General Guidelines for country applications in 2017 for the following types of Gavi support only:

New and underused Vaccines Support (NVS)
Cold Chain Equipment (CCE) Optimisation Platform

Document dated: March 2017
(This document replaces all previous versions)

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Purpose of this document:

This document provides general guidelines for countries applying for all vaccines under Gavi's New and underused Vaccine Support (NVS) and Cold Chain Equipment (CCE) Optimisation Platform support **only**. It provides information on the types of support provided, country eligibility, the application process and grant cycle, as well as Gavi's overarching approach/ requirements for country support.

The complete guidance for countries applying for **Japanese Encephalitis (routine/campaign), Meningococcal Conjugate A (routine/campaign), Pneumococcal Conjugate Vaccine (routine), Rotavirus (routine), and Yellow Fever (routine/campaign) vaccine support** is available in this document. There are additional guidelines for applications for **CCE Optimisation Platform, Human papilloma virus (HPV) and Measles and Rubella support**, however countries should first read these general guidelines.

Countries requesting new Health System Strengthening (HSS) support in 2017 **should not** refer to these guidelines and should contact their Gavi Senior Country Manager (SCM) for further information. These countries will follow a new process that will combine applications for HSS, NVS and CCE Optimisation Platform.

Weblinks and contact information:

All application documents are available on the Gavi Apply for Support webpage: www.gavi.org/support/apply. For any questions regarding the application guidelines please contact countryportal@gavi.org or your Gavi SCM.

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Key to symbols used in the document	
	Priority information relating to Gavi's application process and requirements for countries in 2017
	New/ changed information relating to Gavi's application process and requirements for countries in 2017
	Additional/ detailed references (weblinks)
	Link to detailed information available in another document forming part of the set of application guidelines for 2017

WHAT'S NEW AND WHAT'S CHANGING

New or updated information relevant for country applications is summarised below with references to detailed information in specific sections in this document and other web links. Some information is evolving and countries are advised to refer to the web links provided for the most up to date information.

Area	Description	Reference
Gavi's new focus on coverage, equity and sustainability	Recognising that one in five children still miss out on their basic vaccinations, Gavi is prioritising approaches aimed at sustainably enhancing immunisation coverage in order to reduce inequities in countries. Focus on equity must receive due attention during the development of any request for support.	Section 1 and Annex 2
Cold Chain Equipment (CCE) Optimisation Platform	Gavi has further developed its approach to the CCE Optimisation Platform to support countries improve their cold chains, complement efforts to strengthen other supply chain strategy "fundamentals" and contribute to efforts to sustainably enhance immunisation coverage with a view to addressing inequities.	Section 4.2 and additional guidelines for CCE Optimisation Platform available at www.gavi.org/support/apply/
Gavi support for HPV vaccines	Gavi's new strategy for HPV no longer requires a country to first introduce HPV vaccines through a demonstration programme. As such, countries can now apply directly for national introduction of the HPV vaccine, with an option for a phased introduction. In line with SAGE's recommendation, Gavi also supports HPV multi-age cohort vaccination for girls aged 9-14 years, in the first year of introduction.	Additional guidelines for HPV available at: www.gavi.org/support/apply/
Gavi support for Japanese Encephalitis (JE) routine immunisation	Gavi is now supporting JE routine vaccination in eligible countries.	Sections 4.1.3 and 5.3.2
Gavi support for measles	Countries are now required to fully self-finance the first dose of measles vaccine in their national immunisation programme and have a long term budgeted plan for measles and rubella activities, to ensure financial and programmatic sustainability. As such, routine immunisation will be complemented, as needed, by higher-quality, better-planned, more targeted and independently monitored campaigns.	Additional measles-specific vaccine guidelines available at www.gavi.org/support/apply/
Gavi support for Yellow Fever	The Gavi Board approved an update to the Yellow Fever Strategy to intensify Gavi's engagement, in line with WHO's revised Global Strategy to Eliminate Yellow fever Epidemics (EYE). Gavi now requires that countries requesting support for preventative mass campaigns, that have not yet introduced Yellow fever vaccines into the routine EPI, commit to introducing routine immunisation within 6 to 12 months after conducting the campaigns. For Africa, the EYE strategy has reclassified countries and proposes preventive strategies accordingly.	Sections 4.1.3 and 5.3.2 and Annex 10

Area	Description	Reference
Vaccine Introduction Grants (VIGs)	Gavi has revised the method for calculating VIGs, to progressively reduce the funding levels as countries approach transition. VIGs are not intended for recurrent delivery costs. However, unused funds from VIGs can be rolled into a country's Health Systems Strengthening (HSS) grant to contribute towards longer term systems investments such as cold chain expansion.	Section 4.1.2
Operational support for campaigns (Ops)	Gavi has revised the Operational support for campaigns calculations, to progressively reduce the funding levels as countries approach transition. These grants are not intended for recurrent delivery costs (such as investments in human resources), however unused funds from the Ops can be rolled into a country's Health Systems Strengthening (HSS) grant for longer term systems investments.	Section 4.1.2
Product and Presentation Switch Grants	Gavi has revised the eligibility criteria and calculations for product and presentation switch grants.	Guidelines on Reporting and Renewals
Guidance on country Coordination Forums (ICC/HSCC)	Gavi now provides guidance on requirements and recommendations on the membership, mandate and governance of country Coordination Forums (ICC/HSCC or equivalent).	Section 5.2 and Annex 6, with further information at: www.gavi.org/support/coordination/
Financial reporting	Gavi has updated guidance on financial management and reporting requirements.	Annex 5 provides information on the current approach and further information is available at: www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/guidance-on-financial-reporting/
Risk management and fiduciary oversight	Gavi no longer conducts a Financial Management Assessment, instead a more comprehensive Programme Capacity Assessment (PCA) is conducted to ensure that the country's programme management, financial management and vaccine and cold chain management are robust and transparent	Section 7.1.1 and Annex 5

1. INTRODUCTION

1.1. General principles for Gavi support

Gavi's mission is to "**save children's lives and protect people's health by increasing equitable use of vaccines in lower income countries**". Despite tremendous progress in a number of Gavi-eligible countries, one in five children still miss out on their basic Expanded Programme on Immunisation (EPI) vaccinations. **Gavi's strategy for the 2016-20 period therefore focuses on sustainably enhancing immunisation coverage with a focus on reducing inequities in countries.**[1]

Gavi support should target countries' needs in a holistic manner. Applications to Gavi should build on national strategies and aim to address specific areas identified through a gap analysis and public health needs assessment.

Gavi's model for support to countries is built on the principle of country ownership. Applications should highlight the plans of the country in addressing bottlenecks to coverage, in particular barriers to reaching low coverage geographies and marginalised populations. It is equally important for the countries to build sustainability components into the application, including considerations on financial and programmatic continuity of immunisation programmes. Gavi support is intended to be catalytic and countries are encouraged to complement support by investing in their immunisation programmes to ensure long-term sustainability.

To assist countries in achieving this objective, Gavi is emphasising the following aspects in its grant-making mechanisms:

- Alignment of immunisation programmes with national health plans and systems.
- Strong emphasis on reaching the unreached "fifth child" and leaving no child behind.
- Evidence-based proposals reflecting lessons learned.
- Prioritised approaches and strategies with the highest potential for impact.
- Special attention to strategic areas that are common bottlenecks to achieving improvements in equitable immunisation coverage:
    - Leadership, management and coordination
    - Supply chain and vaccine management systems
    - Information systems and data quality
    - Demand generation for immunisation services
- Investments that support long term programmatic and financial sustainability of the country's immunisation programme.

[1] Key equity dimensions include gender, geography, and wealth, amongst others.

1.2. Specific information for countries applying for HSS support in 2017

Countries requesting new Health System Strengthening (HSS) support in 2017 will follow a new application process that integrates all Gavi support to the country. The key features of this new approach include:

- Bringing together all types of vaccine and financial support (i.e. HSS, complementary allocations[2], New and underused Vaccine Support (NVS) and Cold Chain Equipment (CCE) Optimisation Platform) into a single portfolio view to facilitate longer-term predictability, visibility on complementarities, and more effective grant planning and budgeting. **Note that countries requesting new HSS support in 2017 will include requests for NVS or CCE Optimisation Platform in that process and will not need to make separate requests in 2017.**
- Strengthening in-country engagement and dialogue across country stakeholders and Alliance partners, moving towards a holistic approach to priority setting and programming of Gavi support, including operational planning.
- Differentiation to better support the needs of different types of countries (e.g. fragile countries, countries with low capacity, and/ or countries in transition).

Gavi will work with these countries on a one-to-one basis, using a separate set of guidelines that will be issued in early 2017. More information on the new approach can be found in Annex 2 of this document.

Countries applying solely for **New and underused Vaccine Support (NVS)** or for the **Cold Chain Equipment (CCE) Optimisation Platform** in 2017 will follow the current process, as reflected in this set of guidelines. Certain policies and programmatic principles of the new approach also appear in these guidelines as they pertain to NVS and CCE Optimisation Platform, as outlined upfront in the section on **"What's new and what's changing."**

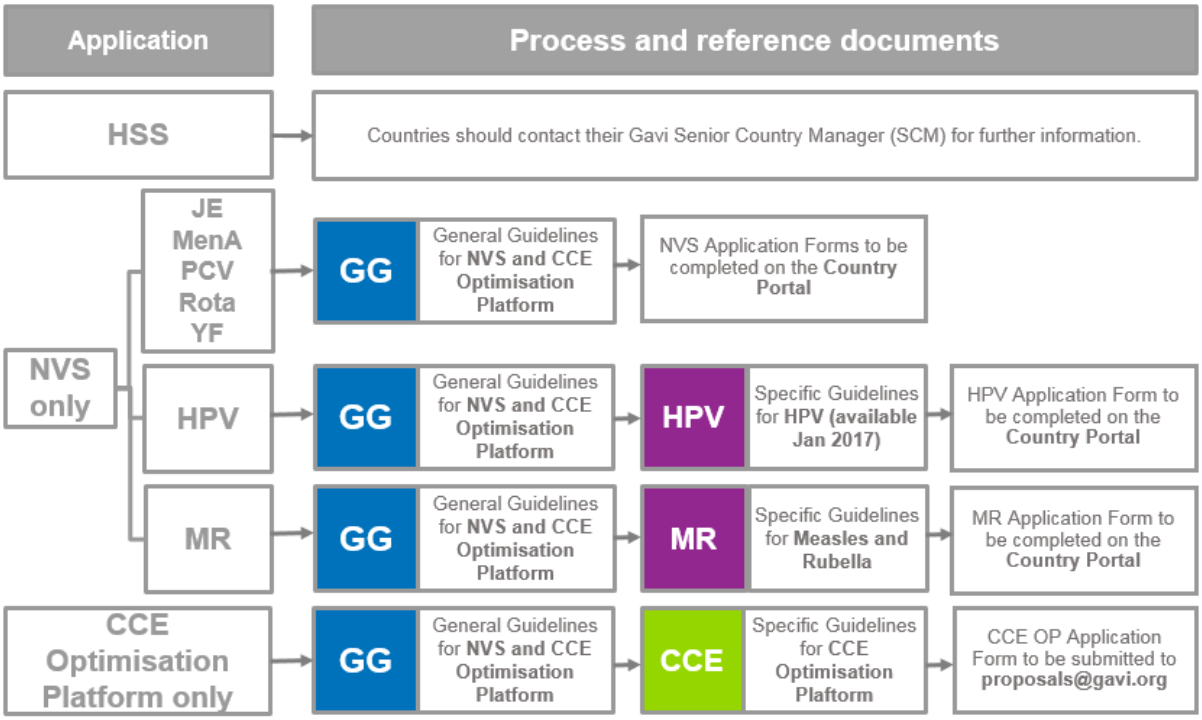
2. WHAT TYPES OF SUPPORT ARE COVERED IN THESE GUIDELINES?

These guidelines are for countries applying for New and underused Vaccine Support (NVS) and Cold Chain Equipment (CCE) Optimisation Platform only. They include all required information for Japanese Encephalitis (JE), Meningococcal Conjugate A (MenA), Pneumococcal Conjugate Vaccine (PCV), Rotavirus, and Yellow Fever applications. For HPV, Measles and Rubella and CCE Optimisation Platform, countries should also refer to the additional guidelines specific to these types of support (available here: www.gavi.org/support/apply). Figure 1 below outlines the process to follow and guidelines to consult in order to apply for support from Gavi.

☆	Countries requesting **Health System Strengthening (HSS) support in 2017** (whether as a standalone or with NVS or CCE Optimisation Platform support) should contact their Gavi Senior Country Manager (SCM) for further information on the new process. Gavi will make available detailed guidance on HSS support in early 2017 which will be accessible to all countries.

[2] Complementary allocations include: Performance Payments (PBF reward); Vaccine Introduction Grants (VIGs); Operational support for Campaigns (Ops); Product and Presentation Switch Grants; Operational support for Outbreak Response Campaigns; Operational support for Human Papillomavirus (HPV); Vaccine Demonstration Projects; and Transition Grants.

Figure 1: Process for applying for Gavi support



3. WHICH COUNTRIES CAN APPLY FOR GAVI SUPPORT IN 2017?

The main criterion that determines a country's eligibility to apply for Gavi support is its World Bank's estimate of Gross National Income per capita (GNI pc). The eligibility threshold is revised annually to adjust for inflation.[3]

☆	In 2017, countries are eligible for Gavi support if their average GNI pc over the past three years is equal to or below the threshold amount of US$1,580. A full list of Gavi eligible countries based on this criteria is provided in Annex 3. Additional criteria apply for accessing different types of support. A country that surpasses this threshold in 2017 may still apply for Gavi support subject to certain criteria. These are described in Table 1 below.

Table 1: Additional criteria for accessing Gavi NVS and CCE Optimisation Platform support

Avg. GNI pc for last 3 years	NVS	CCE Optimisation Platform
Initial self-financing countries: GNI pc equal to or below US$1,025	The national WHO/UNICEF estimate for DTP3 coverage for 2015 (released in July 2016) should be greater than or equal to 70% for all new vaccines support ***except*** JE, MenA and YF.[4,5]	Eligible for up to 80% joint investment from the platform
Preparatory transition countries: GNI pc between		Eligible for up to 50% joint investment from the platform

[3] Gavi uses World Bank GNI data (based on the Atlas method) released in July of each year. This data is for the annual GNI of a country in the previous year (i.e. in July 2016, the World Bank releases GNI data for 2015). Thus, for eligibility to apply in 2017, Gavi will consider the GNI data for 2013, 2014 and 2015.
[4] This is the same as the Penta3 coverage rate.
[5] Specific criteria for HPV, measles and rubella are provided below.

Avg. GNI pc for last 3 years	NVS	CCE Optimisation Platform
US$1,025 and US$1,580		
Accelerated transition countries: GNI pc over above the US$1,580 threshold in 2017	As above, but for one last time in 2017 (the "grace year"), with the following exceptions: • Countries that have been approved for an HPV demonstration project during their "grace year" or have surpassed the GNI pc threshold while implementing an HPV demonstration programme, will be eligible to apply for Gavi support for national introduction for one last time in the year after completion of the demonstration programme. • For MCV2 and MR routine, countries may apply for a maximum of four years and will be required to fully self-finance in the fifth year.	Countries eligible for Gavi support until at least 2018 qualify for up to 50% joint investment from the platform.[6]

Following the end of Gavi support i.e. for fully self-financing countries, some vaccine manufacturers have committed to offering prices similar to those Gavi pays for select vaccines under specific circumstances. For more information, please visit: www.gavi.org/library/gavi-documents/supply-procurement/vaccine-price-commitments-from-manufacturers/. For any questions, please contact your Gavi Senior Country Manager (SCM) or the vaccine manufacturer contact listed in the FAQs.

In addition to the eligibility criteria mentioned above, countries applying to the following vaccines must make note of the following vaccine-specific eligibility criteria:

Table 2: Additional criteria for accessing specific vaccine support

Vaccines	Additional eligibility criteria
Japanese Encephalitis (JE)	Only at-risk Gavi-eligible countries that have not yet applied for support can apply. These include: Bangladesh, DPR Korea, Myanmar and Pakistan. Countries can also apply for support in the following circumstances: • If a country has previously conducted campaigns for a portion of the population not reaching up to 14 year olds, the country will be eligible to apply for the remaining target age group up to 14 years. This includes campaigns done using donated vaccines. • If a country has already done a campaign in a targeted area, with or without Gavi support, and surveillance data identify new areas at risk of JE transmission, the country will be eligible for Gavi support for another campaign. • If a country has conducted campaigns in the past without incorporating JE into the routine programme afterwards, the country will be eligible for Gavi support for unreached cohorts within the 9 months through 14 years old age group. Countries in the process of establishing surveillance systems that already have sufficient data to warrant introduction or expansion of JE vaccination are

[6] India is not eligible to receive joint-investment share from Gavi but could benefit from CCE Optimisation Platform arrangements and prices which could be financed through HSS grants, country funding or other sources.

Vaccines	Additional eligibility criteria
	encouraged to apply even though new areas at risk may be identified in the future.
Meningococcal Conjugate A (MenA)	Only countries that are endemic in the African meningitis belt can apply for support. These include: Burkina Faso, Benin, Burundi, Cameroon, Central African Republic, Chad, Cote d'Ivoire, DR Congo, Eritrea, Ethiopia, The Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Mali, Mauritania, Niger, Nigeria, Rwanda, Senegal, South Sudan, Sudan, Tanzania, Togo and Uganda.
Pneumococcal Conjugate Vaccine (PCV)	All countries below the eligibility threshold can apply for support. In addition, countries with DTP3 coverage levels greater than or equal to 70% (2015) that have crossed the GNI pc eligibility threshold can still apply for Gavi support and access Gavi's favourable Advance Market Commitment (AMC) price. As of October 2016, these countries include: Bhutan, Cuba, Indonesia, Sri Lanka, Timor-Leste and Vietnam. Note that these countries will need to fully fund the costs of the vaccine, cannot apply for a VIG and the procurement of the vaccine needs to be carried out by UNICEF (i.e. self-procurement is not possible). The vaccine price that these countries will pay under the AMC is determined by the AMC "tail price" and is set at a maximum of US$3.50 per dose.
Yellow Fever	Countries are eligible for the following types of support: • **Routine immunisation:** Countries that have not yet introduced YF vaccine into their routine EPI schedules (Ethiopia, South Sudan, Sudan and Uganda). • **Preventive mass campaigns:** Countries currently considered at high risk for YF virus circulation (Chad, DR Congo, Ethiopia, Guinea Bissau, Kenya, Mauritania, Niger, South Sudan, and Uganda). • **Outbreak response:** Countries experiencing a significant YF outbreak of national public health importance, which cannot respond fast enough with local funding (domestic epidemic response funds or donor funding).

PCV	Application guidelines for countries that have crossed the eligibility threshold in 2017 and would like to apply for PCV after the grace years is available here: www.gavi.org/support/apply

4. GAVI'S SUPPORT FOR NVS & CCE OPTIMISATION PLATFORM

4.1. New and underused Vaccine Support (NVS)

4.1.1. `Vaccines and delivery strategies supported

Gavi NVS support is provided for the accelerated introduction of life-saving vaccines. Gavi NVS support is intended to present an opportunity for countries to strengthen their routine immunisation services and to ensure integrated delivery of immunisation with other health interventions. For example, the introduction of a new vaccine may entail strengthening of the supply chain system, re-training of health workers, etc. which would benefit the Expanded Programme on Immunisation (EPI) as a whole. These activities should be complementary to Gavi Health Systems Strengthening (HSS) support and investments by government, development partners, private sector, and civil society.

Gavi provides support for the following vaccines and associated vaccines supplies in routine immunisation programmes, campaigns and other delivery strategies (Table 3).

Table 3: Overview of vaccines, delivery strategies supported and complementary financial support for vaccines provided by Gavi

Vaccines	Delivery strategies		Complementary financial support for vaccines	
Type of vaccine	**Routine immunisation**	**Campaigns/ other delivery strategies**	**Vaccine Introduction Grant (VIG)**	**Operational support for campaigns (Ops)**
Japanese encephalitis vaccine (JE)	✓	✓ Catch-up campaigns	✓	✓
Meningococcal A Conjugate vaccine (MenA)	✓	✓ Preventive mass vaccination & one-time mini catch-up campaigns	✓	✓
Measles-rubella combined vaccine (MR)	✓	✓ Catch-up campaigns Follow-up campaigns	✓	✓
Measles vaccine	✓ Gavi supports second dose. First dose must be funded by country.	✓ Follow-up campaigns	✓	✓
Pneumococcal conjugate vaccine (PCV)	✓	X	✓	X
Rotavirus vaccine (RV)	✓	X	✓	X
Yellow fever vaccine (YF)	✓	✓ Preventive mass vaccination campaign	✓	✓
*Human papillomavirus vaccine (HPV)	Specific guidelines for HPV vaccines are available at: www.gavi.org/support/apply/			

For information on specific vaccine products, refer to the Summary Product Profiles which contains the following information for each product: serotypes covered; vaccine type; dose schedule; presentation; price; product availability; and links to WHO Pre-Qualification information and WHO Position Papers. The Summary Product Profile will be updated if information changes, so please check www.gavi.org/support/apply/ regularly for updates.

More detailed information on specific vaccine products can be found at: www.gavi.org/about/gavis-business-model/vaccine-supply-and-procurement/. Click on the "Detailed Product Profiles" tab and download the "Detailed product profiles" document under "Related Downloads".

Gavi encourages countries to introduce multiple new vaccines concurrently where relevant and programmatically feasible, and to identify synergies in activities across these introductions (e.g. in demand generation, health worker training and launch activities). Emerging evidence from countries indicates that introducing multiple vaccines simultaneously can **produce significant savings** in programme costs, as well as **speed up the health benefits** from receiving new vaccines. Costs can be saved through conducting joint trainings and social mobilisation, updating National Immunisation Programme tools in one go and conducting one Effective Vaccine Management (EVM) evaluation.

In addition to the NVS support outlined above in Table 3, Gavi also provides support for:

- Global vaccine stockpiles for oral cholera, meningitis, and yellow fever vaccines. Stockpiles are managed by the International Coordinating Group (ICG) Secretariat within WHO. Countries experiencing an epidemic may apply for emergency supplies directly through the ICG Secretariat or through its member agencies and should share their applications with the Gavi Secretariat for additional follow-up.[7]
- An outbreak response fund for measles, which is managed by the Measles and Rubella Initiative (M&RI)[8]. Countries that are experiencing a significant measles and/or rubella disease outbreak of national public health importance and cannot respond to the outbreak fast enough with local funding (domestic epidemic response funds or donor funding) should consider applying to the M&RI Outbreak Response Fund. Eligibility requirements are available at: http://measles.wpengine.com/wp-content/uploads/2013/06/SOP-Funding-Request.pdf

4.1.2. Complementary financial support for vaccines: Vaccine Introduction Grant and operational support for campaigns

	Updated calculations for the VIG and operational support for campaigns progressively reduce the funding levels as countries approach transition. There are also specific updates on what these grants are intended to be used for as well as restrictions on use.

In addition to support for vaccines and associated supplies, Gavi provides the following complementary financial support for vaccines for countries:

- **Vaccine Introduction Grant (VIG)**, which is a one-time grant intended to facilitate the timely and effective introduction of new vaccines into **routine** immunisation programmes with Gavi support. The grant is expected to cover a share of the pre-introduction activities, with the remainder being funded by the government and partners, if necessary. The VIG is intended for time-limited, start-up investment costs associated with the introduction of a new vaccine, rather than the incremental recurrent costs that would occur year after year. However, unused funds from a VIG can be rolled into a country's HSS grant to go towards systems investments such as cold chain expansion.
- **Operational support for campaigns,** which is a one-time grant intended to facilitate the timely and effective delivery of vaccines to the target population of a Gavi-supported **campaign**. The grant is expected to cover a share of the campaign operational costs, with the remainder being funded by the government and partners, if necessary. Activities funded through this grant should be leveraged for strengthening the routine immunisation systems, where possible, and unused funds can be rolled into a country's HSS grant.

[7] For more information please see the WHO websites:
Global stockpile of oral cholera vaccine: www.who.int/cholera/vaccines/ocv_stockpile_2013/en/
Global stockpile of meningitis vaccine: www.who.int/csr/disease/meningococcal/icg/en/
Global stockpile of yellow fever vaccine: www.who.int/csr/disease/icg/yellow-fever/en/ and www.who.int/emergencies/yellow-fever/response/en/

[8] Further details available at:
www.who.int/immunisation/diseases/measles/SOP_MRI_Outbreak_Response_Fund_June2014_Final.pdf

Countries are encouraged to use the funding to support concurrent introductions and integrated delivery of immunisation with other health interventions. Countries are also encouraged to find synergies across these different investments (i.e. countries should coordinate the use of financial support when more than one type of support is provided).

Table 4 provides more details on these grants.

Table 4: Explaining the VIG and Operational support for campaigns

Detail	Vaccine Introduction Grant (VIG)	Operational support for campaigns
How is the grant amount calculated? *(For a definition of these country classifications, please refer to Section 3)*	**Initial self-financing countries:** $0.80 per infant in the birth cohort in year of introduction, or a lump sum of $100,000, whichever is higher **Preparatory transition phase countries:** $0.70 per infant in the birth cohort in year of introduction, or a lump sum of $100,000, whichever is higher **Accelerated transition phase countries:** $0.60 per infant in the birth cohort in the year of introduction, or a lump sum of $100,000, whichever is higher	**Initial self-financing countries:** $0.65 per targeted person **Preparatory transition phase countries:** $0.55 per targeted person **Accelerated transition phase countries:** $0.45 per targeted person Countries applying for phased campaigns may allocate operational support funds flexibly across phases
What type of activities can be supported under the grant?	Example activities include: • Health worker training • Demand generation • Technical assistance • Micro-planning • Document production and distribution • Waste management • Data-related costs (including M&E of the new vaccine introduction)	Same as VIG, plus: • Transport • Short-term supply chain costs[9] (e.g. cold boxes and ice packs, rental of temporary cold room space) • Monitoring and social mobilisation Perverse incentives (i.e. those incentives which lead to undesirable behaviours) for vaccine delivery are discouraged.
Are there any particular requirements for use of funds for HR compensation?	Use of VIG funds for human resource (HR) compensation is discouraged.	Eligibility to use operational support for campaigns funds for HR compensation varies by transition stage as follows: • **Initial self-financing:** Can use Operational support for HR compensation (but countries should weigh the potential implications) • **Preparatory transition phase:** Discouraged from using Operational support for HR compensation • **Accelerated transition phase:** Cannot use Operational support for HR compensation

[9] Longer-term supply chain costs are not covered.

MR	Exceptions apply for VIG and operational support for Measles and Measles-Rubella. Further details are available in the Measles and Rubella guidelines. These guidelines can be found at www.gavi.org/support/apply/

	A switch in product and presentation can be requested through the annual monitoring process. Details on application for product switch are included in the Guidelines on Reporting and Renewals, available here: www.gavi.org/support/renew/

4.1.3. Additional information on vaccines supported

Japanese Encephalitis (JE)

WHO stipulates that the most effective immunisation strategy in Japanese encephalitis (JE) endemic settings is a one-time catch-up campaign targeting at-risk populations, followed by incorporation of JE vaccines into the national routine immunisation schedule.

	WHO position paper on Japanese Encephalitis, available at: www.who.int/wer/2006/wer8134_35.pdf?ua=1

Gavi provides support for catch-up campaigns and is now supporting the introduction of JE into the national routine immunisation programme. For catch-up campaigns, Gavi provides JE vaccines and associated supplies for a target population aged 9 months through 14 years.

	Gavi does not provide JE support for outbreaks or epidemic responses, for which countries should seek support from other sources.

Meningococcal Conjugate A (MenA)

In the 26 countries[10], where Neisseria meningitidis A (NmA) meningitis is endemic, WHO recommends the following strategy:

1. A **preventive mass campaign** with MenA vaccine in the population aged 1-29 years old.
2. Introduction of MenA vaccine into the **routine infant vaccination schedule** within one to five years of having completed the preventive mass MenA vaccination campaign.
3. To complement the introduction of MenA vaccine into the routine infant schedule, a simultaneous **one-time "mini catch-up" campaign** with MenA vaccine should be carried out. The target population for this one time mini catch-up campaign includes the susceptible cohorts born between the preventive mass vaccination campaign and the introduction of the routine infant vaccination schedule. The exact age range for the one time mini catch-up campaign will depend on the specific epidemiology and situation of the country.

	MenA guidance: WHO (2015) Meningococcal conjugate vaccine: Updated Guidance. Weekly Epidemiological Record (WER), 20 Feb, 2015, No. 8, 2015, 90, 57–68. www.who.int/wer/2015/wer9008.pdf?ua=1

[10] The 26 endemic countries are Burkina Faso, Benin, Burundi, Cameroon, Central African Republic, Chad, Cote d'Ivoire, DR Congo, Eritrea, Ethiopia, The Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Mali, Mauritania, Niger, Nigeria, Rwanda, Senegal, South Sudan, Sudan, Tanzania, Togo and Uganda.

Gavi provides support for all delivery strategies. That is, preventive mass campaigns, introduction into the national routine immunisation programme, and mini catch-up campaigns in a one dose schedule as well as associated injection supplies.

Gavi also provides support for Controlled Temperature Chain (CTC). This is available for countries wishing to make use of a CTC strategy when implementing a MenA preventive mass campaign or one-time mini catch-up campaign. Countries interested to use MenA vaccine in a CTC during their preventive mass campaign are encouraged to summarise in their application how they will use CTC, when they plan to start using it, and how they will comply with the WHO guidelines during implementation.

	The WHO CTC guidelines are available at: www.who.int/immunization/documents/WHO_IVB_13.04_5_6/en/

Pneumococcal Conjugate Vaccine (PCV)

WHO recommends that pneumococcal vaccines be given priority in childhood immunisation programmes, especially in countries with under-five mortality of greater than 50 per 1,000 live births.

For PCV administration to infants, WHO recommends: 3 primary doses (the 3p+0 schedule); or 2 primary doses plus a booster (the 2p+1 schedule).

- If the 3p+0 schedule is used, vaccination can be initiated as early as 6 weeks of age with an interval between doses of 4-8 weeks, with doses given at 6, 10, and 14 weeks or at 2, 4, and 6 months, depending on programmatic convenience.
- If the 2p+1 schedule is selected, the 2 primary doses should be given during infancy as early as 6 weeks of age at an interval preferably of 8 weeks or more for the youngest infants and 4-8 weeks or more between primary doses for infants aged ≥7 months. One booster dose should be given between 9-15 months of age.

In 2015, the Strategic Advisory Group of Experts on Immunization (SAGE) reviewed the evidence on the administration of multiple injectable vaccines during the same visit and found that evidence supports co-administration. Therefore, **countries should not make modifications to recommended immunisation schedules with the aim of preventing multiple injections** during the same visit when such modifications are not evidence-based. To this extent, countries should provide training to health-care workers on vaccine co-administration practices (e.g., techniques to mitigate pain at the time of vaccination, information about safety and effectiveness of vaccines when co-administered, effectiveness and value of multiple vaccine injections) and develop a communication strategy to address vaccine hesitancy and refusals.

	WHO Pneumococcal vaccine information: www.who.int/ith/diseases/pneumococcal/en/ WHO position paper on pneumococcal conjugate vaccines www.who.int/immunization/documents/positionpapers/en/index.html Introduction of pneumococcal vaccine: A handbook for district and health facility staff: • for PCV13: apps.who.int/iris/bitstream/10665/90380/1/WHO_IVB_13.10_eng.pdf • for PCV10: apps.who.int/iris/bitstream/10665/90378/1/WHO_IVB_13.09_eng.pdf SAGE recommendation on multiple injectable vaccines in a single vaccination visit: www.who.int/wer/2015/wer9022.pdf?ua=1

Gavi provides support for the introduction of PCV into national routine immunisation programmes in a three dose schedule (3+1 or 2+1) as well as associated vaccines supplies (i.e. auto-disable (AD) syringes, reconstitution syringes and safety boxes). Gavi does not provide support for catch up campaigns for pneumococcal vaccines.

Three WHO-prequalified pneumococcal conjugate vaccines (PCV) are currently available with Gavi support, which show comparable vaccine efficacies for serotypes contained in the vaccines according to WHO:[11] 10-valent (PCV10) in a 2-dose vial; 13-valent (PCV13) vaccine in 1-dose vial; or 13-valent (PCV13) vaccine in 4-dose vials.

Gavi also expects that 10-valent PCV in 4-dose vials will become WHO-prequalified and available in 2018, so countries will be able to select this presentation when applying for PCV support in 2017; however, if selecting this presentation, countries will need to indicate a second preferred presentation.

☆	Due to the presentation of the PCV10 in a two-dose vial without preservative, WHO requires that the country confirms its programmatic readiness before vaccines are shipped. This confirmation should be provided in writing to UNICEF, by WHO, not the country directly, confirming adequate training and the placement of stickers on refrigerators. Additional information on the PCV10 requirements are available on the WHO website.

Rotavirus

WHO recommends that rotavirus vaccine for infants should be included in all national immunisation programmes and considered a priority in countries with high rotavirus gastroenteritis (RVGE) associated death rates, such as in south and south-eastern Asia and sub-Saharan Africa.

WHO recommends that the rotavirus vaccine administered in a two-dose schedule should be administered at the time of DTP1 and DTP2 contacts, with an interval of at least four weeks between doses. The vaccine administered in a three-dose schedule should be administered at the time of the DTP1, DTP2 and DTP3 contacts, with an interval of at least four weeks between doses.

Because of the typical age distribution of Rotavirus gastroenteritis (RVGE), WHO does not recommend rotavirus vaccination of children >24 months of age. Prematurely born infants should follow the vaccination schedules recommended for their chronological age.

WHO recommends that all immunisation programmes have routine Adverse events following immunisation (AEFI) monitoring in place, regardless of which vaccines are included in the national immunisation schedule. For rotavirus vaccines, countries should:

- provide proper planning and training of staff for pharmacovigilance prior to introducing the vaccine;
- develop a strategy to inform relevant health staff that although the benefits of vaccination outweigh the risks of intussusception, a small potential risk of intussusception after rotavirus vaccination remains;
- ensure that caregivers are adequately trained to recognise danger signs of dehydration or intussusception that need immediate medical consultation; and

[11] www.who.int/immunization/position_papers/PP_pneumococcal_April_2012_summary.pdf

- establish the baseline incidence of intussusception at sentinel sites and to use epidemiological studies, such as the self-controlled case series method, to assess the safety of rotavirus vaccines.

A plan for monitoring of AEFIs and training of staff that will be responsible for AEFI monitoring should be in place before the vaccine is introduced.

WHO recommends that health staff must be encouraged to strengthen the detection, reporting and investigation of intussusception cases and RVGE cases, so that risks and benefits of this vaccine can be further assessed.

	WHO rotavirus vaccine information: www.who.int/immunization/diseases/rotavirus/en/ WHO position paper on rotavirus vaccines: www.who.int/wer/2013/wer8805/en/index.html PATH rotavirus disease and vaccine information: sites.path.org/rotavirusvaccine/rotavirus-disease/ sites.path.org/rotavirusvaccine/key-messages-rotavirus-disease-and-vaccines/ WHO Introduction of Rotavirus Vaccines: Information for Policy Makers, Programme Managers, and Health Workers www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/sentinel/rotavirus_intro_guidance_who_july31_2013.pdf

Gavi provides support for the introduction of Rotavirus into national routine immunisation programmes in a two or three dose schedule (depending on the vaccine) as well as associated vaccines supplies (safety boxes).

Two rotavirus vaccines are currently pre-qualified by WHO and available with Gavi support, one in a 2-dose schedule (Rotarix) and one in a 3-dose schedule (Rotateq). Both vaccines have demonstrated very good safety and efficacy profiles in large clinical trials around the world.

Based on current estimates on supply capacity, availability of Rotarix will be dependent on the number and size of countries being approved for vaccine introduction support. Rotateq vaccine, however, is available for earlier introduction. In order to facilitate management of vaccine supply, countries are encouraged to provide the first and second preferred product presentation in their application. Gavi may not be in a position to accommodate all countries' first product preferences. If their first preferred product is not available, they will be contacted by Gavi Secretariat to discuss their second preferred product presentation.

A new presentation for Rotateq vaccine with Vaccine Vial Monitor, VVM7, and smaller cold chain requirements is expected to be WHO pre-qualified by 2017. In addition, new rotavirus vaccine products manufactured by developing country manufacturers in a three-dose schedule are estimated to be WHO pre-qualified and available by 2019.

If and when a country needs to switch from one vaccine to another (for supply or programmatic reasons) infants who have already had a dose administered should complete the schedule with that vaccine.

Yellow Fever (YF)

Yellow fever (YF) cannot be eliminated as it has an animal reservoir and mosquito vectors. However, the risk of outbreaks can be substantially reduced through immunising a minimum

of 80% of the at-risk population. In order to achieve this high coverage rate and maintain immunity for life, WHO and UNICEF recommend a three-pronged YF control strategy:

1. The nationwide integration of the YF vaccine (YFV) in **routine infant immunisation** programmes for infants (9 months in Africa and 12 months in the Americas) in countries where a risk of YF epidemic has been identified.
2. The implementation of **preventive mass vaccination campaigns** designed to rapidly increase population immunity in high-risk areas and control the risk of YF epidemics, as well as help to strengthen health equity.
3. **Rapid outbreak response,** through rapid case detection, reactive vaccination, good case management, vector control and community mobilisation.

A combined strategy of routine immunisation and preventive mass vaccination campaigns will provide long term coverage and impact. It is therefore recommended that if a high risk country has not yet introduced the YFV in its routine immunisation, the country should plan to do so within 6 to 12 months of conducting a preventive mass campaign.

WHO recommendations for countries applying for **YFV routine** support are as follows:

- All countries at high risk of YF virus circulation are recommended to introduce and sustain high YF vaccine coverage in their national infant routine immunisation system.
- High risk countries are therefore recommended to introduce routine immunisation nationwide or at a sub-national level depending on key findings and results of risk assessments.
- Based on available risk assessment results, Kenya is recommended to expand routine immunisation coverage to additional high risk regions.

WHO recommendations for **countries at moderate risk of YF virus circulation or at potential risk** are currently not expected to introduce preventive mass campaigns or routine immunisation in their systems, unless:

- They have reported laboratory confirmed YF cases;
- There is evidence of YF virus circulation or perceived risk of expansion due to geographical location, population movements, climate and ecological-environment factors etc.; or
- Results of a risk assessment or modelling confirm the required strategy.

In addition, **all countries** should note that YF virus circulation and risk can change or expand to additional new countries or regions not currently considered high risk. WHO therefore recommends that countries, including moderate risk countries:

- Consult with the Secretariat of the Elimination of Yellow Fever Epidemics (EYE) at WHO.
- Refer to YF WHO guidance notes which are revised annually. These documents can be found on WHO YF webpage or from relevant WHO country offices.
- Annex 10 has the current list of endemic countries and this will be updated depending on expansion of YF to additional countries.

	Further YF information is available here: www.who.int/csr/disease/yellowfev/en/ WHO Global Strategy to Eliminate Yellow fever Epidemics (EYE), 2016, available here: www.who.int/entity/immunization/sage/meetings/2016/october/2_EYE_Strategy.pdf?ua=1

Gavi provides support to the three-pronged YF control strategy, covering **Routine immunisation programmes**; **Preventive mass campaigns**; and **Outbreak response**.

Human papillomavirus (HPV), Measles and Rubella (MR)

HPV MR	Additional information specific to HPV and Measles and Rubella are provided in a separate document, available at www.gavi.org/support/apply/

4.2. Cold Chain Equipment (CCE) Optimisation Platform

Sufficient, well-functioning and well-maintained cold chain equipment is a “fundamental” prerequisite for an effective immunisation supply chain, complementing four other fundamentals comprising: 1) supply chain managers; 2) data for management; 3) optimised & efficient design of the distribution system; and 4) a continuous improvement process over time (e.g. Effective Vaccine Management Improvement Plan (EVM IP)). These supply chain fundamentals contribute to the achievement of overall EPI programme objectives of improved coverage and equity and reduction of child mortalities. Effective inter-linkages of these five fundamentals will enable countries to increase the availability and potency of vaccines as well as improve the efficiency of the entire supply chain.

Through the CCE Optimisation Platform support, Gavi will jointly invest in the purchase, deployment and installation of high-performing cold chain devices, including training healthcare workers and technicians on maintenance requirements. Products eligible for platform funding include a subset of WHO Performance, Quality and Safety (PQS) listed devices that meet the technical requirements of the platform. The CCE Optimisation Platform aims to support countries to:

- Accelerate upgrading of existing equipment through the deployment of higher-performing, innovative devices to health facilities in Gavi-supported countries;
- Extend appropriate cold chain devices into health facilities which have no equipment to improve the capacity of these health facilities to reach underserved populations/areas;
- Incentivise better management and maintenance of CCE;
- Make supply chains more efficient and effective through the use of equipment better adapted to needs; and
- Amplify countries’ progress on the other supply chain strategy "fundamentals”: supply chain managers, data for management, optimised distribution system design and continuous improvement.

It will be critical to ensure that the investments through the CCE Optimisation Platform are linked with other Gavi support, including HSS, VIGs, Ops, and NVS. The request for support should clearly highlight these links.

CCE	Further details are available in the CCE Optimisation Platform Guidelines. This can be found at www.gavi.org/support/apply/

5. WHAT ARE THE PROCESSES AND REQUIREMENTS FOR APPLYING FOR GAVI SUPPORT?

5.1. Step-by-step application, review and approval process

The step-by-step application process is as follows:

1. **Application development by countries**: As described in Section 5.2, countries are required to develop their applications to Gavi through a participatory approach with relevant stakeholders and based on national plans. The national Coordination Forum (ICC, HSCC or equivalent body) is required to ensure the participatory approach, and to review and endorse the application.
2. **Application submission by countries:**
   - For NVS support applications are submitted through Gavi's online country portal (accessed via https://portal.gavi.org). The country portal will be open for applications two months prior to the submission deadline.
   - For CCE Optimisation Platform support, applications are submitted via email to proposals@gavi.org.
   - The cut off dates for application submission are provided in table 5 below and applications cannot be submitted after the deadline.
3. **Completeness screening and pre-review by Gavi:** Gavi screens applications to ensure that mandatory requirements have been met and reviews the validity and consistency of information submitted. If incomplete, Gavi will work directly with countries to address gaps before proceeding.
4. **Application review by the Independent Review Committee (IRC):** The IRC (an independent committee comprising experts in public health, epidemiology, supply chain, development, finance and economics) reviews applications for all types of support. Countries are informed of the review outcome via "Information Letters", with a recommendation for either approval or resubmission (see Section 5.4 below).
5. **Additional information/ clarification from countries:** Whilst the IRC may recommend the application be approved, there may be a number of minor issues that need to be clarified by the country.
6. **Approval by Gavi:** Gavi will consider and decide on IRC recommendations. Countries and partners are notified of the final outcome through a "Decision Letter", explaining the vaccine and/ or programmatic financial support amount and terms of the grant, and to which is attached the updated agreed performance framework.

Key timelines for application submission, review and approval are provided in Table 5 below.

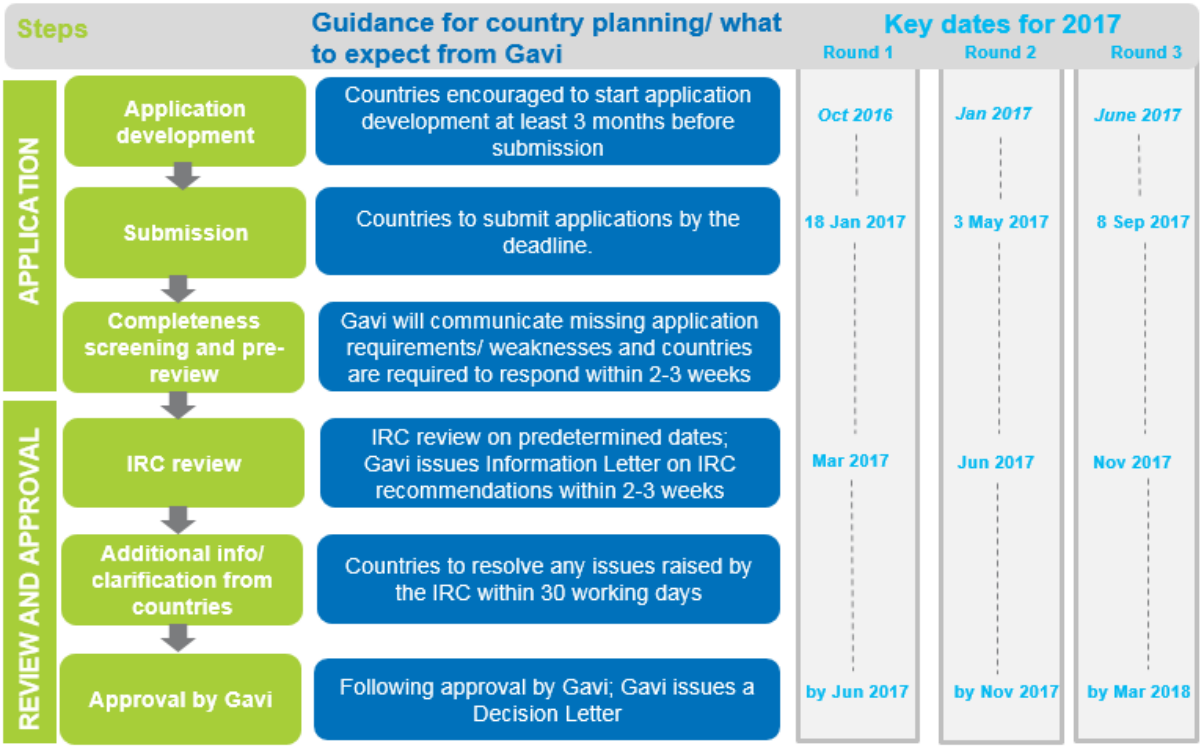
Table 5: Key application related timelines

	Round 1	Round 2	Round 3
Cut-off for submission of country applications for review at next IRC meeting	18 Jan 2017	3 May 2017	8 Sep 2017
IRC application review dates	8-17 Mar 2017	14-23 Jun 2017	3-17 Nov 2017
Gavi decision	by Jun 2017	by Nov 2017	by Mar 2018

☆	Country applications will be accepted on a rolling basis, so if a country misses a deadline for cut-off date for submission, the application will be reviewed at the subsequent IRC meeting.

Figure 2 provides guidance to countries on how they should plan for their application development given the above noted timelines, as well as what they should expect from Gavi during the review and approval stages. **Please note that approval by Gavi should be within a 5-6 month period from the time of submission of an application by the country.**

Figure 2: Application and approval process and timelines for new support



☆	Countries can request guidance (e.g. information, clarifications) from the Gavi Secretariat during the application development process. In addition, countries can request technical assistance from WHO, UNICEF and other relevant partners for detailed application development. Training workshops, usually delivered by WHO, are held on a regular basis to provide support to countries with the preparation of applications.

5.2. Gavi's requirements for all applications

☆	Gavi emphasises that all types of applications focus on improving equitable coverage of vaccines as well as consider financial and programmatic sustainability. Gavi also requires that the requested support align with the national plans and strategies as well

	as basic functionality of the in-country Coordination Forum (Interagency Coordinating Committee (ICC), Health Sector Coordinating Committee (HSCC) or equivalent).

Each of these is explained in turn below. There are other support-specific requirements that are described in the respective support-specific guidelines.

Focus on coverage, equity and sustainability

Gavi support to countries focuses on issues relating to improvements in immunisation coverage and equity, as well as financial and programmatic sustainability in country applications. Countries are encouraged to place a strong emphasis on **coverage and equity** in terms of "reaching the unreached "fifth child" and leaving no child behind" and to clearly articulate their coverage and equity agenda and priorities.

This ambition goes beyond geographic equity to ensure that all children are reached considering factors like gender, ethnicity, mobility/displacement, birth order, etc. In addition, these children need to be reached sustainably, requiring approaches that are viable and financed in the long term.

In line with Gavi's Gender Policy, countries are required to provide key data related to gender equity, including:

- Sex disaggregated DTP3 coverage data, which is a core indicator in Gavi's grant performance frameworks. The source of this data can either be administrative or survey based. In most countries this would come from surveys (e.g. DHS, MICS). Gavi is not requiring countries routinely collect sex disaggregated data through administrative systems.
- An analysis of any gender-related barriers to accessing health services.[12]

In application materials, countries are strongly encouraged to highlight the lessons learned and what has already been effective in addressing coverage and equity constraints. Countries should describe underserved communities identified through coverage and equity assessments, prioritise interventions to specifically reach these underserved communities, and design tailored interventions to reach them. Additionally, countries should make provision to regularly monitor these communities to ensure that they are being reached with immunisation services.

Sustainability should be integrated in the design and implementation of all types of Gavi support. For example, when countries apply for Gavi NVS support, they should consider their co-financing obligations over the longer term. The impact of the additional co-financing obligations on total financial requirements for immunisation should be assessed, as well as their impact on general government health expenditures. Countries should also consider required delivery cost of their immunisation programs, in addition to funds needed to procure the vaccines.

[12] Gender-related barriers are obstacles to the access and utilisation of health services that are related to social and cultural norms about men and women's roles. Mothers tend to be the primary caretakers of children and in societies where women have low status, their children – both girls and boys – are less likely to be immunised. When women are empowered, immunisation coverage increases. Strategic and catalytic interventions targeting women, men, families and communities can help countries overcome gender-related barriers to accessing immunisation services, improve coverage and reach the unreached.

All types of Gavi financial support should consider the strategic use of funds and their long term programmatic and financial sustainability. Gavi support should be adapted to the needs of countries given their transition phase:

- Countries that are in earlier stages of transition are encouraged to prioritise systemic, long-term change (e.g. redesigning data systems or supply chains) and may use Gavi funds to finance recurrent cost (e.g. support to human resources financing).
- Countries in later stages of transition are encouraged to focus on investments with a shorter term impact, or ones where systemic change is urgently needed prior to transition (e.g., building capacity to procure vaccines at appropriate prices). Alliance support should not be used to finance recurrent costs, particularly in countries in the accelerated transition phase.

Alignment of Gavi support with country plans

In line with the International Health Partnership (IHP+)[13], Gavi supports the principles of alignment and harmonisation, by requiring the following for country applications:

For NVS applications, all planned vaccine introductions and/ or campaigns need to be reflected in the country cMYP (or equivalent multi-year plan), which should be valid for at least one year from the proposed date of introduction. NVS support is approved for the duration of the cMYP only.[14] The national in-country Coordination Forum (ICC/HSCC or equivalent) and the National Immunisation Technical Advisory Group (NITAG) or equivalent body is required to be involved in the process of deciding whether to introduce a new vaccine and the approach to integration of immunisation initiatives through endorsement of the proposal.[15]

For CCE Optimisation Platform applications, countries are required to demonstrate how the requested support addresses gaps identified in the country cMYP and other national documents; how other government/ partner support contributes to country supply chain targets; and how the in-country Coordination Forum (ICC/HSCC) has been involved in the application process.

In support of this, Gavi requires key country planning documents to be attached with the application. The full set of mandatory and optional attachments with country applications for NVS applications are provided in Annex 8.

CCE	For CCE Optimisation Platform support, the full set of attachments are provided in the support-specific guidelines.

Basic functionality of the in-country Coordination Forum (ICC/HSCC or equivalent)

Achieving national immunisation goals relies on functioning oversight and coordination of the EPI programme. National-level Coordination Forums, such as ICC, HSCC and other

[13] www.internationalhealthpartnership.net/en/

[14] Gavi's application guidelines and form are aligned with WHO's guidance on the principles and considerations for adding a vaccine to a national immunisation programme, in order to ensure that country effort is invested in strengthening its own plans, rather than the separate requirements of an external funding agency.

[15] In the absence of a NITAG, countries are required to clarify the role and functioning of the equivalent advisory group for the national immunisation programme and describe plans to establish a NITAG.

equivalent bodies, are critical to bringing together government and other key immunisation stakeholders in a participatory and transparent manner.

The main objectives of the Coordination Forum include:

- To provide strategic direction, oversight and transparency on the EPI and related health sector programmes as a whole to ensure sustainable coverage and equity of immunisation;
- To ensure a coherent view on strategy, planning, funding and performance of the EPI programme within the context of the broader health system; and
- To promote complementarity and harmonisation of activities and investments among stakeholders.

To help countries achieve these objectives and ensure the functionality of their Coordination Forum, Gavi has introduced a 'support package' for countries. This includes a set of requirements and recommendations with regard to the membership, mandate and governance of the Coordination Forum, designed to build on existing coordination structures, while ensuring government ownership and leadership.

To be eligible for support NVS and CCE Optimisation Platform support, Gavi requires countries to ensure a basic functionality of their Coordination Forum. Countries can demonstrate this by adhering to the requirements listed in Table 6. A set of documents submitted along with the grant application will help the Independent Review Committee (IRC) to assess adherence to these requirements.

Gavi recognises that improving the functionality of Coordination Forums is an ongoing effort for countries that may take time. Therefore, there will be a degree of flexibility in approving NVS and CCE Optimisation Platform support if the Coordination Forum does not have a basic functionality yet, but the application coherently points out the requirements not met, and the approach to address these. In the future, some recommendations may be gradually added as additional requirements.

	Additional elements of the **'support package'** available to countries include a number of tools (e.g. templates for ToR and meeting minutes) and trainings/ technical assistance for Coordination Forums. Details are available at: www.gavi.org/support/coordination/. Annex 6 provides the full set of guidance for Coordination Forums, including Gavi's recommendations.

In addition to a Coordination Forum that has the objectives mentioned above, some countries have coordinating bodies at a more operational and technical level. The requirements and recommendations are intended to apply to the high-level Coordination Forum.

Table 6: Gavi requirements to ensure basic functionality of the Coordination Forum[16]

Coordination Forum requirements
Membership[17]
Context: While countries will determine the members of the Coordination Forum, the required **member profile** described below can typically bring expertise, insight and authority to help the Coordination Forum perform its strategic mandates. Membership should **represent the full range of voices** needed to coordinate on high-level, strategic issues of the EPI programme.

[16] Annex 6 provides further details including Gavi's recommendations.
[17] The requirements for membership come into effect for May 2017 and later applications to give countries sufficient time to prepare for the change

Coordination Forum requirements
1. The Coordination Forum Chair is a senior leader from the Ministry of Health (MoH) with decision making authority (e.g., Minister or Permanent Secretary)
2. Members include senior-level representatives with decision–making authority from each of the following categories: • EPI programme (e.g., EPI manager and direct leadership of EPI manager) • Ministries related to budget, financial plans and other topics related to EPI financing (e.g. Ministry of Finance) • MoH planning departments/ divisions and other directorates related to HSS • Ministries (other than MoH) with high relevance to EPI programme implementation (e.g. Ministries of Social Services, Education, Devolution) • Civil society most active in immunisation and representing the voice of constituencies (e.g. advocacy groups, parent associations, religious groups) • Key donors most active in immunisation, maternal/neonatal/ child health, and/or health system strengthening in the country (e.g., a few bilateral donors or representatives of a functioning donor coordination body) • Key (implementing) partners most active in immunisation and health system strengthening in the country, i.e. as part of Gavi Alliance representatives from WHO and UNICEF with technical fluency in EPI and HSS and representatives of other implementers.
Mandate
3. Review and approve applications for Gavi support (including HSIS[18]), Gavi grant renewals[19] and Partners' Engagement Framework (PEF) submissions for 2018 in a broad and participatory process, ensuring their alignment with national strategic and operational plans and a focus on sustainable coverage and equity. 4. Ensure a broad and participatory process in application development also on the operational and technical level, involving the relevant institutions described above. 5. Review and endorse operational plans and budgets for HSIS support 6. Oversee progress of Gavi investments based on discussion and approval of Joint Appraisal and, if possible, based on insights from the EPI team and operational/ technical Coordination Forums.
Governance[20]
Context: The required governance best practices below can typically improve the joint understanding of the Coordination Forum's role, the inclusiveness of decision making and can ensure a constant flow of information between all Coordination Forum members.
Terms of Reference (TOR) 7. The role of the Coordination Forum defined through a formal TOR, signed and shared with all members, including objective and mandates of the Coordination Forum; membership composition, selection process, and membership rules; meeting rules (frequency and timing of meetings); decision-making procedures (including quorum, presence of chair, voting rules for approving different types of decisions); support functions (including who is responsible); roles and organisational structure of the Coordination Forum secretariat (or equivalent); and terms of reference for committees and/or working groups (if applicable) Decision-making procedures 8. The Coordination Forum follows the quorum (presence of at least a certain share of members during Coordination Forum meetings to make any decisions) as defined in the TOR.

[18] See Annex 2 for details on HSIS support
[19] HSS renewals as of 2017
[20] The requirements for the Terms of Reference and decision-making procedures come into effect for May 2017 applications and later applications to give countries sufficient time to prepare for the change. Until then countries can submit the existing ToR.

Coordination Forum requirements
Support functions 9. The Coordination Forum takes minutes for each meeting and share with all members within a defined time period after a meeting, including a list of members attending the meeting and whether quorum was met.

Grant performance framework

As part of any application, Gavi requires countries to propose updates to their grant performance framework. The performance framework is an upfront agreement between a country and Gavi on the key metrics to be used to monitor and report grant performance during implementation. Each country has one single grant performance framework which should reflect its entire portfolio. The framework contains inputs, activities / processes, outputs and outcomes based on two types of indicators:

(i) Core indicators, which are mandatory, based on standard definitions, and for the most part, already monitored by countries (e.g., vaccine coverage rates); and

(ii) Tailored indicators, which are a small number of additional indicators to enable monitoring of the complete results chain for each specific grant (if not appropriately captured with core indicators).

At the time of application, countries need to provide all required information for core indicators (baseline values, specified data sources and targets for future years) and decide whether any additional tailored indicators should be included.

5.3 Gavi's requirements for vaccine support

5.3.1 Requirements for all vaccines

Gavi has specific requirements for all NVS applications. A full list of mandatory documents to be included with NVS applications is provided in Annex 8.

Vaccine management

All countries are required to attach the following documents for all NVS applications:

- An **Effective Vaccine Management (EVM) assessment report (or equivalent)**. The EVM is valid for NVS applications for a maximum of five years from the date the EVM assessment was conducted, after which it will need to be repeated, along with an indication of progress against the assessment findings.
- For vaccines to be delivered through the routine immunisation programme, a **New Vaccine Introduction Plan (NVIP), New Vaccine Introduction Checklist** and **Activity List & Timeline** must be included. For a vaccine to be introduced through campaigns, a **Plan of Action (PoA)** needs to be included. For vaccines that will be delivered by campaign and introduced into the routine schedule, both an NVIP and a PoA are required.

	The WHO template and guidance on the NVIP, New Vaccine Introduction Checklist and Activity List & Timeline are available here: www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/

	Guidance on the development of a **PoA** is provided in Annex 7.

Financial management

A **detailed budget for the Vaccine Introduction Grant (VIG) and/ or operational support for campaigns (Ops)** needs to be provided as per the prescribed Gavi template, and included in the country's annual operational plan.

MR	Countries are required to have a long term budgeted plan for measles and rubella activities, to ensure financial and programmatic sustainability. Further details are available in the Measles and Rubella guidelines. These guidelines can be found at www.gavi.org/support/apply/

Countries are required to propose an appropriate financing mechanism as part of their application for direct financial assistance from Gavi. The mechanism chosen should receive the endorsement of the relevant Coordination Forum (ICC, HSCC or equivalent). The proposal will be discussed between the government, in-country development partners and the Gavi Secretariat, and a Performance Capacity Assessment (PCA) will be conducted. Annex 5 provides further principles on Gavi's financial management approach.

	For detailed guidance on financial management requirements, see: www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/guidance-on-financial-reporting/.

Data quality and strengthening

The reports from desk reviews, in-depth assessments and surveys along with a national immunisation data quality improvement plan, serve as requirements to be provided with a country application for all types of Gavi support. An immunisation data quality improvement plan is a document that describes a country's plans for improving the availability, quality and use of immunisation coverage data. It does not need to be a stand-alone document and would ideally be a part of an integrated country planning document. The progress against the improvement plans will be reviewed as part of the regular grant cycle at Gavi.

5.3.2 Requirements for specific vaccines

In addition to the aforementioned Gavi requirements, countries applying for specific vaccines must make note of the following vaccine-specific requirements:

Japanese Encephalitis (JE)

Epidemiology, disease burden and description of the target population

In their application, countries are required to provide the rationale for the introduction of JE using available disease burden data. If countries do not have national or sentinel JE and/or Acute Encephalitis Syndrome (AES) data, they should plan to establish systems or conduct studies to collect this data and stipulate these activities in the JE introduction plan. The epidemiological information should include:

- JE data from the JE/AES surveillance system including the definition of the geographical extent of high risk areas for JE; and
- Reports on outbreak or clustering of cases in the past three years; or

- In case of absence of data from JE/AES surveillance, data from rapid assessments and/or an argumentation on environmental and biological plausibility.

Based on this information, countries must describe the target population for the Gavi supported campaign and for routine introduction. Note that geographical areas identified for the introduction of JE in routine immunisation should be at the minimum the same areas as for the Gavi supported campaign. Countries that already conducted campaigns in geographical areas and/or age groups other than the ones identified in this application must provide evidence of such campaigns areas, targets and coverage.

JE surveillance

Although not a requirement, countries are also requested to provide information on the following indicators of the quality of JE surveillance for at least two years prior to application:

- Reporting rate at national level: (number of reported AES cases per 100,000 population).
- Laboratory confirmation rate: (% of tested AES cases that were JE IgM-positive).

Country PoA and NVIP

For vaccines which will be delivered by campaign and introduced into the routine schedule, both an NVIP and a PoA are required. The PoA for JE catch-up campaign and NVIP for JE introduction can be combined into one document. In addition to the requirements for the PoA provided in Annex 7.1, countries must provide a description of their plans for the JE campaign, as well as for the introduction into the routine programme after the campaign. The objective is to ensure good coordination between campaign and routine introduction planning. This includes:

1. A comprehensive vaccination strategy for introduction of the JE vaccine, including a description of:
    - The initial JE campaign, including the planning process and plans to reach remote rural populations.
    - Implementation plan for smooth transition to the routine immunisation programme, which specifies geographical extent, timing of routine introduction, and projected coverage.
2. A description of the following surveillance activities:
    - Acute Encephalitis Syndrome (AES)/JE surveillance: status of reporting system, existence of a national laboratory for confirmation of JE, data management; or if not in place, plans to establish AES surveillance.
    - Adverse event following immunisation (AEFI) surveillance: status of the reporting system, awareness of health care workers on AEFI reporting, AEFI data management, status of AEFI expert committee.
3. A communication strategy for the introduction of JE vaccine for campaigns and routine.
4. Vaccine coverage monitoring and reporting including a description of plans to track individual vaccination status.

5. Under the NVIP, countries are required to provide the estimated date for introduction into the routine programme, with appropriate plans to ensure that no cohorts are missed.

Meningococcal Conjugate A (MenA)

Mainstreamed applications: since the WHO prequalification of MenA infant presentation in December 2014, countries that have not yet introduced the vaccine can submit an application that includes both MenA mass preventive campaigns and routine immunisation.

Timing and coordination of the application for the three delivery strategies

- Applications for (a) routine introduction and (b) one time mini catch-up campaign should be prepared together and include a detailed NVIP for both mini catch-up and routine immunisation.
- Countries that are yet to conduct a preventive mass vaccination campaign are expected to submit one application including two components (preventive mass campaigns and routine immunisation) detailed in the NVIP, as well as a separate annex for the Plan of Action for the preventive mass campaign.

Although separate budgets are required for (i) VIG; (ii) one time mini catch-up campaign; and (iii) preventive mass campaigns, (iv) Controlled Temperature Chain countries are encouraged to identify cross-cutting synergies (e.g., communications, training).

Country PoA

The following aspects should be considered when developing the MenA PoA:

- Summarised Implementation Plan for the smooth transition for routine introduction, outlining geographical extent, timing of routine introduction, timing of mini catch-up campaigns, and projected coverage of each component. This should include how some of the lessons learned from preventive mass campaigns will be integrated into the one time mini catch-up campaigns and routine immunisation implementation.
- The geographical areas identified for the introduction of MenA in routine and catch-up campaigns should be the same areas as for the Gavi-supported preventive mass campaigns. Countries that have already conducted mass vaccination campaigns in geographical areas and/ or age groups other than the ones identified in their application must provide evidence of the areas, targets and coverage achieved (administrative and post campaign survey).
- Areas where MenA mini catch up will be conducted as well as the target population per district or region must be listed and include a source.
- Applications are expected to provide a rationale for expanding routine immunisation or one time mini catch-up campaigns to areas not covered by the preventive mass vaccination campaign. The rationale could include, but is not limited to: (i) anticipation of climate variability which could result in evolution of at-high-risk areas; (ii) maintenance of herd protection benefits of the mass campaigns in the meningitis belt, and (iii) enhancement of vaccine coverage in the second year of life.
- Countries should provide evidence that once MenA has been introduced in routine systems, they will be able to finance potential mop-up campaigns (to catch-up low routine coverage), if these are required in the future.

- Identify and summarise the possible linkages and complementarities between routine immunisation and mini catch-up campaigns. In particular, there should be strong coordination between the VIG for routine introduction and direct financial support for the one-time mini catch-up campaigns.
- A comprehensive national communication strategy and communication plan for routine immunisation, including the introduction of MenA into the routine immunisation system and the one time mini catch-up campaign.
- A description of the Meningitis control surveillance system: either a meningitis-specific system or preferably, an integrated surveillance system that includes Neisseria meningitidis A (NmA) with other diseases. Details of the status of the reporting system, data management processes, and the national laboratory and other systems for handling and confirmation of Meningitis cases related to all the sero groups, should be provided, or indicate if these are not in place.

For applications to **MenA preventive mass vaccination campaigns**, the following documents are required to be submitted:

- **Risk Assessment Report:** A risk assessment report is required to determine the epidemiological information on MenA circulation and relevant data, disease burden, the target population at risk, with a statement that WHO has endorsed the report.
- **District Prioritization Tool (DPT) report:** when the DPT methodology is used, the DPT report must be attached to the application.

Pneumococcal Conjugate Vaccine (PCV) and Rotavirus vaccine

Integrated disease prevention and control

As highlighted in the WHO/UNICEF Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD), the use of pneumococcal vaccines needs to be part of a comprehensive and integrated strategy alongside other related interventions such as oral rehydration therapy, exclusive breastfeeding, zinc treatment, improvements in water, sanitation, and hygiene, as well as proper nutrition. Countries are encouraged to provide the following information in line with GAPPD objectives:

- A high-level description of any existing interventions for the prevention and treatment of pneumonia and diarrhoea and the status of implementation;
- A description of how pneumococcal or rotavirus vaccination could be used to strengthen joint delivery of services and communication about healthy actions such as exclusive breastfeeding and hand washing with soap, safe drinking water and sanitation, and guidance around care-seeking behaviours; and
- A description of potential barriers to the integration of activities (e.g., policy development, management and coordination, supply and data management, service delivery, financing, health worker training, communication and social mobilisation, monitoring and evaluation).

GAPPD is considered an important initiative and Gavi's application will request information to develop an understanding of any existing interventions and any barriers to integration

activities. If a country would like to pursue GAPPD interventions, they may consider to apply for support through Gavi's HSS application process.

	The GAPPD is available here: www.who.int/maternal_child_adolescent/documents/global_action_plan_pneumonia_diarrhoea/en/

Yellow Fever (YF)

Gavi's aim to support a more comprehensive approach to YF control over a longer time period necessitates **long-term planning.** In addition to the documents noted in Section 5.3.1, an **annual EPI plan,** including detailed planning of all activities related to YF in that year, is required to be submitted with an application for support.

For countries requesting support for **preventive mass campaigns**, there is an expectation that they will maintain high routine coverage rate following campaigns. **Countries are required to first contact WHO for further guidance, at least 6-12 months before they can decide to submit their NVS application for preventive mass campaigns to Gavi.**

In order to receive support for preventive mass campaigns**, a country should have already introduced the YF vaccine into the routine EPI.** If a country has not yet introduced routine immunisation at the time of applying for preventive mass campaigns, the country should submit a statement with timeframes committing to introduce routine immunisation within 6 to 12 months after introducing campaigns. This is an important pre-condition as it ensures that the benefits of a preventive campaign will be sustained through the subsequent protection of newer cohorts.

Risk Assessments

A comprehensive risk assessment methodology was applied in the last eight years, implemented in several countries.[21] Countries that have already conducted risk assessments are expected to consult with the WHO governance structure to receive technical assistance to:

- validate the level of country risk;
- prioritise preventive mass campaign introductions; and
- validate vaccine dose requirements per phase and per year.

Moderate risk countries, including Eritrea, Burundi, Somalia and Tanzania and Zambia, that have not yet conducted risk assessments are not expected to submit an application for support unless if there is validation of identified risk (see Section 4.1.3 YF) in consultation with the WHO governance structure.

	For more information on conducting a risk assessment, refer to the WHO annual guidance notes, which will be updated annually. www.who.int/csr/disease/yellowfev/risk_assessment/en/

Achieving high quality yellow fever vaccination campaigns

All Gavi–supported campaigns must be planned and implemented using available tools and best practice to achieve high coverage (>95%), with coverage validated by independent

[21] Central African republic, Chad, Democratic Republic of Congo, Ethiopia, Guinea Bissau, Kenya, Niger, Rwanda, Sudan, South Sudan and Uganda.

reliable post campaign coverage surveys at least at the district and national level. These tools include:

- The WHO **Supplementary Immunisation Activity (SIA) Readiness Assessment Tool** to ensure that all preparatory activities have been conducted before the campaign. If required, technical assistance on the use of the tool can be requested from WHO.
- The WHO **SIA Planning and Implementation Guide.** Particular attention should be paid to:
    - Microplanning to identify the best strategies to reach the unvaccinated; and
    - Post-campaign independent monitoring.

	WHO SIA Readiness Assessment Tool is available at: www.who.int/immunization/diseases/measles/SIA-Field-Guide_DRAFT.pdf

Conducting a post mass campaign coverage survey

Following all Gavi-supported campaigns, countries are required to conduct an independent, statistically and technically sound post-campaign household coverage survey with probability sampling, to assess levels of vaccination coverage achieved, within 1 to 3 months after completion of the mass campaign.

For countries with multiple campaign phases, there must be a description of plans to conduct a post campaign vaccine coverage survey within 1 month after the completion of each phase to allow for subsequent campaign corrections.

Countries must include the budget for the post-campaign coverage survey in their request for support from Gavi, or provide justification for why this has not been included as part of the campaign operational budget (e.g. funding is already secured from a different source for the conduct of such a survey). Gavi expects that the post-campaign coverage survey be included in the campaign budget, or funded from another source. Gavi does not provide additional funds beyond the operational funding (adjusted according to the transition stage of the country) to support a coverage survey.

Identify synergies across investments

1. It is recommended that as countries develop their applications for YF support, they coordinate and identify, when possible, synergies with other approaches such as MCV1, Meningitis A routine immunisation, HSS support, Joint Appraisals and reviews of support to ensure possible linkages and alignment on improving coverage.

Human papillomavirus (HPV), Measles and Rubella (MR)

HPV MR	Additional information specific to HPV and Measles and Rubella are provided in separate documents, available at www.gavi.org/support/apply/.

5.4 Application review criteria and outcomes

An overview of the main application review criteria are provided below:

1. Basic functionality of country Coordination Forum (HSCC/ ICC or equivalent body) including a participatory approach to application development.
2. Evidence based analysis of current immunisation and health programme status and strong linkage with the support being requested in the application.
3. Robust analysis of barriers related to increasing coverage and enhancing equity in access and utilisation of immunisation services (including socio-economic, geographic and gender-related issues) and evidence driven linkage with programmatic actions to address these issues.
4. Demonstration of prioritising highest impact approaches and strategies
5. Realistic and logical description of activity plans and budgets, showing that activities are complementary and not duplicative across the different types of Gavi support.
6. Adequacy of planned measures to reduce related funding gaps and ensure longer term sustainability.
7. Updated and sound grant performance framework with proposed metrics, baselines and targets to track grant progress and results.
8. Robustness of financial management arrangements for financial support.
9. Adequacy of country's efforts to improve the availability, quality and use of immunisation data.

Once the IRC has reviewed applications, it will make recommendations on how to proceed with an application. The outcome of the IRC review will be to recommend either:

- **Approval**: The application meets all criteria and is recommended for approval. The IRC may identify minor issues for the country to address, which countries are required to resolve or develop a resolution action plan within 30 working days. Country responses will be reviewed by the Secretariat.
- **Resubmission**: This implies that there are material conditions that need to be met before approval can be considered and/ or there are major gaps in the proposal and/ or there is a need for a strategic re-think of the proposal. Consequently, the proposal would need to be substantially revised, and as such, needs to be signed and endorsed again by the Ministries of Health and Finance as well as the relevant Coordination Forum (ICC/HSCC or equivalent). If only additional information/ documents are required to clarify specific points raised by the IRC, countries should submit these within six months. In this case, countries are requested to enclose minutes from the ICC meeting endorsing the changes and additional clarifications. In the event that these additional documents or clarifications are not submitted in the noted timeline, countries would need to resubmit an entirely new proposal. When resubmitting, countries are recommended to provide a summary of the main changes made.

	Detailed IRC review criteria are provided in Annex 9, tailored to the relevant type of support. For CCE Optimisation Platform support, the IRC review criteria are provided in the support-specific guidelines.

6. CO-FINANCING REQUIREMENTS AND PROCUREMENT FOR VACCINES

6.1. Co-financing requirements for vaccine support

What is the aim of the co-financing requirement?

Gavi requires governments to share the cost of Gavi-supported vaccines by procuring a portion of the vaccine doses and devices required by the country, with Gavi covering the rest. This is to increase ownership of vaccine financing and ensure that countries are on a trajectory towards financial sustainability and the eventual phasing out of Gavi support.

Which vaccines and delivery strategies require co-financing?

The requirement for co-financing applies for Gavi support for the use of all vaccines in routine immunisation programmes and does not apply for Gavi vaccine support for use in campaigns (with an exception for measles and measles-rubella as detailed in Table 7 below).

Co-financing is not a payment made to Gavi. Countries co-procure a share of their new vaccines and injection safety supplies directly from a procurement agent. Co-financing obligations include the cost of vaccines, related injection safety devices (except for countries in the initial self-financing phase) and freight charges. Costs and fees of procurement agencies are not included.

What are countries' co-financing requirements?

Gavi classifies all eligible countries into 'co-financing groupings' based on their GNI pc, with the following minimum co-financing requirements by grouping:[22]

☆	If a country surpasses the threshold for its co-financing grouping as defined in Section 3, following the release of World Bank GNI pc data in July of each year, the country will be informed by Gavi in September of the same year. The first year in a new co-financing category is considered as a 'grace year' during which co-financing obligations from the previous group still apply. Countries thus have approximately just over one year after Gavi's communication to revise budgets and begin co-financing at the new level.

Initial self-financing countries are required to finance a small proportion of doses every year, equivalent to US$0.20 per dose of all vaccines requiring co-financing.

Preparatory transition countries are required to co-finance an increasing share of the weighted average price of the vaccine presentation. The total co-financing amount paid during the first year in this phase is used to calculate the fraction of the total cost of vaccines being co-financed by the country. This fraction will then increase by 15% every year throughout the preparatory transition phase for each of the co-financed vaccines.[23] New vaccines introduced during this phase are co-financed at the same proportion of the vaccine price as other vaccines.

[22] Please refer Section 3 on country eligibility for details on the specific GNI pc data used by Gavi.
[23] For example, in a given year a country could be financing 10% of the pentavalent vaccine price, 10% of the HPV vaccine price, etc. In the following year (following a 15% increase of the price fraction), this country would be financing 11.5% of the pentavalent vaccine price, 11.5% of the HPV vaccine price, etc.

Accelerated transition countries will have the following co-financing requirements: in the grace year, the co-financed share (or in case of measles and measles-rubella, the co-financed amount per dose) of vaccines increases by 15% (as it did in the preparatory transition phase). Afterwards, countries will see their co-financing requirements ramp up linearly over five years to reach the full projected Gavi price for the first year without Gavi support. The projected price is based on the weighted average price for the chosen vaccine presentation. If a country introduces a new vaccine after the grace year, the number of years with Gavi support is limited to 4 years.

At the end of the accelerated transition phase, countries are required to fully self-finance their vaccines. Countries should contact UNICEF Supply Division for more information on expected vaccine costs after transition.

	Co-financing requirements must be fulfilled by 31 December of each year. All countries are required to co-finance at the minimum levels described above (which will also be communicated to countries through the Country Notification Letter and the Decision Letter). Higher contributions are encouraged to facilitate achievement of financial sustainability. The co-financing commitments of a country should be clearly reflected in the cMYP.

	More information on Gavi's co-financing policy is available here: www.gavi.org/about/governance/programme-policies/co-financing/ Specific procedures apply if a country does not fulfil its co-financing requirements as detailed: www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/co-financing-default/

Vaccine-specific co-financing requirements

Countries applying for the following vaccines must make note of exceptions to Gavi's standard co-financing requirements.

Table 7: Vaccine-specific co-financing requirements and information

Vaccines	Co-financing requirements
Japanese Encephalitis (JE)	Countries will need to demonstrate plans to introduce JE vaccine into the routine programme following the completion of the catch-up campaign.
Measles and Rubella (MR)	Countries are now required to fully self-finance the first dose of measles vaccine in their national immunisation programme. Measles and Measles-Rubella follow-up campaigns implemented in 2017 will not require co-financing. Follow-up campaigns for implementation in 2018 onwards will include a co-financing requirement.
Pneumococcal (PCV)	Countries that have crossed the GNI pc eligibility threshold and meet Gavi's DTP3 coverage criteria will need to fully fund the costs of the vaccine.
Rotavirus	**For initial self-financing countries:** The co-financing amount is the same for a 2- or 3-dose schedule, adjusted to match that for the 2-dose vaccine. **For preparatory or accelerated transition countries:** The co-financing amount is based on the projected price for the chosen presentation and corresponding number of doses required.

HPV	Additional information specific to HPV is provided in a separate document, available at www.gavi.org/support/apply/

6.2. Procurement options for vaccines and vaccine devices

Countries receiving NVS support have the following two options for the procurement of vaccines and vaccine devices:

1. through a Gavi procurement agency (UNICEF or the Pan American Health Organization (PAHO) Revolving Fund); or
2. self-procurement, wherein countries receive the equivalent financial support directly from Gavi.

These options are available for all vaccines supported by Gavi, **except for the pneumococcal vaccine** (including the co-financed portion), which has to be procured through UNICEF due to the terms and conditions of the pneumococcal AMC. Countries procuring pneumococcal vaccine through UNICEF can still self-procure vaccine devices.

Requirements for self-procuring countries

All countries may procure their co-financed portion through UNICEF or an alternative mechanism (to be specified in the application). In the former option, countries should transfer funds directly to UNICEF as outlined in the Procurement Services Memorandum of Understanding between UNICEF and the country (either to UNICEF Supply Division or to the country office). Co-financed funds should never be transferred to the Gavi Secretariat. The country agrees with the procurement partner to share information with Gavi on the status of the purchase of co-financed portion of the vaccines and supplies.

Countries proposing to self-procure using Gavi funds are required to include a description of their procurement mechanism, details on how vaccine and vaccine devices will be procured and managed (including timings for procurement and their coordination with national planning and budgeting cycles), and assurances on the procurement of quality products (as described below) in their application.

To assure the procurement of quality products, countries are required to adhere to the following self-procurement conditions:

For vaccines:

- these need to be selected from the list of WHO pre-qualified products; or
- fully functional National Regulatory Authorities (as assessed by WHO) in both the country of manufacture and the country of purchase must assure that the proposed vaccine complies with WHO's definition of quality vaccines (as described in WHO's Technical Report Series)[24] and has no unresolved quality problems reported to WHO.

[24] Available at: http://who.int/biologicals/technical_report_series/en/

For auto-disable syringes and cold chain equipment:

- these products need to be pre-qualified under WHO's Performance, Quality and Safety system.
- for disposal boxes, countries must either procure devices that appear on the relevant WHO list of pre-qualified products or submit to WHO a certificate of quality from the relevant national authority.

Prior to self-procurement, Gavi will review the country procurement mechanism to assess whether it satisfies acceptable procurement methods and to make recommendations on minimum reporting requirements and possible improvements.

How self-procurement works

The country will receive the total funding for the procurement in a lump sum from Gavi only after the country agrees to conform to the above-mentioned Gavi recommendations. The amount of financial support provided by Gavi is based on the weighted average price for the vaccine (across all products and presentations) as forecasted by the Gavi Secretariat, in consultation with Gavi's procurement agencies. If a country's negotiated procurement price is higher than the amount of financial support provided by Gavi, the government is required to pay the difference in order to purchase enough vaccines to reach the target population. If the price is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.

	Further information on Gavi's policy for self-procurement is available here: www.gavi.org/about/governance/programme-policies/self-procurement-policy.

7. WHAT IS THE PROCESS FOR IMPLEMENTING AND RENEWING GAVI SUPPORT?

7.1. Application approval to vaccine delivery/disbursement

7.1.1. Programme Capacity Assessment

	Gavi no longer conducts a Financial Management Assessment, instead a Programme Capacity Assessment (PCA) is conducted to ensure that the country's programme management, financial management and vaccine and cold chain management are robust and transparent.

Prior to grant implementation, a Programme Capacity Assessment (PCA) is conducted by an external contractor appointed by Gavi, if not completed prior to proposal development. The PCA ensures that the country's programme management, financial management and vaccine and cold chain management are robust and transparent, in line with Gavi's Transparency and Accountability Policy (TAP), discussed in Section 7.4.1. Additional reviews relating to checks on unused funds in a country (if the country has previously received direct financial assistance) will also be carried out by the Gavi Secretariat.

Key terms are included in a Financial Management Requirement document, which forms an annex to the Partnership Framework Agreement (PFA) between Gavi and the country.[25] Note that applications will not be reviewed by the IRC if the country has not entered into a PFA with Gavi.

7.1.2. Guidance on vaccine introduction planning and Gavi's processes

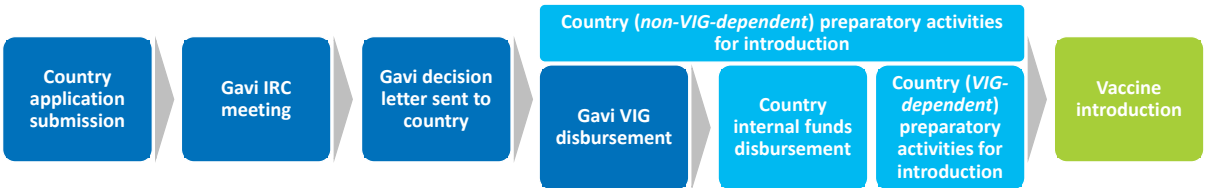
Alongside these arrangements, Gavi will also initiate internal processes for the transfer of funds to countries and/ or vaccine purchase (with UNICEF). The country should begin to plan activities to prepare for the vaccine introduction, for example discussing with the UNICEF country office regarding shipment plans, ensuring country product licensing requirements are met, etc.[26]

Countries should ensure that their target vaccine introduction date and plans for preparatory activities are compatible with the timelines for the likely receipt of Gavi funds. Specifically, planning should take into account the following considerations (refer to Figure 4):

- The VIG is typically disbursed within 5-6 months after Gavi approval/the issuance of the Decision Letter (which occurs 5-6 month after the country application submission, as noted above), with a goal of disbursing the funds at least 6 months prior to the target introduction date;[27]
- Adequate time needs to be provided for the country's subsequent internal disbursement of funds to the relevant national and subnational entities, and then for preparatory activities funded by the VIG.

This means that it will usually not be feasible for a country to introduce less than 15-18 months after the Gavi application submission deadline. Moreover, introducing 15 months after the application deadline requires the country to initiate time-intensive, less costly activities prior to receipt of the VIG.[28]

Figure 4: Overview of the process from application submission to vaccine introduction



	Guidance for countries on key issues to consider while developing operational plans for new vaccine introduction is available here: www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/guidance-for-developing-vaccine-introduction-plans/.

[25] The PFA sets out the terms and conditions by which Gavi provides support and the country undertakes to implement Gavi-supported programmes.
[26] Each country may have its own vaccine licensing requirement. The Ministry of Health is responsible for facilitating this process with National Regulatory Authority and the manufacturer of the chosen product. UNICEF Supply Division (SD) may provide support.
[27] This timeframe of 5-6 months assumes a country's swift response to clarification questions from Gavi.
[28] Examples of such activities are central-level work planning, informing lower levels, development of materials for social mobilisation and training, revisions of data tool templates, early launch ceremony preparation.

Gavi also provides guidance on how to develop demand generation plans suitable to the country context and needs. EPI managers are further encouraged to discuss the design of such plans with technical partners.

	Information on developing demand generation plans are available at: http://www.gavi.org/library/gavi-documents/guidelines-and-forms/guidance-on-developing-demand-generation-plans/

7.1.3. Changes in introduction dates and plans

The following key procedures apply if there are changes to the vaccine introduction dates and plans.

Delays in vaccine introduction following Gavi approval

The projected date for vaccine introduction must be no later than two years from formal notification of Gavi approval. Following the approval of a country's NVS application, if there are delays in vaccine introduction the following rules apply:

- If the country delays introduction for more than two years from the formal notification of Gavi approval, Gavi does not require a new application but requires new and updated information from the country on the planned introduction (e.g., including an updated introduction plan, targets and cold chain capacity).[29]
- If the delays are due to supply constraints, once supply is confirmed and discussions have taken place with the country on a new timeline for introduction, the country should send new and updated information on the planned introduction (e.g., including an updated introduction plan, targets and cold chain capacity).
- If in either of the above two situations, the cMYP has expired, the country needs to submit a new updated cMYP as soon as possible.

Changes in vaccine introduction and/or coverage plans

Countries are required to communicate to the Gavi Secretariat and its Partners (e.g. UNICEF Supply Division or WHO) if there are any changes in introduction and/or coverage plans (e.g., accelerated or delayed introduction or increases or decreases in vaccine use). Any changes should be endorsed by the relevant Coordination Forum (ICC, HSCC or equivalent). Revised plans should be communicated through the routine reporting to Gavi, however, in urgent situations, especially those impacting vaccine requirements or shipments, any changes should be brought to the immediate attention of the Gavi Secretariat and its Partners.

7.2. Grant monitoring and reporting

Grant monitoring and reporting on Gavi grants comprises periodic (quarterly or semi-annual) routing reporting through the grant performance framework, joint appraisals, financial reporting, campaign reporting and providing updates on general programme information. The

[29] For countries in the accelerated transition phase, delays in vaccine introduction due to supply constraints or circumstances outside the control of the country will not impact the country's co-financing.

majority of Gavi's grant reporting is conducted through the online country portal, which is accessible all year round (accessed via https://portal.gavi.org).

Details on Gavi's routine grant monitoring and reporting requirements are available in the Guidelines on Reporting and Renewals, available here: www.gavi.org/support/renew/

7.3. Grant review and renewal

As part of the ongoing grant cycle, Gavi reviews and renews its support to the country annually, which results in vaccine delivery and/ or cash disbursement for the next year.

The Gavi High Level Review Panel (HLRP), or an appropriate Secretariat body, reviews the joint appraisal report, monitoring data, as well as country renewal requests on projected needs/ plans for the next year (including any modifications to the original approved application, if required), and makes recommendations for continued funding as well as suggestions to strengthen grant performance and accountability. Countries should note that for the HLRP to be able to consider the renewal request, the relevant Coordination Forum (ICC, HSCC or equivalent) is required to review and endorse the joint appraisal report and renewal request. Grant renewals are ultimately approved by the Gavi Chief Executive Officer (CEO).

Details are available in the Guidelines on Reporting and Renewals, available here: www.gavi.org/support/renew/

7.4. General requirements for implementing all types of Gavi support

7.4.1. Transparency and accountability

Gavi support to countries, including all types of financial assistance as well as vaccines and vaccine devices, need to be managed in a transparent and accountable manner. Specifically, as per Gavi's Transparency and Accountability Policy (TAP), all Gavi support to countries should:

- Be used for the purposes stated within the country application or as agreed through any subsequent revisions;
- Be managed in a transparent manner with clear accountability structures for regular monitoring and oversight;
- Be supported by the provision of accurate and verifiable reports on a regular basis as specified by individual funding arrangements;
- Be managed within processes that meet national legal requirements and international standards regarding transparency, accountability, and anti-corruption.[30]

Additional related guidance on Gavi's requirements for direct financial assistance and vaccine support as well as how cases of misuse are approached are as outlined below. Gavi's Risk Policy provides an overarching framework for Gavi's risk management approach. For more information, see: www.gavi.org/Library/GAVI-documents/Policies/Risk-policy/.

[30] Gavi's TAP includes a set of key principles that govern all forms of oversight extended by Gavi with regards to transparency and accountability. These principles are in line with the commitments of the Paris Declaration, the Accra Agenda for Action and the Busan Partnership for Effective Development Co-operation on Aid Effectiveness.

New vaccine support

A country applying for or receiving Gavi vaccine support needs to identify vaccine oversight responsibility and accountability structures (e.g. the Ministry of Health, a Coordination Forum (ICC, HSCC or equivalent), NITAGs, Gavi implementing partners) to oversee compliance with Gavi's TAP with regards to vaccines and related devices. Gavi will work with the country and in-country partners in situations deemed to be associated with high risk for misuse of vaccine support to determine if, when and where to launch spot checks or more extensive assessments.

Misuse, suspected misuse and corrective action

The Gavi Secretariat, with support from its partners, will monitor country compliance with the TAP, including, if relevant, specific requirements for individual countries.

Should the Gavi Secretariat receive information suggesting that Gavi direct financial assistance or vaccine support has been misappropriated or misused, Gavi will launch an investigation in collaboration with the country. The purpose of such an investigation will be to evaluate whether misuse has occurred, and if so, to determine the value of misused funds. In cases where there is evidence of misuse, verified to the Gavi Secretariat's satisfaction, the Secretariat may, at its own discretion, suspend further direct financial assistance and begin the process of recovering misused funds. In general, in the case of misuse of vaccines, Gavi will not suspend vaccine programmes. However, other mitigation actions may be agreed on a case by case basis where misuse of vaccine support has been confirmed.

Gavi's TAP is available here: www.gavi.org/library/gavi-documents/policies/transparency-and-accountability-policy

7.4.2. Procurement of cold chain equipment

Country applications to Gavi that include the procurement of cold chain equipment are required to procure equipment that is pre-qualified by WHO under their Performance Quality and Safety (PQS) programme only. For NVS support, the purchase of non-PQS equipment will only be considered on an exceptional basis, with justification and advance agreement from Gavi.

7.4.3. Availability, quality and use of immunisation data

Quality and timely immunisation coverage data are essential for programme planning and monitoring. Establishing routine mechanisms for assessing, monitoring and strengthening the availability, quality and use of immunisation coverage data should be an ongoing institutionalised process. It should be accompanied by the development and monitoring of costed improvement plans, incorporating activities addressing all administrative levels and promoting local capacity-building in data collection, analysis and use, with timely and appropriate feedback mechanisms.

To support country efforts to strengthen the availability, quality and use of immunisation coverage data for strengthened programme management and accountability, Gavi requires that countries applying for all types of Gavi support:

1. Undertake routine monitoring of the availability, consistency and quality of immunisation coverage data through an annual desk review;
2. Conduct periodic (once every five years or more frequently where appropriate) in-depth assessments of routine administrative immunisation coverage data;
3. Conduct periodic (at least once every five years) nationally representative immunisation coverage surveys; and
4. Develop and monitor plans for improving immunisation coverage data quality as a part of their own core work plans for ongoing data strengthening. These plans should be part of the broader annual operational plan for immunisation.

	Annex 4 provides further details on data quality requirements, including technical recommendations.

ANNEX 1: ACRONYMS

AEFI	Adverse event following immunisation
AES	Acute Encephalitis Syndrome
AMC	Advance Market Commitment
CCE	Cold Chain Equipment
CEO	Chief Executive Officer
cMYP	Comprehensive Multi-year Plan for Immunisation
CSO	Civil Society Organisation
CTC	Controlled temperature chain
DHS	Demographic and Health Survey
DPP	Detailed Product Profile
DPT	District prioritisation tool
DTP3	Diphtheria-Tetanus-Pertussis, 3rd dose
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management
EYE	Elimination of Yellow Fever Epidemics
FMA	Financial Management Assessment
GAPPD	Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea
GMR	Grant Management Requirements
GNI	Gross National Income
HLRP	High Level Review Panel
HMIS	Health Management Information Systems
HPV	Human Papillomavirus vaccine
HR	Human Resource
HSCC	Health Sector Coordination Committee
HSIS	Health System and Immunisation Strengthening
HSS	Health System Strengthening
ICC	Inter-Agency Coordinating Committee for Immunisation
ICG	International Coordination Group
IEC	Information, education, and communication
IHP+	International Health Partnership
IRC	Independent Review Committee
JA	Joint appraisal
JE	Japanese Encephalitis vaccine
JRF	Joint Reporting Form
M&E	Monitoring and Evaluation
MCV1	Routine measles first dose
MCV2	Routine measles second dose
MenA	Meningococcal A Conjugate vaccine
MR	Measles and Rubella
MICS	Multi indicator cluster surveys
MoH	Ministry of Health
MR	Measles and Rubella (combined vaccine)
NGO	Non-governmental organisation
NITAG	National Immunisation Technical Advisory Group
NRA	National Regulatory Authority
NVIP	New Vaccine Introduction Plan
NVS	New and Underused Vaccine Support
Ops	Operational Support for Campaigns
PAHO	Pan American Health Organization
PCA	Programme Capacity Assessment
PCV	Pneumococcal Conjugate Vaccine
PEF	Partnership Engagement Framework
PFA	Partnership Framework Agreement
PMVC	Preventive mass vaccination campaign
PoA	Plan of Action
PQS	Performance Quality and Safety
RA	Risk Assessment
RV	Rotavirus Vaccine

RVGE	Rotavirus gastroenteritis
SAGE	Strategic Advisory Group of Experts on Immunization
SCM	Senior Country Manager
SIA	Supplementary Immunisation Activity
TAP	Transparency and Accountability Policy
TOR	Terms of Reference
VIG	Vaccine Introduction Grant
VVM	Vaccine Vial Monitor
YF	Yellow Fever
YFI	Yellow Fever Initiative
YFV	Yellow Fever vaccine

ANNEX 2: GAVI'S NEW APPROACH ON COUNTRIES' ACCESS TO FINANCIAL SUPPORT

Gavi is introducing a new approach to the way it provides financial support to countries in 2017. Countries requesting new Health System Strengthening (HSS) support in 2017 will follow a new application process that integrates all of Gavi's support to the country. This new approach aims to contribute to **sustainably enhancing immunisation coverage with a focus on reducing inequities** (i.e., geographic, socio-economic or gender-related barriers or marginalised populations) in countries.

The key features of this new approach include:

- Bringing together all types of vaccine and financial support (i.e. HSS, complementary allocations, New and underused Vaccine Support (NVS) and Cold Chain Equipment (CCE) Optimisation Platform) into a single portfolio view to facilitate longer-term predictability, visibility on complementarities, and more effective grant planning and budgeting. **Note that, countries requesting new HSS support in 2017 will include, requests for NVS or CCE Optimisation Platform in that process and will not need to make separate requests in 2017.**
- Strengthening in-country engagement and dialogue across country stakeholders and Alliance partners, moving towards a holistic approach to priority setting and programming of Gavi support, including operational planning.
- Differentiation to better support the needs of different types of countries (e.g. fragile countries, countries with low capacity, and/or countries in transition).

In addition, Gavi has integrated the various forms of Gavi financial support to countries under the umbrella of **'Health System and Immunisation Strengthening (HSIS)'.** This includes the following forms of financial support:[31]

- Health System Strengthening (HSS); and
- Complementary allocations including: Performance Payments (PBF reward), Vaccine Introduction Grants (VIGs), Operational support for Campaigns (Ops), Product and Presentation Switch Grants, Operational support for Outbreak Response Campaigns, Operational support for Human Papillomavirus (HPV) Vaccine Demonstration Projects and Transition Grants

While the Alliance has made considerable efforts to strengthen Gavi's HSIS support to date, evidence has shown that programmes could benefit from an increased focus on equitable coverage with prioritisation of evidence-based approaches, and that the complexity of having multiple windows of financial support was hindering effectiveness, efficiency and alignment of grants.

The new approach to HSIS aims to address these issues by targeting investments that contribute to sustainable improvements in coverage and equity, and moving towards integrated planning and budgeting across all HSIS support to improve synergies across

[31] The following grants are not included as part of HSIS: Gavi supported vaccines or related injection safety devices, resources provided through the Partners' Engagement Framework (PEF) and Gavi's contribution to cold chain equipment procured through the CCE Optimisation Platform.

investments, promote holistic planning and management, and reduce the opportunity costs from applying to multiple separate funding windows.

☆	Gavi will be phasing in this new approach for countries that are requesting new HSS support in 2017. Gavi will contact these countries directly regarding these changes. For countries with ongoing HSS support, that are applying only for new vaccine support or for the CCE Optimisation Platform in 2017, several key principles of the new approach have been incorporated in this set of guidelines, mainly in relation to country programming for VIGs and Operational support for campaigns. The application process for these countries remains unchanged from previous years and is reflected in this set of guidelines.

The new approach to financial support (i.e. HSIS) will result in two key types of changes:

1. Programming for HSIS support i.e. "what" can be funded

The focus will be on the strategic prioritisation of investments that would help "reach the unreached" mainly through:

- **Strengthening the focus on equity in coverage,** targeting investments that contribute to sustainable improvements in coverage in low performing areas and among neglected populations across all countries.
- **Strategic Focus Areas**: Investments in a number of key areas that are recognised as important bottlenecks to improving immunisation coverage with a focus on reducing inequities, including:
    - strong **leadership, management** and **coordination**, including amongst government teams/ departments responsible for managing EPI, coordination forums (e.g. ICCs, HSCCs), and immunisation technical advisory groups (e.g. NITAGs).
    - an effective and efficient **supply chain** system that supports the successful roll-out of new vaccines and more equitable access to hard-to-reach populations.
    - strengthened **information systems**, alongside efforts to improve **data quality** over time.
    - relevant interventions aimed at **creating awareness** and **demand generation** for immunisation services.
- **Tailoring support by transition stage** to promote long-term programmatic and financial sustainability of HSIS investments. For example, initial self-financing countries (i.e. low income) are encouraged to use HSS grants to address issues requiring long-term systemic change. Such countries may also use HSS grants to support the recurrent costs of immunisation programmes (including human resource remuneration and transport costs) providing there is a clear justification, including a strong link to coverage and equity outcomes. However, countries in the preparatory transition phase or accelerated transition phase are discouraged from using HSS grants for recurrent costs.
- Prioritisation of investment needs identified through Gavi's **Programme Capacity Assessments (PCAs)**, described in Section 7.1.1 above.
- **Targeted and efficient use of financial support for vaccine introductions, campaigns and product switches** (i.e. VIGs, Ops and product switch grants,

respectively) – considering both synergies with other Gavi investments as well as how best these grants can be used to strengthen the routine immunisation system and reduce dependence on campaigns. There should be robust incentives to reward performance and perverse incentives should be discouraged (e.g., routine per diems for health workers and supervisors) in order to promote sustainability. Countries should also leverage these grants when multiple vaccines are being introduced concurrently.

The changes relating to the other forms of HSIS (such as VIGs, Ops, etc.) have been included in these guidelines. Specific guidance for programming of HSS support will be made available directly to the countries applying for new HSS support in 2017.

	Section 4.1.2 provides guidance on programming of VIGs and Ops, reflecting the new approaches being employed through HSIS. Changes for product and presentation switch grants are available in the Guidelines on Reporting and Renewals, available here: www.gavi.org/support/renew/

2. Processes for accessing and implementing HSIS support i.e. "how" the support will be provided.

	The processes described here are only applicable for those countries applying for HSS support in 2017, and not for those applying for only NVS or CCE Optimisation Platform support. Regarding the latter, the application process remains unchanged from previous years (reflected in this set of guidelines) despite the changes to the programming of VIGs and Ops, as mentioned above,

Gavi is also changing how countries can request new support, with the aim of moving towards an integrated and responsive support model to foster synergies across investments. Some examples of what this means in practice include:

- Emphasis on evidence-driven requests for support that take into account assessments and lessons learned.
- Prioritisation of approaches and strategies with the highest potential for impact.
- Rather than having separate processes for countries to apply for different forms of support (vaccines and HSIS), there will now be an integrated long-term planning process at the country-level to set priorities and targets, aligned with national health and immunisation plans. This will take place approximately every five years, aligned with the national strategic immunisation period.
- The emphasis will shift from proposal development to operational planning through the development of integrated operational budgets and work plans. This is intended to allow countries to identify opportunities for synergies and efficiencies across multiple HSIS grants. It is also intended to support countries in implementation readiness. There will also be regular (annual) updating of these operational budgets and work plans in response to new data, evidence, and implementation experience, leveraging the Joint Appraisal process.
- Residual funding from other HSIS grants and savings following introductions, campaigns and product switches should be rolled into the HSS grant as operational budgets and work plans are updated. Funding cannot be reallocated from the HSS grant to support introductions, campaigns or product switches.

ANNEX 3: LIST OF ELIGIBLE COUNTRIES AND CO-FINANCING GROUPINGS

Eligibility status	Eligible for new support			Eligible to apply for new support in 2017 (grace year)	No longer eligible	
Co-financing grouping	**Initial self-financing countries**		**Preparatory transition countries**	**Accelerated transition countries**		**Fully self-financing**
List of countries	Afghanistan Benin Burkina Faso Burundi Central African Republic Chad Comoros Congo DR Djibouti Eritrea Ethiopia The Gambia Guinea Guinea-Bissau Haiti Korea DPR Liberia	Madagascar Malawi Mali Mozambique Nepal Niger Rwanda Senegal Sierra Leone Somalia South Sudan Tanzania Togo Uganda Zimbabwe	Bangladesh Cambodia Cameroon Cote d'Ivoire Kenya Kyrgyzstan Lesotho Mauritania Myanmar Pakistan Sao Tome and Principe Sudan (Republic of) Tajikistan Yemen Zambia	Ghana India Lao PDR Nigeria Solomon Islands	Angola Armenia Azerbaijan Bolivia Congo Republic Georgia Nicaragua Papua New Guinea Timor-Leste* Uzbekistan Vietnam*	Bhutan* Cuba* Guyana Honduras Indonesia* Kiribati Moldova Mongolia* Sri Lanka* Ukraine*

**Accelerated transition countries that are still eligible to procure PCV directly from UNICEF Supply Division under the AMC.*

ANNEX 4: DATA QUALITY REQUIREMENTS FOR ALL TYPES OF GAVI SUPPORT

This annex provides guidance to countries to meet the data quality requirements for all types of Gavi support. In general, the requirements are consistent with principles of good data practice supported by Alliance partners, including encouraging country programmes to align immunisation coverage data quality related activities within the larger health sector context and promoting a "culture of data use" wherein there exists appropriate ownership, use and feedback of data that allow for timely and well-informed actions to optimise the performance and impact of the programme while increasing accountability and strengthening health systems.

☆	Country programmes are encouraged to budget for requirements 1-3 through funding requests if additional funds for activities are required. Ideally, if additional external funding is necessary, countries will include a graduated budgeting scheme that promotes eventual transition to national financing.

Requirement 1. Routine monitoring through annual desk review of immunisation coverage data

Countries receiving Gavi support are required to conduct an annual desk review in order to assess changes in data quality and to develop and/or monitor the implementation of plans to improve data quality.

Countries are encouraged to focus the annual desk reviews on describing current situations and practices mainly related to immunisation coverage data across sources of data (i.e. whether data are collected by the immunisation programme or through an integrated health management information system (HMIS)), while seeking to understand root causes that drive performance in order to inform corrective activities and interventions to be incorporated into plans for improving data quality. The reviews should also be used to monitor whether data quality strengthening activities are being implemented and sustained over time.

For the annual desk review, it is **recommended** that countries:

- Conduct the annual desk review at the national level, with or without partner support, as deemed necessary by the country.
- Closely link the annual desk review to the national planning process (i.e. annual health sector review, national EPI evaluations) to ensure that any issues identified during the review can be appropriately included in a data quality improvement plan. This would ideally be as part of the EPI annual plan and/or in the comprehensive multi-year plan (cMYP). It is also recommended that the annual desk review is conducted prior to any scheduled Gavi joint appraisal (JA) mission. An option is to schedule the annual desk review at the same time as the national programme prepares their data to complete the WHO/UNICEF Joint Reporting Form (JRF) on Immunisation.
- Track progress on indicators of data quality summary measures that incorporate multiple dimensions including, but not limited to: a) completeness and timeliness of reporting across administrative levels and data sources (e.g. EPI and HMIS data); b) analysis (i.e. trend) and consistency of reported numerator (i.e. number of children vaccinated), denominator (i.e. number of children in the target population) and across geographies (or other sub-national disaggregation); and c) verify reporting consistency between sources.

- Develop and monitor improvement indicators to assess progress in development and implementation of the plan for improving data quality, including updating plans as appropriate.

Some examples of types of analyses that may be included but not limited to:

- assessment of the percentage of expected data reports (e.g. district, facility) that are actually received by each level on an annual basis;
- assessment of the presence of established reporting dates and a standard in the country for assessing timeliness of reporting (e.g. from district, facility levels);
    - if yes to above, assessment of the percentage of submitted reports that are received on time in a given period, usually in the previous year
    - if no to above, programme needs to establish standard procedures for reporting timeliness assessment
- assessment of data consistency between vaccines and doses and across geographies (or other sub-national disaggregation); and
- assessment of any differences between data collected and processed via EPI vs. HMIS, where appropriate.

	WHO EPI Systems and Data Assessment WHO Data Quality Review Tool Kit

Requirement 2. Periodic in-depth assessment of routine administrative immunisation coverage data

Countries receiving Gavi support are required to conduct an in-depth review of the routine administrative reporting system once every five years, or more frequently where appropriate. In most instances this requirement will be satisfied by a data quality self-assessment (DQS), or an EPI review including a data quality module. In order to reduce bias, the assessment should involve external evaluators and/or national evaluators from outside the regions being assessed.

For the periodic in-depth assessment of routine administrative immunisation coverage data, it is **recommended** that countries:

- Align the in-depth review of routine data reporting with the national planning process (as also indicated above).
- If a country programme has never conducted a data quality self-assessment or other in-depth review of the routine administrative monitoring system, or if there is insufficient institutional memory since the last conducted assessment, consider seeking partner technical assistance for planning and implementation of the in-depth assessment.
- Incorporate data sources and information systems (e.g. EPI and HMIS, where appropriate) used in-country, from the point of contact with immunisation services to the national level (i.e. across all data collection and reporting levels), in the scope of the assessment. Data of interest include the number of children or other targeted groups in a given target population vaccinated with a given vaccine during a specified

period of time as well as the data sources and processes used to obtain the denominators for calculating administrative immunisation coverage.

- Include assessments of data agreement between the various administrative levels, as well as data and reporting completeness and timeliness.
- Describe in full in report form the administrative recording / reporting process(es), tools (paper and electronic) and data flow in the country from the point of contact with immunisation services to the national level.
    - This includes a description of the information systems (norms and manuals, tools, and human resources roles and responsibilities) that are in place, particularly if there are separate systems for EPI and HMIS, to produce the data.
- Describe in full in report form the methods used (including sampling strategy), results and recommendations of the in-depth assessment of the routine administrative reporting system.
- Utilise implementers for the assessment from areas other than their own geographical programme area and include a description of the implementers in the report.
- Provide documentation that the results, or a report, from the in-depth assessment were shared in a timely manner with decision-making bodies (i.e. relevant Ministry of Health Departments, Coordination Forum such as ICC, HSCC or equivalent) and that corrective actions were or will be included in an improvement plan, ideally as part of a country immunisation or other health sector plan.

	WHO Systems and Data Assessment Module Annex 1. Questionnaires for Field Visits WHO data quality self-assessment tool: whqlibdoc.who.int/hq/2005/WHO_IVB_05.04.pdf

Requirement 3. Periodic population-based surveys to measure immunisation coverage

Countries receiving Gavi support are required to conduct a high quality, nationally representative survey assessment of immunisation coverage at least once every five year period with interim / targeted surveys, as appropriate. For many countries the survey-based assessment requirement may be satisfied through the conduct of a Demographic and Health Survey (DHS), Multiple Cluster Indicator Survey (MICS) or other population-based, nationally representative multi-indicator survey designed to collect data on a wide range of population and health topics, including immunisation, in a standardised manner.

In countries where a DHS, MICS or other multi-indicator survey is not periodically conducted, it may be necessary for the national immunisation programme to plan and implement a stand-alone immunisation coverage survey. In either case, it is ideal for the immunisation coverage survey assessment to be designed to support a country's immunisation programme and planning.

The following key principles are highlighted for countries and should be kept in mind when considering a survey:

- Survey efforts should foster country ownership, be country-driven with the involvement of the national immunisation programme staff, and be viewed as an opportunity to build national capacities.
- Survey assessments should be included in a country's national plans and involve the National Immunisation Technical Advisory Group (NITAG) and the relevant Coordination Forum (ICC, HSCC or equivalent), as appropriate, very early in the process.
- Countries are encouraged to align survey implementation with existing national planning cycles based on the cMYP and health system strengthening activities.
- National immunisation programme staff should be involved in the development of the survey questionnaire and training, and interpretation of data results.
- Interim assessments of immunisation coverage might be considered where appropriate to assess coverage in select sub-populations defined by person and/or place characteristics to further guide programme planning for targeted intervention and corrective action. Oversampling during a national survey, or other similar strategies, could be considered to assess coverage of special or at-risk populations.
- Countries with very large birth cohorts may consider conducting sub-national surveys.
- In special circumstances, for example where coverage is known to be very low (i.e. under 50%), the survey requirement may be waived in favour of investing in activities to increase immunisation coverage. The country should contact the Secretariat and Alliance Partners to discuss further.

Technical partners are available to provide technical consultations and assistance as appropriate and agreed by the country during the planning and implementation of surveys, including data analysis, as well as supporting country-led interpretation and use of survey results.

When a recent DHS, MICS or other standardised multi-indicator survey is not available, countries are encouraged to refer to the World Health Organization's most recent update of the immunisation coverage cluster surveys reference manual (see Suggested Resources below). The immunisation coverage survey has been used extensively over the past 30 years to measure immunisation coverage at national and sub-national levels, and the reference manual was updated most recently in 2015.

When conducting an immunisation coverage survey, it is **recommended** that the survey:

- Be population / community-based and representative.
- Target a full birth cohort that has completed its infant immunisation schedule, most often children aged 12-23 months for vaccines recommended during the first year of life (i.e. 0-11 months), as they represent the most recent cohort of children who should have completed their infant immunisation schedule. In countries where the recommended age for vaccination of interest in the survey is administered between 12-23 months (e.g. MCV1 if recommended at 12 or 15 months, MCV2 and DTP-containing vaccine), it is recommended that the survey also target a cohort aged 24-35 months.

- Be consistent with the EPI schedule(s) recommended for all people in the target population, i.e. takes into consideration changes to the immunisation schedule in the period being assessed.
- Be of sufficient sample size relative to the target population of interest and the purpose of the survey (e.g. monitoring programmatic objectives or testing hypotheses).
- Allow selection of households to be completed centrally by the survey coordinator or statistician and not by field teams.
- Utilise standardised survey questionnaires (see WHO reference manual) or questionnaires that have been reviewed by an external expert committee to ensure conformity with best practice and validated questions for collecting data on immunisation coverage.
- Include a report with:
    - sufficiently detailed description of the rationale and purpose of the survey, scope of the survey, target population, sampling procedures, planned sample size, and strategies used to minimise bias (e.g. revisits to target populations), in order to facilitate the interpretation of the results and replication of the survey in the future;
    - sufficiently detailed description of the actual sample from whom data on vaccination history were collected.
- Conduct the appropriate statistical analysis given the survey sampling design.
- Report on coverage by vaccine and dose, if pertinent, using standard reporting formats (see WHO reference manual) and by documented vaccination (in home-based or facility-based records) as well as caregiver history in the absence of documented evidence of vaccination history. However a premium should be placed on documented evidence of vaccination history (from home-based records, and where possible, from facility-based records).

Countries conducting surveys following supplementary immunisation activities (SIAs) or vaccination campaigns are encouraged to consider the above recommendations as well.

	World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual, 2015: www.who.int/immunisation/monitoring_surveillance/Vaccination_coverage_cluster_survey_with_annexes.pdf?ua=1

Assessment of applications in meeting data quality requirements

Country achievements and progress over time with regards to data quality form a key criteria for review of applications for all types of Gavi as well as ongoing routine grant monitoring, review and renewal. It is **important for national immunisation programmes to take seriously their responsibilities in improving the collection, analysis, and use of data to measure and improve immunisation program performance** through appropriately resourced plans and activities.

ANNEX 5: GAVI BUDGETARY, FINANCIAL MANAGEMENT & AUDIT REQUIREMENTS

	Gavi has created Programme Capacity Assessments (PCA), a new approach to risk management and fiduciary oversight that replaces the Financial Management Assessments (FMA). The PCA examines the capacities in Programme Management, Financial Management, and Vaccine & Cold Chain Management.

	• New budget templates have been developed for all applications, which are now mandatory for all applications. • Recommended financial reporting templates will be revised based on the new budget templates, which will apply to reporting periods commencing on or after 1 January 2017. • With the discontinuation of the Annual Progress Report (APR) and associated submission date, countries are required to provide standard financial reporting per the timeframes noted in the guidance on financial management and audit requirements.

	For detailed guidance on financial management and audit requirements, as well as the recommended formats for financial reporting, see: www.gavi.org/support/renew. The Reporting and Renewals guidelines is also available at this link. For detailed guidance on financial management requirements, see: www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/guidance-on-financial-reporting/.

In accordance with the IHP+ principles of national ownership, countries are encouraged to manage Gavi funds using their own country systems. Equally, all countries and organisations receiving Gavi funding must also comply with the principles of transparency and accountability, presented in Gavi's TAP.

The TAP requires the country and implementing entities of all programmes financed by Gavi funds to maintain financial management systems acceptable to Gavi. A country or an entity's financial management arrangements are considered acceptable to Gavi if its budgeting, financial management, accounting, internal controls, financial reporting and auditing arrangements:

1. are capable of correctly and completely recording all transactions and balances relating to the programme;
2. delegate authority and responsibility for budgetary ownership and project management;
3. instigate fiduciary discipline and accountability for expenditure against budget on an ongoing basis;
4. facilitate the preparation of regular, timely and reliable financial reports;
5. safeguard the programme's assets, and
6. are subject to auditing arrangements acceptable to Gavi.

In countries where fiduciary assessments have revealed capacity concerns or heightened fiduciary risk, the country shall put in place alternative funding mechanisms and fiduciary arrangements (e.g. a parallel system or ring-fenced approach). However, Gavi will aim to prioritise country systems where possible and encourage countries to build long term capacity, and in particular, established and disciplined financial and budgetary management capacity.

Part of Gavi's risk management approach, the Programme Capacity Assessment (PCA) covers three main areas of assessment including: Programme Management, Financial Management, and Vaccine & Cold Chain Management replacing the previous Financial Management Assessment (FMA). The aim of the PCA is to identify capacity gaps and support Government in addressing these gaps through technical support and, if necessary, reallocation of financial support. A PCA, including the financial management portion, will be conducted prior to the development of the new proposal or at the start of a new grant period once a grant has been recommended for approval, and will be reassessed every 3-5 years. The assessment is conducted by an external contractor who will work closely with the SCM and Gavi PCA team. The PCA will build on and utilise prior Gavi and other partner evaluations to avoid duplication.

Stages of the PCA process

A PCA includes the following five phases:

1. **Planning the PCA**: Appropriate timing is agreed between the country, Gavi and the Gavi-identified contactor. The PCA team will send detailed terms of reference to the country at least four weeks before the PCA.
2. **Tailoring the PCA scope for each country**: PCA team and SCM draft Scoping Note to set our key priorities for assessment tailored to country needs.
3. **Desk Review**: External contractor reports preliminary findings, based on a document review.
4. **In-Country review**: The SCM will introduce the external contractor to the country and outline the PCA process, including documents to be reviewed and people to be interviewed. During the country visit, the contractor will use the PCA tool, covering programme management, financial management, and vaccine & cold chain management issues. The contractor will submit key findings and recommendations to Gavi.
5. **Review and finalize**: PCA team and SCM team review report and agree on key recommendations for grant implementation. SCM will then discuss and agree these with the country.

General requirements relating to all types of financial support

Continued disbursement of Gavi grants to the country are dependent on:

- Adhering to the principles of Gavi's TAP and implementing and complying with the Grant Management Requirement (GMR) provisions;
- Instigating suitable fiduciary discipline and procedures, through continuous budgetary ownership and accountability and maintaining an ongoing and regular review of expenditure against budget;
- Timely submission of annual financial statements in line with the guidelines on financial management and audit requirement, and any relevant provisions of the PFA;;
- Ensuring annual external audits relating to Gavi grants are executed according to the guidelines on financial management and audit requirement and to the provisions of the PFA;
- Overall compliance with Gavi's Terms and Conditions set out in the PFA.

The minimum requirements to which the country must adhere for budgetary and financial management are the following:

1. Cash disbursed must be used solely to fund Gavi's programme activities. These funds may not be used to purchase vaccines or meet Gavi's requirements to co-finance vaccine purchases, and shall not be used to pay any taxes, customs, duties, toll or other charges imposed on the importation of vaccines and related supplies. The government shall make reasonable efforts to set up appropriate mechanisms to exempt from duties and taxes all purchases made locally and internationally with Gavi funds.
2. The country shall maintain budgetary and financial management systems in accordance with the provision of Gavi's TAP for cash support.
3. All procurement activities required for Gavi programmes and financed by Gavi shall be conducted in the most transparent, fair and efficient manner and ensure value for money, in accordance with the national procurement requirements (as indicated by the country as part of the Gavi budget template) or any other procurement procedures agreed upon between Gavi and the recipient.
4. Funds will be managed according to agreed budgets in a transparent and accountable manner with financial records and accounts meeting national requirements for budgeting, financial management, accounting, internal controls, reporting and auditing. Gavi funds should be incorporated in the national budget.
5. Gavi funds must be used in line with the activities and budget set out in the approved application and shall be subject to oversight by the in-country Technical Advisory Group or the relevant Coordination Forum (ICC, HSCC or equivalent). The funds must be used for the expenditures of the planned activities as approved by the Coordination Forum.
6. The country shall prepare periodic financial reports for all types of financial support depending on the frequency determined in the PFA, and as amended by the GMR, comparable with the agreed budget and in the same format as the annual report. The country shall provide grant specific Financial Statements of Gavi support in accordance with the provisions of Section "Audits and Records" of Gavi's Grant Terms and Conditions and Guidance for Financial Statements. Each audit of the Financial Statements shall cover the period of one government fiscal year of the country, commencing with the fiscal year in which the first payment was made under the Gavi support. The Financial Statements must include a statement of expenditure against approved budget.
7. The External Audit for Gavi support to the country shall be performed by independent external auditors (Office of Auditor General or private auditing firms) with suitable qualifications and experience that are acceptable to Gavi and in line with the Terms of Reference provided by Gavi and agreed with the country.
8. The External Audit shall cover all aspects of Gavi support implemented in the country. The audit shall include verification of expenditure eligibility, procurement, budget and financial management, and physical inspection of goods, works and services acquired.
9. The audited Financial Statements for each such period shall be provided to the Gavi Secretariat no later than six months after the end of such period.

10. Gavi reserves the right to commission an external audit of the accounts at any time during or after the duration of the Gavi support. Gavi in-country partners and the members of the relevant Coordination Forum (ICC/HSCC or equivalent) can communicate any concerns they might have about the use of funds to the Gavi Secretariat at any time through the Ethics hotline available on Gavi website.[32]

During the course of the grant and as part of on-going monitoring, Gavi may conduct monitoring reviews and programme audits to ensure the above requirements are met.

Specific financial requirements in the case of fund transfers to Civil Society Organisations (CSOs)

The CSO or CSO Network/Consortium must:

- provide 3 most recent published financial statements, audited by a qualified independent external auditor; and will be subject to the TAP and PFA process (as described above).
- agree to provide annual financial statements in the format prescribed by the Gavi Secretariat.
- organise an independent external audit on an annual basis under Terms of Reference provided by Gavi and submit a copy of this external audit report within 6 months of the end of their financial year.
- agree to cooperate, if required, with a 3rd party audit of any Gavi CSO funds that it receives, if deemed necessary by the Gavi. The cost of such an audit would be covered by Gavi.

[32] https://secure.ethicspoint.eu/domain/media/en/gui/101802/index.html.

ANNEX 6: GUIDANCE ON COUNTRY COORDINATION FORUMS

Recognising the critical role of Coordination Forums (ICC/HSCC or equivalent), Gavi has developed the following guidance to help countries strengthen Coordination Forums functioning to better support national immunisation and health sector goals. Coordination Forums should bring together governments and other relevant key immunisation stakeholders in a **participatory and transparent manner** and with the **objectives** (relating to all programmes, not just Gavi support) to:

- Provide strategic direction, oversight and transparency on the Expanded Programme on Immunisation (EPI) and related health sector programmes to ensure sustainable coverage and equity of immunisation;
- Ensure a coherent view on strategy, planning, funding and performance of the EPI programme within the context of the broader health system
- Promote complementarity and harmonization of activities and investments among stakeholders
- Promote linkages of EPI with the broader health system
- Ensure that the EPI and the coordination of the programme remains government-owned and government-led

The design and functions of Coordination Forums vary widely across countries, and it should be the **responsibility of each country's government** to decide what design and functions are best suited to national needs. Typically, however, coordination should **reside at a level in the health ministry with the authority to link to the broader national health planning and financing system, and authority relative to immunisation**. At a high level the **common responsibilities of Coordination Forums** should include ensuring strategic direction and oversight on key strategic topics. These **strategic topics** generally fall into **five categories**:

1. Strategic planning of the programme (e.g. review and approve comprehensive strategic planning)
2. Programme financing (e.g. create long term visibility on resources and facilitate resource mobilization)
3. Coordination (e.g. create transparency and promote coordination amongst stakeholders, ensure critical issues rise up from the operational/technical level to be addressed)
4. Operational planning and performance oversight (e.g. input into operational work plan, oversee progress of the overall EPI program)
5. Information dissemination (e.g. share relevant information for the EPI programme, key stakeholders, and Gavi)

Beyond these categories, countries often have coordinating bodies at a more operational and technical level. The guidance in this document is intended to apply to coordination forums that perform the high-level strategic functions mentioned above, rather than the more detailed operational and technical coordinating functions.

The **objective of this Coordination Forum guidance** is designed to enable countries to build on existing coordination structures and achieve the objectives of the Coordination Forums

while ensuring government ownership and leadership. It is part of a broader **'support package'** for countries to help ensure functionality of their Coordination Forums. This guidance document includes **requirements** and **recommendations** with regard to**:**

- **Coordination Forum membership:** Guidance on the types of members to be represented, with descriptions and examples.
- **Coordination Forum mandates:** Guidance on the key strategic mandate.
- **Coordination Forum governance:** Guidance on governance best practices and supporting activities for the Coordination Forum to function effectively.

In many countries, both an ICC and HSCC exist, in which case these requirements and recommendations would only apply to one body. Gavi recommends the ICC is best positioned for this and recommends creating strong linkages between the ICC and HSCC to ensure alignment, such as structuring the ICC as a sub-committee of the HSCC, holding joint meetings or exploring other means of cooperation.

To be **eligible for NVS, CCE Optimisation Platform and HSIS support**, Gavi asks countries to ensure a **basic functionality** of their Coordination Forum. Countries can demonstrate this by adhering to the **requirements** as these are seen most critical to the functioning of the Coordination Forum. A set of documents submitted along with the grant application will help the Independent Review Committee (IRC) or an equivalent review body to assess adherence. Gavi recognises that improving the functionality of Coordination Forums is an ongoing effort for countries that may take some time. Therefore, there will be a degree of flexibility in approving NVS and CCE Optimisation Platform support if the Coordination Forum does not have a basic functionality yet but the application coherently points out the requirements not met, and the approach to address these.

In the future, some suggestions may be gradually added as further requirements.

	Additional elements of the 'support package' available to countries include a number of tools (e.g. templates for ToR and meeting minutes) and trainings/ technical assistance for Coordination Forums. Details are available at: www.gavi.org/support/coordination/

Coordination Forum Membership

Coordination Forums bring together governments and other relevant key immunisation stakeholders together in a participatory and inclusive manner. While countries will determine the actual members of the Coordination Forum, these guidelines describe potential member profiles that can bring expertise, insight and authority to help the Coordination Forum perform their strategic mandates. Membership should include senior-level leaders who can make decisions on behalf of their organisations, represent the full range of voices needed to coordinate on high-level, strategic issues of the EPI programme, and whenever possible, strive for gender balance, equity and inclusiveness in participation amongst the stakeholder groups.

Table A.1: Gavi requirements and recommendations for Coordination Forum membership

Coordination Forum membership	Examples
Required members[33]	

[33] The requirements for membership come into effect for May 2017 and later applications to give countries sufficient time to prepare for the change. Until then countries can submit the existing ToR.

Coordination Forum membership	Examples
1. Coordination Forum Chair is a senior leader from the Ministry of Health (MoH) with decision making authority.	• Minister • Permanent Secretary
2. Members include at least one senior-level leader with decision–making authority from each of the following categories:	
• EPI programme	• Direct leadership of EPI manager (if any) • EPI manager
• Ministries related to budget, financial plans and other topics related to EPI financing	• Ministry of Finance and/or Budget
• MoH planning departments/ divisions and other directorates related to HSS	• Planning department of MoH • HSS coordinating unit in MoH
• Ministries (other than MoH) with high relevance to EPI programme implementation	• Ministry of Social Services • Ministry of Education • Ministry of Devolution
• Civil society most active in immunisation and representing voice of constituencies	• Advocacy groups • Parent associations • Religious groups
• Key donors most active in immunisation, maternal/neonatal/ child health, and/or health system strengthening in the country	• A few bilateral donors or representatives of a functioning donor coordination body
• Key (implementing) partners most active in immunisation and health system strengthening in the country	• As part of Gavi Alliance representatives from WHO and UNICEF with technical fluency in EPI and HSS and representatives of other implementers.
Recommended members	
Members may also include individuals/ representatives who bring key areas of expertise and knowledge on immunisation and country realities, and/or ensure that the Coordination Forum remains connected to technical advisory groups. This could include, for example: • Immunisation experts (e.g. academics/ researchers), including experts on equity • Chairman of the immunisation technical advisory group (e.g. National Immunisation Technical Advisory Group (NITAG)) • Representative of the National Regulatory Authority (NRA) • Private sector representatives involved in service delivery	
Recommended selection process and membership rules	
The Coordination Forum should define a rigorous member selection process and membership rules (including criteria and processes for members to be identified, selected, and removed; attendance and participation expectations; and term limit), and outline these in the Terms of Reference (TOR).	

Coordination Forum mandate

As listed in Table A.2 below, Gavi provides a set of requirements and/or recommendations on the strategic mandate of Coordination Forums across five categories: (i) strategic planning of the programme; (ii) programme financing; (iii) coordination; (iv) operational planning and performance oversight; and (v) information dissemination. While the scope of functions of the

Coordination Forum will vary from country to country, the mandates listed below represent critical responsibilities focused on the overall EPI programme, with a few which are specific to Gavi support, as noted.

Table A.2: Gavi requirements and recommendations for Coordination Forum mandate

Coordination Forum mandate
Strategic planning of the programme
Recommendation: • Participate in the development of comprehensive strategic plan[34], including setting and aligning on specific goals and targets (where relevant)
Programme financing
Requirement (specific to Gavi support): • Review and approve Gavi grant applications (includes HSIS support), renewals[35] and Partners' Engagement Framework (PEF) submissions of partners for 2018 and ensure their alignment with national strategic and operational plans and a focus on sustainable coverage and equity • Ensure a broad and participatory process in grant application development also on the operational and technical level, involving the relevant institutions described in table A.1 *Recommendation:* • Create long-term visibility on funding for EPI across domestic and donor sources in support of the national strategic plan, and near-term visibility on government budget and donor grant disbursements • Advocate to government and partners to mobilize greater resources for EPI and facilitate dialogue among them to shape a resource mobilization plan • Participate in development of grant proposals and renewals (for non-Gavi stakeholders) in alignment with national strategic and operational plans
Coordination
Recommendation: • Create transparency on programmatic coordination among key stakeholders • Define structure/organisation of operational/technical Coordination Forum (not including NITAG) and ensure processes exist for major bottlenecks to surface to strategic Coordination Forum • Create transparency and linkages with coordination bodies for the broader health sector (incl. HSS) and those related to EPI (e.g. NITAG)
Operational planning and performance oversight
Requirement (specific to Gavi support): • Review and endorse operational plans and budgets for HSIS support • Oversee progress of Gavi investments based on discussion and approval of Joint Appraisal and if possible based on insights from the EPI team and operational/ technical Coordination Forums *Recommendation:* • Review and input into annual EPI work plan aligned with strategic goals • Oversee performance of the EPI programme, including regular review of performance indicators and implementation status of annual work plan, with a focus on tacking and assessing progress against coverage and equity goals • Raise critical issues impeding progress of the EPI programme to relevant government stakeholders *Recommendation (specific to Gavi support):*

[34] Comprehensive strategic plan refers to high-level plans for immunisation (e.g., Costed Multi-Year Plans, CMYPs) and immunisation-related aspects of health systems that are most relevant for the country.
[35] HSS renewals as of 2017.

Coordination Forum mandate
• Review findings and recommendations from EPI review, Programme Capacity Assessments (PCA) and other assessments (including regular review of management capacity of the EPI team) and translate into actions • Oversee progress of key PEF activities (including discussion and approval of PEF functions and PEF milestones) based on insights from the EPI team and operational/ technical coordination forums
Information dissemination
Recommendation (specific to Gavi support): • Share information highly relevant to the EPI programme, Coordination Forum members, and the Gavi Alliance

Coordination Forum governance

This section outlines guidance for governing Coordination Forums, and includes a set of norms and best practices for conducting effective meetings. Adhering to best practices can typically improve the joint understanding of the Coordination Forum's role, the inclusiveness of decision making and would ensure a constant flow of information between all Coordination Forum members.

Table A.3: Gavi requirements and recommendations for Coordination Forum governance

Coordination Forum governance[36]
Terms of Reference
Requirement: The role of the Coordination Forum is defined through a formal TOR, signed and shared with all members, including: • Objective and mandates of the Coordination Forum • Membership composition, selection process, and membership rules (e.g., attendance and participation expectations, term limits) • Meeting rules (frequency and timing of meetings) • Decision-making procedures (including quorum, presence of chair, voting rules for approving different types of decisions) • Support functions (including who is responsible) • Roles and organisational structure of Coordination Forum secretariat (or equivalent) • Terms of reference for committees and/or working groups (if applicable)
Meeting rules
Recommendation: • Adhere to meeting frequency (suggested to be at least 4 meetings per year) and timing as defined in the TOR • Schedule meetings in advance (suggested to be at least 2 months, especially if the Minister of Health is the chair) • Align meeting times with key grant cycle events (e.g., HSIS/NVS grant application, Joint Appraisal) • Schedule additional ad-hoc meetings when needed (e.g. key approvals)
Decision-making procedures

[36] The requirements for Terms of Reference and decision-making procedures come into effect for May 2017 and later applications to give countries sufficient time to prepare for the change. Until then countries can submit the existing ToR.

Coordination Forum governance[36]

Requirement:

- Follow quorum (presence of at least a certain share of members during Coordination Forum meetings to make any decisions, e.g. 75%) as defined in the TOR

Recommendation:

Follow other decision-making procedures as defined in the TOR, including:

- Presence of the Chair (or approved alternate) to take any decision
- Voting rules for approving different types of decisions. For example, defined distribution of votes among members to ensure an equitable balance of voices (potentially capping votes of donors and ensuring minimum number of votes for civil society), minimum share of votes to make different types of decisions

Support function

Requirement:

- Take minutes for each meeting and share with all Coordination Forum members within a defined time period after a meeting (e.g., 5 working days)[37], minutes should include list of members attending the meeting and whether quorum was met

Recommendations:

- Supporting the operations of the Coordination Forum requires significant preparation and follow-up; dedicated staff capacity on the EPI team (including EPI manager's capacity) should be devoted to this. A dedicated Coordination Forum Secretariat is an option for countries to provide this support. The responsibilities would include:
  - "Content" activities, e.g. develop agenda and pre-reads, shape a coherent meeting document, track follow-up on decisions taken (potentially through a Coordination Forum dashboard)
  - Administrative activities, e.g. schedule meetings (place, date, invitation), collect and share pre-reads, share agenda, organize meeting logistics (room, food/drink), create transparency on attendance and key decisions
- The following are suggested best practices for structuring a Coordination Forum Secretariat:
  - EPI manager (or deputy manager) takes the lead on "content" activities (e.g. follow-up on decisions with key stakeholders);
  - Dedicated EPI team member(s) are in charge of administrative activities and supporting execution of "content activities";
- Coordination Forum Secretariat or other group dedicated to supporting the Coordination Forum is funded by the government in most of the cases. Exceptional support could be provided by Coordination Forum members, Gavi, and/or other donors (e.g., through time-bound funding, temporary capacity support, capability building through a secondee).

[37] Minutes can be made available to the public through a website, where possible.

ANNEX 7.1: OUTLINE OF PLAN OF ACTION FOR JE CAMPAIGNS

A Plan of Action (PoA) is mandatory for MR, JE, YF and Men A campaigns. For vaccines which will be first delivered through campaigns and then introduced into the routine immunisation schedule (e.g. MR, JE), a New Vaccine Introduction Plan (NVIP) is also mandatory. **The PoA for JE catch-up campaign and NVIP for JE introduction can be combined into one document to minimise duplication.**

The launch of a new vaccine can mobilise communities to increase demand for immunisation services. Campaigns, while not the primary means for strengthening systems, also provide unique opportunities to strengthen routine immunisation services.

It is important that countries should include the following information when developing the PoA. Please also see Section 5.3.2 for any additional vaccine-specific requirements.

General considerations

1. **Context**: a situation analysis of the routine immunisation programme
2. **Objectives, targets and, justification for the campaign**, using either local or regional disease burden data. Countries are required to provide adequate data on incidence or burden of disease(s), based either on reported cases or appropriate estimate of the burden of disease (if necessary, also referencing regional literature and surveillance data). It is essential for the plan to include available data on barriers to access including socioeconomic status, geography, and gender considerations that could limit coverage or quality of the campaign and how to address those. For multi-year campaigns, the application must specify timing of campaigns and vaccine requirements per year.
3. **Linkages with other interventions**:
    a. The country is asked to list any other vaccine introductions or campaigns planned for the year and explain how the timing and organisation of the proposed campaigns will take these other activities into account.
    b. Identify where joint planning of activities can benefit the impact of the introductions
    c. To strengthen linkages between Gavi-supported campaigns and other support and plans related to immunisation, such as linking routine immunisation and catch-up campaigns, countries currently receiving Gavi funding for HSS and any other support should detail how these will be used to complement the campaign funding to strengthen routine immunisation activities and improve campaign quality, where possible.
    d. Countries should also describe any other health, nutrition or hygiene interventions to be integrated with and/or delivered together during the campaign.
4. **Costing and financing**: It is necessary for countries to provide a budget using the VIG/ Operational cost for campaigns template reflecting the campaign costs and financing sources. The budget must show how routine immunisation strengthening activities integrated into the campaign are to be funded, e.g. extra day of training on injection safety practices.
5. **Lessons learned:** The plan should identify the primary lessons from previous campaigns, and indicate how they are being addressed in planning the current campaign. It is essential

to provide information on vaccine coverage reached in the most recent three campaigns of any vaccine and relevant information such as target group, national or subnational.

6. **Partner support:** Identification of partners (local and international) and their potential roles including technical assistance (epidemiologist, logistician, external monitors, laboratory support, etc.) and social mobilisation.

Planning and implementation

Countries must provide an outline for all preparatory activities:

1. **Campaign planning and task forces:** The task forces (also called "commissions" or "sub-committees") to be created for the campaign planning should be listed. The establishment and work of task forces are recommended to be included in the detailed campaign timeline. Typical task forces include:
    a. **Communications task force:** This task force typically develops a communications plan and timeline for implementation, develops key messages and materials, prepares briefing documents, etc. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also document lessons learned in coordination with technical task force after implementation of the campaign.
    b. **Technical task force:** This task force typically develops the operation plan and guidelines for the campaign, prepares a macro-budget, coordinates micro-planning (develops a template; holds trainings, meetings, reviews; syntheses into a national revised budget), develops training guides, recording and reporting tools, and forms for the campaign (coordinating with communications and logistics task forces), develops materials for training and coordinates training of vaccination teams and supervisors, etc.
    c. **Post-campaign steering committee**: This committee, typically formed from members of the technical task force, the implementing partner for the survey, and other interested partners, will oversee the development of the campaign coverage survey, monitor its implementation, review the results, and interpret the findings.
    d. **Logistics task force**: Logistics planning is best ensured through establishment of a logistics task force well in advance of the campaign. The logistics task force should be charged with developing a detailed supply chain management plan that includes storage and distribution plan for vaccines and devices to ensure adequate cold chain, transportation and logistics capacity and oversight at all levels. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also develop and implement waste management plan.
    e. **Advocacy and Inter-sectorial coordination:** This task force advocates with other partners, decision makers, etc. for support to the campaign, describes how other sectors of the government may be involved in campaign planning and implementation. Education ministries, for example, might play a key role in campaigns that include school-age children.
2. **Supply Chain and cold chain**: The plan should describe current cold chain capacity (at central and local levels), needs for the campaign, and a clear strategy for management of surge capacity of the supply chain and cold chain systems. Funding needs should be

estimated to temporarily increase storage, distribution and transportation capacity for the campaign. This description should include not just vaccines but also immunisation supplies (e.g. injection equipment).

3. **Strategies**, including descriptions of vaccination strategies to be used to ensure the campaign is of high quality and reaches high coverage, such as vaccination sites (e.g. healthcare facilities, temporary fixed sites, outreach, mobile teams, and school-based immunisation), and vaccination teams (e.g. types of teams, their composition and average number to be vaccinated per day). Plans should give broad strategies for reaching the hard to reach, previously unreached or insecure areas. If vaccinating older age groups, plans should consider school based vaccination and what is needed to ensure that this will happen. The plans must include approaches to equitably immunise all socio-economic groups, geographic areas, and males and females.
4. **Vaccination cards and recording / reporting tools distribution** for monitoring and where possible the cards should integrate different vaccines if the target age group is the same.
5. **Communications and social mobilisation**: This section should focus on strategies to inform parents and local leaders about the campaign, its importance, and the need to vaccinate > 9 months in catch-up campaigns and all in the target group for routine EPI. Social mobilisation strategies should be reflected in other aspects of the plan as appropriate (e.g. under “Strategies” above). This section should include a clear indication of how crisis communication will occur, such as in the case of an AEFI.
    - Gavi encourages countries to identify synergies and build linkages between its cash support on social mobilization / IEC activities of various antigen grants and with Country overall comprehensive and integrated social mobilization strategies or plans for routine immunisation. Countries will need to demonstrate in their applications that they have identified and are prepared to leverage synergies between cash support provided for IEC activities by Gavi and other development partners, to ensure that this grant will contribute in building community demand to immunisation
6. **Strengthening routine immunisation through the campaign:** Specific priority activities to strengthen routine immunisation, pre, intra and/or post campaign must be described and reflected in the timeline and budget, and how these will be monitored and evaluated.
7. **Waste management:** Countries must have a detailed waste management plan as appropriate for their campaign immunisation activities. This should include details on sufficient availability of waste management supplies (including safety boxes), safe handling equipment, storage, transportation and disposal of immunisation waste, as part of a healthcare waste management strategy.
8. **Adverse event reporting and management:** The plan should reflect the approach for establishing or strengthening management and reporting of serious and non-serious adverse events following immunisation (AEFI). Plans should include how potential AEFIs will be detected and investigated, what committees will be established to determine causality, and how communications will be handled.

Approach to monitoring and evaluation

Countries must describe their approach to monitoring and evaluation (M&E) including proposed indicators for:

- Pre-campaign, e.g. using campaign readiness assessment tool; collecting baseline data.
- Intra-campaign, e.g. recording, transmission, and timely reporting of data on doses administered and all other interventions given during the campaign, supervision, monitoring to detect pockets of unvaccinated children using standard WHO tools.
- Post-campaign, e.g. must include in the budget a technically and statistically sound post-campaign coverage survey with probability based sampling. For countries with multiple campaign phases, there must be description of plans to conduct an evaluation that includes a vaccination coverage survey within three months after the completion of each phase to allow for subsequent campaign corrections.

Countries should also describe disease surveillance and how it will be strengthened or expanded after the campaign. If not already in place, plans for doing so should be included. Countries are also strongly encouraged to include the following information on M&E:

- implementation of the routine immunisation strengthening activities done pre, intra and/or post campaign;
- impact on scheduled routine immunisation and primary health care services; and
- methods to establish whether previously unreached children were reached through the campaign.

ANNEX 7.2: OUTLINE OF PLAN OF ACTION FOR MENA CAMPAIGNS

A Plan of Action is mandatory for MR, JE, YF and MenA campaigns. For vaccines which will be first delivered by campaign then introduced into the routine schedule (e.g. MR, JE, MenA), a new vaccine introduction plan is also mandatory. The development of a Plan of Action is seen as an iterative process that will involve in-country partners and relevant country coordinating mechanisms. Countries should report progress on campaign planning to Gavi as per activities laid out in the PoA.

The launch of a new vaccine can mobilise communities to increase demand for immunisation services. Campaigns, while not the primary means for strengthening systems, also provide unique opportunities to strengthen routine immunisation services. It is important that countries should include the following information when developing the campaign PoA. Please also see Section 5.3.2 for any additional vaccine-specific requirements.

General considerations

1. **Context:** a situation analysis of the routine immunisation programme
2. **Objectives, targets and, justification** for the campaign, using either local or regional disease burden data. Countries are required to provide adequate data on incidence or burden of disease(s), based either on reported cases or appropriate estimate of the burden of disease (if necessary, also referencing regional literature and surveillance data). It is essential for the plan to include available data on barriers to access, including socioeconomic status, geography, and gender considerations that could limit coverage or quality of the campaign, and how to address those. For multi-year campaigns, the application must specify timing of campaigns and vaccine requirements per year.
3. **Linkages with other interventions**:
    a. The country is asked to list any other vaccine introductions or campaigns planned for the year and explain how the timing and organisation of the proposed campaigns will take these other activities into account.
    b. Identify where joint planning of activities can benefit and increase the impact of the new vaccine introduction
    c. To strengthen linkages between Gavi-supported campaigns and other support and plans related to immunisation (e.g. such as linking routine immunisation and mass campaigns), countries currently receiving Gavi funding for Health System Strengthening (HSS) and any other support should detail how these will be used to complement the campaign funding in order to strengthen routine immunisation activities and improve campaign quality, where possible.
    d. Countries should also describe any other health, nutrition or hygiene interventions to be integrated with and/or delivered together during the campaign.
4. **Costing and financing**: It is necessary for countries to provide a budget using the VIG/ Operational cost for campaigns template reflecting the campaign costs and financing sources. The budget must show how routine immunisation strengthening activities integrated into the campaign are to be funded, e.g. extra day of training on injection safety practices.

5. **Lessons learned:** The plan should identify the primary lessons from previous campaigns, and indicate how they are being incorporated into the planning of the current campaign. It is essential to provide information on vaccine coverage reached in the most recent three campaigns of any vaccine and relevant information such as target group, national or subnational.
6. **Partner support:** Identification of partners (local and international) and their potential roles, including technical assistance (epidemiologist, logistician, external monitors, laboratory support, etc.) and social mobilisation.

Planning and implementation

Countries must provide an outline for all preparatory activities:

1. **Campaign planning and task forces:** The task forces (also called "commissions" or "sub-committees") to be created for the campaign planning should be listed. The establishment and work of task forces are recommended to be included in the detailed campaign timeline. Typical task forces include:
    a. *Communications task force:* this task force typically develops a communications plan and timeline for implementation, develops key messages and materials, prepares briefing documents, etc. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also document lessons learned in coordination with the technical task force after implementation of the campaign.
    b. *Technical task force:* this task force typically develops the operational plan and guidelines for the campaign, prepares a macro-budget, coordinates micro-planning (develops a template; holds trainings, meetings, reviews; develops the national revised budget), develops training guides, recording and reporting tools, and forms for the campaign (coordinating with communications and logistics task forces), develops materials for training and coordinates training of vaccination teams and supervisors, etc.
    c. *Post-campaign steering committee:* This committee, (typically formed from members of the technical task force, the implementing partner for the survey, and other interested partners), will oversee the development of the campaign coverage survey, monitor its implementation, review the results, and interpret the findings
    d. *Logistics task force:* Logistics planning is best ensured through establishment of a logistics task force well in advance of the campaign. The logistics task force should be charged with developing a detailed supply chain management plan that includes storage and distribution plan for vaccines and devices to ensure adequate cold chain, transportation and logistics capacity and oversight at all levels. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also develop and implement waste management plan.
    e. *Advocacy and Inter-sectorial coordination:* this task force advocates with other partners, decision makers, etc. for support of the campaign; and describes how other sectors of the government may be involved in campaign planning and implementation. Education ministries, for example, might play a key role in campaigns that include school-age children.

2. **Supply Chain and cold chain**: The plan should describe current cold chain capacity (at central and local levels), needs for the campaign, and a clear strategy for management of surge capacity of the supply chain and cold chain systems. Funding needs should be estimated to temporarily increase storage, distribution and transportation capacity for the campaign. This description should include not just vaccines but also immunisation supplies (e.g. injection equipment).
3. **Strategies**, including descriptions of vaccination strategies to be used to ensure the campaign is of high quality and reaches high coverage, such as vaccination sites (e.g. healthcare facilities, temporary fixed sites, outreach/mobile teams, and school-based immunization), and vaccination teams (e.g. types of teams, their composition and average number to be vaccinated per day). Plans should give broad strategies for reaching the hard to reach, previously unreached or insecure areas. If vaccinating older age groups, plans should consider school based vaccination and what is needed to ensure that this will happen. The plans must include approaches to equitably immunise all socio-economic groups, geographic areas, and males and females.
4. **Vaccination cards and recording / reporting tools distribution** for monitoring. Where possible, the cards should integrate different vaccines if the target age group is the same.
5. **Communications and social mobilisation**: This section should focus on strategies to inform parents and local leaders about the campaign, its importance, and the need to vaccinate all children or individuals in the target group for the campaign, regardless of their previous vaccination history. Social mobilisation strategies should be reflected in other aspects of the plan as appropriate (e.g. under “Strategies” above). This section should include a clear indication of how crisis communication will occur, such as in the case of an AEFI.

    - Gavi encourages countries to identify synergies and build linkages between its direct financial support on social mobilization / IEC activities of various antigen grants and with country overall comprehensive and integrated social mobilization strategies or plans for routine immunization. Countries will need to demonstrate in their applications that they have identified and are prepared to leverage synergies between direct financial support provided for IEC activities and other activities by Gavi and other development partners, to ensure that this grant will contribute in building community demand for immunization.

6. **Strengthening routine immunisation through the campaign:** Specific priority activities to strengthen routine immunisation, pre-, intra- and/or post-campaign must be described and reflected in the timeline and budget, and how these will be monitored and evaluated.
7. **Waste management:** Countries must have a detailed waste management plan as appropriate for their campaign immunisation activities. This should include details on sufficient availability of waste management supplies (including safety boxes), safe handling equipment, storage, transportation and disposal of immunisation waste, as part of a healthcare waste management strategy.
8. **Adverse event reporting and management**: The plan should reflect the approach for establishing or strengthening management and reporting of serious and non-serious Adverse Event Following Immunisation (AEFIs). Plans should include how potential AEFIs will be detected, investigated, care, follow-up and classified, what committees will be

established to determine incidence, causality, the classification of the cases reported and how communications will be handled.

- Adverse event following immunisation (AEFI) surveillance: status of the reporting system, health care worker awareness of AEFI reporting, AEFI data management, status of AEFI expert committee.
- Vaccine coverage monitoring and reporting including a description of plans to track individual vaccination coverage status.

9. **Pre-campaign readiness assessment tool or checklist:** in order to ensure that all steps to guarantee a successful campaign or introduction of MenA vaccine are planned and budgeted for, that roles and responsibilities are clear, and that a clear timeline is in place, countries are required to use the campaign preparedness assessment tool. Countries are requested to regularly monitor and review these planning tools during planning and implementation.

Approach to monitoring and evaluation and disease surveillance

Countries must describe their approach to monitoring and evaluation (M&E), including proposed indicators for:

Pre-campaign, e.g. using campaign readiness assessment tool; collecting baseline data.

- Intra-campaign, e.g. recording, transmission, and timely reporting of data on doses administered and all other interventions given during the campaign; supervision and monitoring to detect pockets of unvaccinated children using standard WHO tools.
- Post-campaign, e.g. must include in the budget a technically and statistically sound post-campaign coverage survey with probability based sampling. For countries with multiple campaign phases, there must be description of plans to conduct a post campaign coverage survey that includes a vaccination coverage survey within three months after the completion of each phase to allow for subsequent campaign corrections.
- Countries should also describe disease surveillance and how it will be strengthened or expanded after the campaign. If not already in place, plans for doing so should be included.

Countries are also strongly encouraged to include the following information on M&E:

- Implementation of the routine immunisation strengthening activities done pre-, intra- and/or post-campaign.
- Impact on scheduled routine immunisation and primary health care services.
- Methods to establish whether previously unreached children were reached through the campaign.

ANNEX 7.3: OUTLINE OF PLAN OF ACTION FOR YF CAMPAIGNS

A Plan of Action (PoA) is mandatory for MR, JE, YF and Men A campaigns.

The launch of a new vaccine can mobilise communities to increase demand for immunisation services. Campaigns, while not the primary means for strengthening systems, also provide unique opportunities to strengthen routine immunisation services.

It is important that countries should include the following information when developing the PoA. Please also see Section 5.3.2 for any additional vaccine-specific requirements.

General considerations

1. **Context:** a situation analysis of the routine immunisation programme
2. **Objectives, targets and, justification** for the campaign, using both local or regional disease burden data and trends outlined in the RA. Countries are required to provide adequate data on incidence or burden of disease(s), based either on reported cases or appropriate estimate of the burden of disease (if necessary, also referencing regional literature and surveillance data). It is essential for the plan to include available data on barriers to access including socioeconomic status, geography, and gender considerations, which could limit coverage or quality of the campaign and how to address those. For multi-year campaigns, the application must specify timing of campaigns and vaccine requirements per year.
3. **Linkages with other interventions**:
    a. The country is asked to list any other vaccine introductions or campaigns planned for the year and explain how the timing and organisation of the proposed campaigns will take these other activities into account.
    b. Identify where joint planning of activities can benefit the impact of the introductions
    c. To strengthen linkages between Gavi-supported campaigns and other support and plans related to immunisation, such as linking routine immunization and mass campaigns, countries currently receiving Gavi funding for HSS and any other support should detail how these will be used to complement the campaign funding to strengthen routine immunisation activities and improve campaign quality. Countries should also describe any other interventions to be integrated with and/or delivered together during the campaign, where possible.
    d. Countries should also describe any other health, nutrition or hygiene interventions to be integrated with and/or delivered together during the campaign.
4. **Costing and financing**: It is necessary for countries to provide a budget using the VIG/ Operational cost for campaigns template reflecting the campaign costs and financing sources. The budget must show how routine immunisation strengthening activities integrated into the campaign are to be funded, e.g. extra day of training on injection safety practices.
5. **Lessons learned:** The plan should identify the primary lessons from previous campaigns, and indicate how they are being addressed in planning the current campaign. It is essential

to provide information on vaccine coverage reached in the most recent three campaigns of any vaccine and relevant information such as target group, national or subnational.

6. **Partner support:** Identification of partners (local and international) and their potential roles including technical assistance (epidemiologist, logistician, external monitors, laboratory support, etc.) and social mobilisation.

Planning and implementation

Countries must provide an outline for all preparatory activities:

1. **Campaign planning and task forces:** The task forces (also called "commissions" or "sub-committees") to be created for the campaign planning should be listed. The establishment and work of task forces are recommended to be included in the detailed campaign timeline. Typical task forces include:

   a) **Communications task force***:* this task force typically develops a communications plan and timeline for implementation, develops key messages and materials, prepares briefing documents, etc. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also document lessons learned in coordination with technical task force after implementation of the campaign.

   b) **Technical task force:** this task force typically develops the operation plan and guidelines for the campaign, prepares a macro-budget, coordinates micro-planning (develops a template; holds trainings, meetings, reviews; syntheses into a national revised budget), develops training guides, recording and reporting tools, and forms for the campaign (coordinating with communications and logistics task forces), develops materials for training and coordinates training of vaccination teams and supervisors, etc.

   c) **Post-campaign steering committee:** This committee, typically formed from members of the technical task force, the implementing partner for the survey, and other interested partners, will oversee the development of the campaign coverage survey, monitor its implementation, review the results, and interpret the findings.

   d) **Logistics task force:** Logistics planning is best ensured through establishment of a logistics task force well in advance of the campaign. The logistics task force should be charged with developing a detailed supply chain management plan that includes storage and distribution plan for vaccines and devices to ensure adequate cold chain, transportation and logistics capacity and oversight at all levels. This task force should work with the technical task force to support micro-planning and develop logistics tools and forms. This task force will also develop and implement waste management plan.

   e) **Advocacy and Inter-sectorial coordination:** this task force advocates with other partners, decision makers, etc. for support to the campaign, describes how other sectors of the government may be involved in campaign planning and implementation. Education ministries, for example, might play a key role in campaigns that include school-age children.

2. **Supply chain and cold chain**: The plan should describe current cold chain capacity (at central and local levels), needs for the campaign, and a clear strategy for management of

surge capacity of the supply chain and cold chain systems. Funding needs should be estimated to temporarily increase storage, distribution and transportation capacity for the campaign. This description should include not just vaccines but also immunisation supplies (e.g. injection equipment).

3. **Strategies**: including descriptions of vaccination strategies to be used to ensure the campaign is of high quality and reaches high coverage, such as vaccination sites (e.g. healthcare facilities, temporary fixed sites, outreach, mobile teams, and school-based immunization), and vaccination teams (e.g. types of teams, their composition and average number to be vaccinated per day). Plans should give broad strategies for reaching the hard to reach, previously unreached or insecure areas. If vaccinating older age groups, plans should consider school based vaccination and what is needed to ensure that this will happen. The plans must include approaches to equitably immunise all socio-economic groups, geographic areas, and males and females.
4. **Vaccination cards and recording / reporting tools distribution** for monitoring and where possible the cards should integrate different vaccines if the target age group is the same.
5. **Communications and social mobilisation**: This section should focus on strategies to inform parents and local leaders about the campaign, its importance, and the need to vaccinate > 9 months in mass campaigns and all in the target group for routine EPI. Social mobilisation strategies should be reflected in other aspects of the plan as appropriate (e.g. under “Strategies” above). This section should include a clear indication of how crisis communication will occur, such as in the case of an AEFI.
    - Gavi encourages countries to identify synergies and build linkages between its cash support on social mobilization / IEC activities of various antigen grants and with Country overall comprehensive and integrated social mobilization strategies or plans for routine immunization. Countries will need to demonstrate in their applications that they have identified and are prepared to leverage synergies between cash support provided for IEC activities and other activities such as training by Gavi and other development partners, to ensure that this grant will contribute in building community demand to immunization
6. **Strengthening routine immunisation through the campaign:** Specific priority activities to strengthen routine immunisation, pre, intra and/or post campaign must be described and reflected in the timeline and budget, and how these will be monitored and evaluated.
7. **Waste management:** Countries must have a detailed waste management plan as appropriate for their campaign immunisation activities. This should include details on sufficient availability of waste management supplies (including safety boxes), safe handling equipment, storage, transportation and disposal of immunisation waste, as part of a healthcare waste management strategy.
8. **Adverse event reporting and management:** The plan should reflect the approach for establishing or strengthening management and reporting of serious and non-serious AEFI. Plans should include how potential AEFIs will be detected and investigated, what committees will be established to determine causality, and how communications will be handled.

Approach to monitoring and evaluation and disease surveillance

Countries must describe their approach to M&E including proposed indicators for:

- Pre-campaign, e.g. using campaign readiness assessment tool; collecting baseline data.
- Intra-campaign, e.g. recording, transmission, and timely reporting of data on doses administered and all other interventions given during the campaign, supervision, monitoring to detect pockets of unvaccinated children using standard WHO tools.
- Post-campaign, e.g. must include in the budget a technically and statistically sound post-campaign coverage survey with probability based sampling. For countries with multiple campaign phases, there must be description of plans to conduct a post campaign coverage survey that includes a vaccination coverage survey within three months after the completion of each phase to allow for subsequent campaign corrections.

Countries should also describe disease surveillance and how it will be strengthened or expanded after the campaign. If not already in place, plans for doing so should be included, e.g. for congenital rubella syndrome.

Countries are also strongly encouraged to include the following information on M&E:

- implementation of the routine immunisation strengthening activities done pre, intra and/or post campaign;
- impact on scheduled routine immunisation and primary health care services; and
- methods to establish whether previously unreached children were reached through the campaign.

ANNEX 8: INSTRUCTIONS TO COMPLETE THE NVS APPLICATION FORM

This annex provides instructions on how to complete the NVS Application Form. The instructions are generic for all vaccines, and countries should refer to the main body of this guidelines document for vaccine-specific guidelines.

Attachments checklist

A completed application comprises a number of **mandatory attachments**. Countries will be unable to submit their application form until all of these documents have been uploaded. Countries may also wish to provide **optional attachments,** if these are available.

Where possible, approved national documents rather than drafts should be provided. For a decentralised country, relevant state/ provincial level plans, as well as any relevant national level documents, may be provided.

A full list of mandatory and optional attachments is provided in Tables B.1 and B.2 below respectively. Vaccine-specific documents are only mandatory for countries that have submitted an application for these particular vaccines (and are marked in italics below).

Table B.1: Checklist of mandatory attachments

No	Document
Endorsements	
1	Minister of Health Signature (or delegated authority) of Proposal
2	Minister of Finance Signature (or delegated authority) of Proposal
3	*Minister of Education Signature (or delegated authority) of HPV Proposal (mandatory if schools are primary venue for introduction)*
4	Terms of Reference for the relevant Coordination Forum (ICC/HSCC or equivalent) including all sections outlined in Section 5.2 of the General Application Guidelines[38]
5	Minutes of the Coordination Forum meeting endorsing Proposal
6	Signatures of Coordination Forum members in Proposal (including a signature of each member in attendance and date at the endorsing meeting (or a signed meeting attendee list)
7	Minutes of the Coordination Forum meetings from the past 12 months before the proposal
8	Role and functioning of the advisory group/ NITAG and minutes of NITAG meeting with specific recommendations on the NVS introduction or campaign (for countries where a NITAG exists) Description of plans to establish a NITAG (for countries where the NITAG does not exist)
Planning, financing and vaccine management	
9	Comprehensive Multi Year Plan – cMYP
10	cMYP costing tool for financial analysis
11	Monitoring and evaluation and surveillance (M&E) plan for the support requested, within the context of the country's existing monitoring plan for the EPI programme
12	New Vaccine introduction Plan (NVIP), New Vaccine Introduction Checklist and Activity List & Timeline for routine vaccines or Plan of Action (POA) for campaign vaccines

[38] Countries applying before May 2017 can submit their existing Terms of Reference

13	*Introduction Plan for the introduction of RCV/JE/Men A and Yellow Fever into the national programme* (please note that the PoA for JE catch-up campaign and NVIP for JE introduction can be combined into one document to minimise duplication)
14	*HPV District profile*
15	*HPV District map marking delivery strategy*
16	*HPV Workplan*
17	*Evidence of commitment to fund purchase of RCV (in place of the first dose of MCV) / JE for the use in the routine system*
18	Campaign target population documentation
19	Effective Vaccine Management (EVM) Report from an assessment conducted within the last 5 years
20	EVM Improvement Plan
21	EVM Improvement Plan progress report
22	Filled detailed budget template for VIG/Operational costs
23	*Risk assessment and consensus meeting report for Meningitis. If the District Prioritisation Tool (DPT) has been used instead of a Risk Assessment please include this instead)*
24	*Risk assessment and consensus meeting report for Yellow Fever, including information required in the NVS guidelines on YF Risk Assessment process*
25	*List of areas/districts/regions and targets to be supported for meningitis A mini catch up campaigns*
26	Data Quality Assessment (DQA) report
27	Plan of Action for campaigns
28	*Annual EPI plan for measles and rubella support*
29	*For measles and rubella support, evidence that the country is currently financing the measles mono-valent vaccine component of MCV1, or that it can meet the requirement to be self-financing this from government funds from 2018 onwards*

MR	For Measles and Rubella, additional documents are mandatory depending on the type of support being requested and the timing of activities, as outlined in Section 4.3.2 of the Measles and Rubella Guidelines, available at www.gavi.org/support/apply/.

Table B.2: Checklist of optional attachments

No	Document
30	A description of partner participation in preparing the application
31	Minutes of NITAG meeting with specific recommendations on the NVS introduction or campaign
32	DQA improvement plan
33	Other (countries are able to attach further supporting documents if relevant)

Instructions for completing the NVS application form

Guidance on completing the various sections and questions of the application form are provided below.

The guidance is provided for all sections of the application form, however a tailored application is automatically generated for the vaccines being requested for support and hence not all sections below will be required to be completed by the country.

Main page

The first step of the application process is to complete the start and end year of the country's comprehensive Multi-Year Plan (cMYP). Gavi requires all applications for vaccine support to be aligned with existing country plans.

NVS support is approved for the duration of the cMYP only (with renewals linked to the timelines for subsequent cMYPs). By completing these dates on the Main Page, the application form will automatically complete the duration of support countries are eligible to apply for.

Type of support requested

Countries are required to provide information on the vaccine(s) being applied for, which will create a tailored application form for the selected vaccine(s). As Gavi may not always be in a position to accommodate the first product preferences, countries are requested to choose a preferred second presentation. More than one type of vaccine support can be requested in the same application form.

Executive summary

Countries are required to provide a high-level summary of the application form. Basic information relating to the specific vaccines requested, duration of support, projected date of vaccine introduction and baseline data will be automatically completed.

Signatures

Countries should be aware that with the government signatures to be included in this section, the government commits itself to implementing the support as requested and to annual release of the co-financing funds. Applications not signed by *both* the Minister of Health and Minister of Finance or their delegated authority will not be reviewed by the Gavi Independent Review Committee (IRC).

Although all partners are expected to be involved in the development process of the application, the signatures will be added once the form has been filled in and printed.

Background information

In this section of the application form, countries are required to provide information on lessons learned from the introduction of other new or under-used vaccines in country, specifically for storage capacity, protection from accidental freezing, staff training, cold chain, logistics, coverage and drop-out rates, and wastage rate. For each point, information should be provided on any actions previously taken to address these points.

Countries are also required to provide information relating to health planning and budgeting, issues relating to enhancing country coverage and equity as well as details on data quality.

On procurement and management, countries are asked to explain how the vaccine support from Gavi will be managed, including the mechanism for procurement of vaccines.

Specific points of guidance are as follows:

- Countries may choose to procure vaccines and associated supplies through UNICEF/ PAHO Revolving Fund (RF) or through self-procurement (except for PCV vaccines which have to be procured by UNICEF due to the terms of the Advance Market Commitment (AMC)). If a country prefers to use self-procurement, the following information is required: (i) a description of the mechanism; and (ii) assurance that vaccines will meet the quality standards described in Section 6.2.
- Countries are required to describe their financial management procedures for NVS direct support (i.e. cash support for vaccine self-procurement, VIGs, operational support for campaigns).
- Countries are required to provide information on the current licensing status of the product they are applying for, as well as the national product licensure requirements and procedures. As each country may have its own vaccine licensing requirements based on its own legislation, it is important that the timeline for registration is taken into consideration when a country plans for vaccine introduction, to avoid potential delays in vaccine supply. The Ministry of Health is responsible for facilitating the process with the National Regulatory Authority (NRA) and the manufacturer of the chosen product. UNICEF Supply Division will support the process by communicating licensing requirements to the vaccine manufacturers where relevant. In the New Vaccine Introduction Plan and/or the plans of action for campaigns, countries should include activities and timing for product licensure and manufacturer registration into the timeline if applicable.
- Countries are required to provide information on the waste management and monitoring plans, including on the availability of waste management supplies, safe handling, storage, transportation and disposal of immunisation waste.

GG	Section 6.2 provides information on Gavi's requirements and guidance for self-procurement of vaccines and related supplies. Annex 5 provides information on Gavi's financial management and external audit requirements.

New and Under-Used Vaccines (NVS) Routine

In this section, countries are required to fill in the details of the requested vaccine/s for routine introductions. It is therefore advised to have the cMYP and New Vaccine Introduction Plan to hand.

For each vaccine, the following information is requested:

- **Baseline and annual targets**: When filling the baseline and annual targets, it is important to have the cMYP at hand. Countries are required to fill in baseline data for total births, infant deaths, pregnant women, target populations vaccinated and wastage rates, as well as annual targets for vaccines applied for in NVS routine support.

  Wastage rate is calculated as follows:

[(A - B) / A] x 100

where: A = the number of doses distributed for use according to the supply records with correction for stock balance at the end of the supply period; B = the number of vaccinations with the same vaccine in the same period.

- **Introduction date:** Countries are requested to fill in the anticipated introduction time. Due to a variety of factors, the launch date may vary compared to the date stipulated in the application. It will not usually be feasible for a country to introduce less than 15-19 months after the Gavi application submission deadline.
- **Co-financing information:** The minimum co-financing is automatically computed for each country depending on the country grouping. Countries are requested to confirm their co-financing level, either by filling in the minimum amount or a inserting a higher amount if they wish to co-finance at a higher level amount than the minimum.
- **Portion of supply to be procured by the country:** This information is completed automatically. However, it should be noted that the total co-financing amount does not include any costs and fees of the relevant Procurement Agency, such as insurance and handling fees. Information on these extra costs and fees will be provided by the relevant Procurement Agency (i.e. UNICEF Supply Division).
- **Vaccine Introduction Grant (VIG):** In this section, the VIG is calculated automatically based on the country's birth cohort. For each vaccine, countries are required to complete a detailed budget for the VIG as per the prescribed template. The template can be downloaded from the country portal. Countries are then requested to describe how the VIG will be used to facilitate the implementation of critical activities in advance of and during the introduction of the new vaccine. Where the Gavi support is not sufficient to cover the full needs of the introduction, please describe the other sources of funding and the expected amounts to be contributed to cover the total estimated need.
- **Technical Assistance:** Please describe areas where the Ministry of Health would require technical assistance to support the introduction.

NVS Preventive Campaigns

In addition to the information provided in this section, a Plan of Action for each campaign should be uploaded as Document number 13. For each vaccine, the following information is requested:

- **Assessment of burden of relevant diseases:** In this section, countries applying for the NVS preventive campaign vaccines are required to provide information regarding the epidemiology and disease burden for the relevant diseases.
- **Summarise cold chain capacity,** including cold chain capacity (at central and other levels) and readiness to accommodate new vaccines, taking into consideration training, cold chain and other logistic requirements. If cold chain expansion is required, an explanation of how it will be financed and when it will be in place should be provided. All cold chain equipment intended for vaccine storage is required to be pre-qualified by WHO under the Performance Quality and Safety (PQS) program. The purchase of non-

PQS equipment will only be considered on an exceptional basis, with justification and advance agreement from Gavi.

- **Grant support for Operational Cost of the campaign:** Countries are required to describe how the support will be used to facilitate preparation and delivery of the campaign to the target population. If the Gavi contribution is not sufficient to cover the full need, countries should describe how other sources of funding will cover the full need.

Additional information is also requested based on the specific nature of support for the particular vaccine.

Key points to consider before submission

- Prior to submitting the NVS application, the following points should be considered:
- All questions have been answered and nothing has been left blank in the form.
- The application form is consistent throughout – specifically:
    - The Executive Summary reflects the detail provided in the proposal.
    - The data is consistent across the form.
    - The budget figures are correct and consistent throughout the form. Re-check the totals.
    - Relevant dates (e.g. introduction dates) are consistent throughout the form
- Details have been provided for all vaccines listed in the “Type of support requested” (question 1)
- Where relevant, the most recent data is provided and data sources are included.
- All additional documents that are attached are referenced in the main application form.
- All application attachments are in one of the following languages accepted by Gavi – English, French, Portuguese, Russian or Spanish.
- Only countries wishing to change their current banking arrangements are requested to submit Section 11 - banking form.

ANNEX 9: GAVI REVIEW CRITERIA FOR NVS APPLICATIONS

This annex provides information on the criteria used by Gavi's IRC when reviewing vaccine applications for JE, MenA, PCV, Rotavirus and Yellow Fever.

HPV MR	Specific details relating to HPV and measles and rubella applications are provided in separate guidelines.

1. **Basic functionality of country Coordination Forum (Inter-Agency Coordinating Committee/ Health Sector Coordination Committee (ICC/ HSCC) or equivalent body) including a participatory approach to application development.**

   - Is the Coordination Forum functional/ active in providing strategic direction, oversight and transparency of the EPI programme (at minimum of Gavi investments) and has it been adequately involved in the current application development process for Gavi?
   - Is the Coordination Forum representative of a range of stakeholders with relevant authority that are involved in the country health and immunisation sector (government, key donors, partners, key implementers, CSOs)?
   - Does the Coordination Forum adhere to basic governance practices, including developing and sharing a formal TOR and meeting minutes, and adhering to the quorum in meetings?
   - Has the Gavi application been developed with the engagement of the range of stakeholders involved in the country health and immunisation sector (government, key donors, partners, key implementers, CSOs)?
   - Has the country National Immunisation Technical Advisory Group (NITAG) provided advice whether to introduce the new vaccine?

Section 5.2 provides information on requirements to ensure basic functionality for a national-level Coordination Forum.

2. **Evidence based analysis of current immunisation and health programme and status and strong linkage with the support being requested in the application.**

   - Are the coverage targets proposed reasonable given the history of vaccine coverage in the country?
   - Have the lessons from previous vaccine introductions/ campaigns been reflected in the current application?
   - Is the new vaccine introduction/ campaign reflected in the cMYP and is there adequate alignment between the new vaccine introduction/ campaign and country health documents?
   - Is there adequate justification for vaccine introduction given disease burden and other relevant criteria given the country setting and capacity?
   - For self-procuring countries, is there adequate evidence of country capacity for sustainable procurement?

- If campaign-style delivery is used, is there evidence to show that campaign activities will also contribute to the strengthening of routine immunisation?
- Does the country demonstrate adequate readiness for vaccine introduction in terms of cold chain capacity?

3. **Robust analysis of barriers related to increasing coverage and enhancing equity in access and utilisation of immunisation services (including socio-economic, geographic and gender-related issues) and evidence-driven linkage with programmatic actions to address these issues.**
   - Has there been a robust analysis on immunisation equity and are there clear plans to address these?
4. **Demonstration of prioritising highest impact approaches and strategies.**
5. **Realistic and logical description of activity plans and budgets, showing that activities are complementary and not duplicative the different types of Gavi support.**
   - Is there a logical flow in terms of the activities proposed (for vaccine introduction in the country and specifically the VIG activities) and their linkage with planned objectives?
   - Does the application show that the co-financing requirements will be met?
   - Does the application show the government's commitment for ongoing financing of routine immunisation?
6. **Adequacy of planned measures to reduce related funding gaps and ensure longer term sustainability.**
7. **Updated and sound grant performance framework with proposed metrics, baselines and targets to track grant progress and results.**
8. **Robustness of financial management arrangements for direct financial support.**
   - Are the financial management arrangements adequate (e.g. in terms of capacity, planning and systems)?
9. **Adequacy of country's efforts to improve the availability, quality and use of immunization data.**
   - Is there adequate information and evidence to demonstrate that the country is adhering to Gavi's data quality and survey requirements?

Additional review criteria specific to JE vaccine applications

10a. Adequate inclusion of each of the specific requirements, as set out in Section 5.3.2, including:

- Clear rationale for the introduction of JE, using available disease burden data;
- For countries without national or sentinel JE and/ or Acute Encephalitis Syndrome (AES) data, clearly outlined plan to establish systems or conduct studies to collect this data in the JE introduction plan.
- Clear description of the target population, for both the Gavi supported campaign and routine introduction

- Clear plan for both the JE campaign and for the introduction into the routine programme after the campaign
- Provision of estimated date for the introduction into the routine programme and clear plans to ensure no cohorts are missed
- Provision of evidence that the country can fund the introduction of JE in the routine programme

Additional review criteria specific to MenA vaccine applications

10b. Adequate inclusion of each of the specific requirements, as set out in Section 5.3.2, including:

- A jointly prepared application for both routine introduction and one time mini catch-up campaign, including a detailed NVIP for each delivery strategy
- A robust and clear PoA, including all aspects set out in Section 5.3.2 and Annex 7.2, as relevant
- A Risk Assessment Report to determine the epidemiological information on MenA circulation and relevant data, disease burden, the target population at risk, with a statement that WHO has endorsed the report.

Additional review criteria specific to PCV applications

There are no additional review criteria specific to PCV applications.

Additional review criteria specific to Rota vaccine applications

There are no additional review criteria specific to Rota vaccine applications.

Additional review criteria specific to Yellow Fever vaccine applications

10c. Robust and clear Risk Assessment, following guidance set out in Section 5.3.2

ANNEX 10: WHO CLASSIFICATION FOR YF ENDEMIC COUNTRIES IN AFRICA

For Africa, the EYE strategy used a **three-step approach** to reclassify the 35 countries into different risk categories and propose preventive strategies accordingly.

Table A10.1: Risk of YF virus circulation in 35 African countries (by risk level)

	Country	# YF outbreaks 1990–2016	Recent report of YF cases 2011-2016	National PMVC prior to YFI	High sero-prevalence [39]	Ro≥1.25	Risk level
1	Angola	1	Y				High
2	Benin			Y		Y	High
3	Burkina Faso	5		Y		Y	High
4	Cameroon	5	Y	Y			High
5	C. A. R.	3				Y	High
6	Chad	1	Y	Y			High
7	Congo	2	Y			Y	High
8	Côte d'Ivoire	7	Y	Y		Y	High
9	DRC	4	Y		Y		High
10	Eq. Guinea		Y				High
11	Ethiopia	1	Y		N		High
12	Gabon		Y[40]	Y		Y	High
13	Gambia			Y		Y	High
14	Ghana	1	Y			Y	High
15	Guinea	10		Y		Y	High
16	Guinea-Bissau		Y[41]			Y	High
17	Kenya	2			N		High
18	Liberia	5		Y		Y	High
19	Mali	2				Y	High
20	Niger					Y	High
21	Nigeria	3				Y	High
22	Senegal	5	Y	Y		Y	High
23	Sudan	4	Y		Y[42]		High
24	South Sudan	1			Y[43]		High
25	Sierra Leone	3				Y	High
26	Togo			Y		Y	High
27	Uganda	2	Y		Y		High

[39] Serosurvey demonstrating neutralizing antibody prevalence >3% in at least one zone (multidisciplinary risk assessment).
[40] Cases were recently laboratory confirmed.
[41] Imported cases were recently confirmed (area of origin unclear).
[42] In Sudan, the national average was 5.1%, ranging from 2.1–7.3%.
[43] In South Sudan, the national average was 7.2%, ranging from 4.5 to 8.6%.

	Country	# YF outbreaks 1990–2016	Recent report of YF cases 2011-2016	National PMVC prior to YFI	High sero-prevalence [39]	Ro≥1.25	Risk level
1	Burundi					N	Moderate
2	Eritrea					N	Moderate
3	Mauritania					N	Moderate
4	Rwanda				N	N	Moderate
5	Sao Tome & P.					NA	Moderate
6	Somalia					N	Moderate
7	Tanzania (United Republic of)					N	Moderate
8	Zambia				N	N	Moderate

***Notes**:*
Ro = basic reproductive number; PMVC = preventive mass vaccination campaign; YFI = Yellow fever Initiative; Y = yes; N = no; NA = not available.

- *In Ethiopia, the YF risk assessment found evidence of risk and virus circulation limited to the south-western part of the country. South-western Ethiopia only is therefore considered to be at high risk.*
- *National PMVC prior to the YFI refer to the campaigns conducted in francophone West Africa in the 1940s–1960s, except for Gabon and the Gambia, which conducted national mass campaigns in response to epidemics in 1995 and 1979, respectively.*

Figure A10.1 Recommended immunization activities to be completed by high-risk countries, EYE strategy, 2017–2026