatives from relevant partner organisations and constituencies to discuss emerging findings from the review and initial proposals (Annex F).

16. Gender implications

16.1. Strengthening the emergency vaccine stockpiles will help to limit the spread of infectious disease outbreaks, which often disproportionately affect women. Women and girls are more likely than men to be caregivers for the sick, both in health-care settings and at home, and thus are more exposed

to infectious agents. Emergency vaccination to help stop the spread of outbreaks also reduces the risk of major disruption to livelihoods. Studies have reported that the disruption caused by epidemics increases incidence of gender-based violence and teenage pregnancy[21].

Annexes (*available on myGavi*)

Annex A: Summary of stakeholder interviews

Annex B: Lessons learned from the global yellow fever and meningitis vaccine stockpiles and implications for the GAVI-supported oral cholera vaccine stockpile (2014 report)

Annex C: Dalberg meningitis outbreak response situation analysis and strategy summaries

Annex D: Overview of Gavi's engagement in stockpiles and lessons learned

Annex E: WHO/UNICEF Programme Division meningitis outbreak response report

Annex F: Stakeholder consultation meeting background document and meeting report

[21] "Unseen, unheard: Gender-based violence in disasters", International Federation of Red Cross and Red Crescent Societies, Geneva, 2015.