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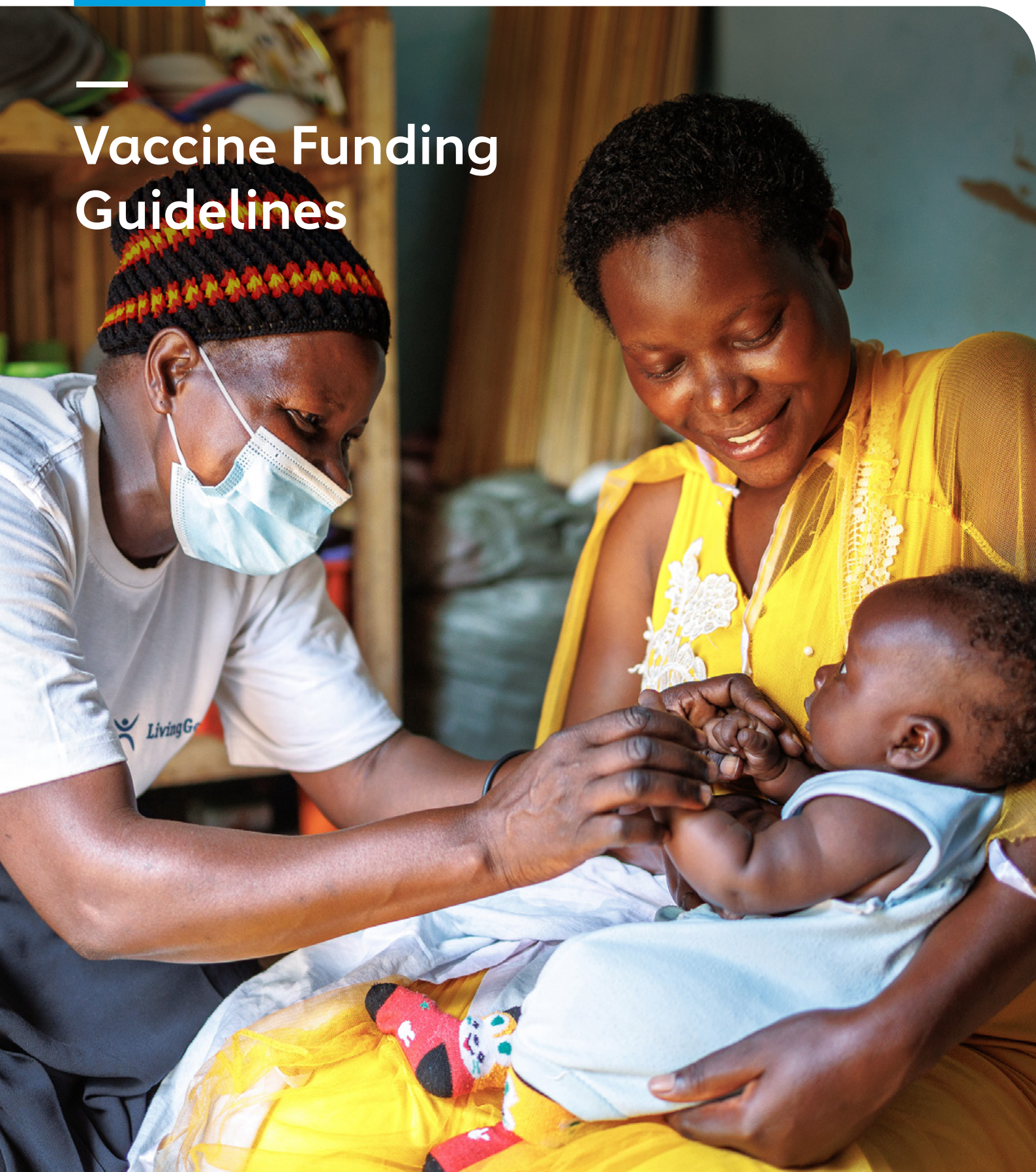
Vaccine Funding Guidelines



Use these guidelines to understand how Gavi, the Vaccine Alliance supports the introduction and scaling up of vaccines; key considerations for applying for new vaccine support and Gavi-supported campaigns; and requirements for each Gavi-supported vaccine.

These guidelines complement other guidance, such as the Gavi *Programme Funding Guidelines* and *Budget Eligibility Guide*.

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1 Introduction

Gavi, the Vaccine Alliance supports countries in strengthening their immunisation programmes. As one of Gavi's strategic goals, this includes support to introduce and scale up vaccines, ensuring no one is left behind with immunisation.

Gavi shares the cost that implementing countries pay for vaccines, which has led to 561 vaccine introductions and campaigns by end 2021, dramatically boosting immunisation against virulent diseases. Complemented by health system strengthening support and technical assistance, Gavi provides vaccines and safe injection devices, as well as time-bound financial support for new introductions of vaccines into the national immunisation schedule and to conduct campaigns. For more information, see Annex 1 on existing and available new vaccine support per country.

These guidelines describe key aspects countries should consider when requesting new vaccine support from Gavi. They should be read in conjunction with Gavi's application process guidelines and other funding guidelines, which can be accessed via the Support Guidelines page on the Gavi website.

Key points in these guidelines

- Vaccine support should be planned for as part of Gavi's comprehensive portfolio of support.
- New vaccine introductions and campaigns should place **equity at the centre of all planning**, ensuring that zero-dose children and missed communities are prioritised for support.
  - Understanding and addressing gender-related barriers is key to ensuring all targeted individuals have equitable access to the full range of vaccines.
- Gavi support is intended to be catalytic, with **country co-financing commitments essential** to ensuring successful programming.
- Gavi support is primarily aimed at supporting the timely delivery of **routine vaccination as the core of the national immunisation programme**. Considerations are explicitly provided for countries requesting campaign support, notably the **expectation that campaigns** are:
  - **epidemiologically and programmatically justified**;
  - well-tailored to sustainably identify and reach zero-dose and under-immunised children and missed communities by employing **differentiated delivery strategies and use of operational cost support**;
  - designed to serve as an **entry point** for children and missed communities into the **routine immunisation system** and generate demand for a full course of vaccines;
  - leveraging **opportunities for integration** with other health campaigns or with catch-up vaccination of routine vaccines;
  - identifying opportunities for Gavi support to **strengthen routine delivery systems** and mitigate any adverse impact on routine immunisation services; and
  - considering more **targeted** alternative strategies to raise routine coverage at national and subnational levels.

2 Gavi support to introduce and scale up vaccines

2.1 Comprehensive planning of Gavi support to reach immunisation goals

Gavi's 5.0 strategy includes a shift towards a Full Portfolio Planning (FPP) approach, which integrates all types of Gavi support to best achieve national immunisation goals, along with cold chain equipment, health system strengthening (HSS) support and needed technical assistance.

Building on national immunisation goals and strategies, it maps out priorities, objectives and activities to be supported by Gavi to achieve identified goals. Through the process, countries are asked to prioritise several key strategic shifts they want to achieve with Gavi support to strengthen their immunisation programme.

Countries must reflect all vaccine support expected over the planning period in their comprehensive request for Gavi support.

There are two ways to apply for specific vaccine support:

1. Countries conducting their FPP process should reflect all planned new vaccine introductions or campaigns in their FPP documents. Detailed requests are expected only for vaccine introductions and campaigns scheduled in the first two years. Introductions and campaigns scheduled later should be reflected in the request, with the application details submitted for independent review and approval closer to the introduction.

2. Countries not conducting an FPP process can still apply for vaccine support on an as-needed basis through the country portal (described as pathway 2 in the *Gavi Application Process Guidelines*). The country portal opens approximately two months before the submission deadlines on the Gavi website.

The different types of support Gavi provides are described in the *Gavi Application Process Guidelines*. They include **vaccine support**, **HSS**, **cold chain equipment** and **technical assistance**.

Gavi provides additional support for specific situations, including support for vaccine product and presentation switches; yellow fever diagnostic capacity strengthening; and support for global stockpiles for cholera, Ebola, meningococcal and yellow fever vaccines via the International Coordinating Group (ICG).

Gavi expects that the decision to introduce a vaccine into the national immunisation schedule, or to conduct a campaign, be discussed and supported by a national technical advisory group, such as the National Immunisation Technical Advisory Group (NITAG).[1]

The recommendations provided by NITAG concern, among others:

- vaccine introduction decisions;
- specific product choices and characteristics; and
- immunisation schedules and practices.

[1] NITAGs guide policy and programme decisions at country level and are critical for sustainable immunisation programmes. They promote evidence-based decisions and enable countries to take full ownership of their policies and immunisation programmes. Where a NITAG does not exist, Gavi expects countries to include plans to establish one with the request for new vaccine support.

2.2 Equity and prioritisation of routine immunisation

Reaching zero-dose children and missed communities with a full schedule of vaccines is the primary objective of Gavi's current strategy. Zero-dose children suffer the disproportionate burden of disease and account for nearly 50% of child deaths that can be prevented using vaccines. Zero-dose and under-immunised children and communities are also a key priority for the Immunization Agenda 2030, endorsed by the World Health Assembly in May 2020.

All requests for Gavi support need to articulate clear strategies for sustainably reaching zero-dose children and missed communities with a drive to achieve equity in immunisation.

Zero-dose children often live in communities that face multiple deprivations, including socioeconomic inequities and lack of access to health services, which gender-related barriers can further exacerbate. Communities with large numbers of zero-dose and under-immunised children are more vulnerable to outbreaks of vaccine-preventable diseases and are often ill-equipped to respond to an outbreak.

The Vaccine Alliance is proposing a common framework for countries to design tailored programmes to reach zero-dose children and missed communities, against which Gavi support can be programmed (see *Programme Funding Guidelines*).

Prioritisation of routine immunisation strengthening

Gavi support is primarily intended to support the timely delivery of routine vaccination as the core of the national immunisation programme.

Examples of routine immunisation-strengthening activities can be found in Annex 4 of this document, Gavi's *Programme Funding Guidelines*, and other guidelines from partners and Gavi.

Addressing gender-related barriers faced by caregivers, health workers and adolescents in the design of vaccine introductions and campaigns

Gender-related barriers significantly impact the demand, coverage, use, sustainability and impact of vaccine introductions and campaigns.

Understanding these and other socioeconomic-related barriers can help countries to adapt immunisation services so that zero-dose and under-immunised children, and missed communities, receive the full range of recommended vaccines.

Countries are expected to include a strong gender lens in their programming, with a clear understanding of gender-related barriers and tailored strategies to address them. See *Programme Funding Guidelines* for further gender resources.

Key stakeholders	
Caregivers/parents	Women are often the primary caregiver and face multiple barriers to accessing immunisation and health services. For this reason, the gendered needs of caregivers should be at the heart of immunisation service delivery.
Health workers	70% of the world's health care workers (HCWs) are women. Specific attention is therefore needed to ensure HCWs can work safely and effectively.
Adolescents	Adolescents are the beneficiaries of specific immunisation programmes, such as HPV, which may require tailored approaches.

All strategies should be designed through the lens of "do no harm", and specifically, measures must be in place to prevent violence, sexual harassment, exploitation and assault, ensuring the safety of health workers and clients.

Establishing and strengthening catch-up vaccination

A catch-up vaccination strategy (which includes a clearly defined catch-up vaccination policy and schedule) is essential to a well-functioning national immunisation programme. It should be implemented continuously as part of routine immunisation services.

Catch-up vaccination refers to vaccinating an individual who, for whatever reason, is missing/has not received doses of vaccines for which they are eligible, per the national immunisation schedule.

Catch-up vaccination can be conducted through routine immunisation service delivery (fixed, outreach, mobile, school-based), periodic intensification of routine immunisation (PIRI) activities, or innovative local strategies that ensure individuals can receive routine immunisations for which they are overdue and eligible. **New routine introductions and campaigns** should also be used as catch-up vaccination opportunities. Countries are encouraged to integrate catch-up strategies into existing funding mechanisms such as HSS and TCA. If catch-up populations are large and intended to be reached through routine immunisation (rather than an explicit campaign), additional vaccines may need to be requested over time through Gavi's vaccine dose adjustment process.

Immunisation services integration

The WHO 2020 *Immunization Agenda 2030: A Global Strategy to Leave No One Behind* recognises that the success of immunisation programmes will increasingly depend on integration and collaboration with stakeholders within and beyond the health sector. Gavi strongly encourages countries to adopt an integrated approach to immunisation programming to ensure efficiency, promote equity and increase access across the life course.

Key resources and references

- WHO: *Immunization Agenda 2030: A global strategy to leave no one behind*
- WHO: *Working together: an integration resource guide for immunization services throughout the life course*
- Health Campaign Effectiveness Coalition: *Decision Guidance Toolkit for People-Centered Integration of Health Campaigns*
- Gavi: *COVID-19 Delivery Support (CDS) - Third Funding Window Guidelines*
- WHO: *Leave no one behind: guidance for planning and implementing catch-up vaccination*

Countries should consider the following:

- Integration with COVID-19 vaccinations: This is an opportunity to use the investments made for COVID-19 vaccinations and restore routine immunisation to pre-pandemic levels.
- Opportunities to use other potential entry points for immunisations, including nutrition, mass drug administration and school health programmes.
- Integration is a continuum rather than an all-or-none phenomenon: consider opportunities for integration of specific components, such as joint planning and advocacy, mapping, community engagement, training, budgeting, social mobilisation, set-up/preparations and other activities such as supervision, monitoring, reporting, coverage surveys and co-delivery of vaccines as applicable.
- Funding applications should indicate the specific components of the different programmes that will be integrated.
- Integrated campaign planning should identify joint activities and should be budgeted in one antigen budget request or the other to demonstrate those synergies.
- Plans should include measures to ensure that coverage of any vaccines in the integrated approach is not adversely affected.
- Countries can make use of the full range of Gavi support types, including Vaccine Introduction Grants (VIGs), Switch Grants, Operational Cost grants (Ops), Partners' Engagement Framework-Targeted Country Assistance (PEF-TCA), HSS grants, EAF and COVID-19 vaccine Delivery Support (CDS). An integrated approach to immunisation service delivery can lead to budget savings. Such savings could be redirected to other activities aligned with improving coverage and reaching zero-dose children and missed communities.

2.3 Gavi support for new vaccine introductions, campaigns and optimisation

Financial support

- **Vaccine Introduction Grants (VIGs):** Financial support for countries to cover a share of the time-limited costs of newly introducing a vaccine, intended to facilitate the timely and successful introduction of new vaccines into routine immunisation programmes.
- **Operational Cost grants (Ops):** Financial support to cover a portion of the costs of a campaign intended to facilitate the timely and effective delivery of vaccines to the target populations. Operational support for campaigns must reflect the elements outlined in section 2.4.
- **Switch Grants:** Financial support to cover a share of the one-off costs to switch product, presentation, schedule or use.

Gavi requires countries to co-finance a portion of vaccine cost to encourage domestic commitment towards creating sustainable immunisation programmes.

The exact co-financing requirement depends on a country's transition status and the vaccine programme.

Please refer to the *Gavi Application Process Guidelines* for further details on co-financing requirements.

Calculation of financial support for new introductions and campaigns and switches

Transition phase	VIGs	Ops grants	Switch
Initial self-financing	**US$ 0.80** per infant in the birth cohort (i.e. live births in the year of introduction) **or a lump sum of US$ 100,000**, whichever is higher	**US$ 0.65** per targeted person	**US$ 0.25** per infant in the birth cohort **or a lump sum of US$ 30,000**, whichever is higher
Preparatory transition	**US$ 0.70** per infant in the birth cohort **or a lump sum of US$ 100,000**, whichever is higher	**US$ 0.55** per targeted person	**US$ 0.25** per infant in the birth cohort **or a lump sum of US$ 30,000**, whichever is higher
Accelerated transition	**US$ 0.60** per infant in the birth cohort **or a lump sum of US$ 100,000**, whichever is higher	**US$ 0.45** per targeted person	**US$ 0.25** per infant in the birth cohort **or a lump sum of US$ 30,000**, whichever is higher

Vaccine-specific rules

Some **vaccine-specific rules** for the calculating of VIGs, operational support for campaigns or switches apply:

- **Preventive cholera campaigns:** Operational support is calculated per dose rather than per targeted person. Countries are expected to use, in particular, the second campaign round to conduct integrated activities to reach under-immunised populations with other vaccines.
- **HPV vaccine introductions:** These are eligible for a VIG of US$ 2.40 per targeted girl in the routine cohort or a lump sum of US$ 100,000, whichever is higher, regardless of the country's transition phase.

Vaccine-specific rules (continued)

- **HPV vaccine switches:** For eligible countries switching product or presentation of the HPV vaccine, Gavi provides US$ 0.80 per targeted girl in the routine cohort or a lump sum of US$ 30,000, whichever is higher.
- **Malaria vaccine introduction:** The VIG amount is calculated based on the subnational birth cohort in the areas targeted for the vaccine introduction. Please refer to section 3.5 for more details on the calculation.
- **Measles or measles-rubella (MR) follow-up campaigns:** Gavi provides flexibility for countries requesting measles or MR follow-up campaign support to apply for Ops grants calculated based on the national 9–59 month population, with the flexibility of the funds to be used for tailored strategies (e.g. national campaigns, subnational campaigns or enhanced routine immunisation activities targeted at reaching missed children). Differentiated use of funding for operational costs to reach zero-dose children is expected. Please refer to section 3.6 of this publication.

Financial support

Gavi provides funding for other immunisation and health systems strengthening (HSS) activities, which countries may use to improve vaccination activities' efficiency, effectiveness and coordination. For more detail, please review Gavi's *Programme Funding Guidelines* and discuss with your Gavi Senior Country Manager.

- Expanding cold chain capacity and logistics, including at subnational levels: Cold Chain Equipment Optimisation Platform (CCEOP) funds.
- Improving surveillance capability to detect and quickly respond to outbreaks: HSS funds.
- Improving human resources capacity and management: HSS funds.
- Improving coordination and planning, including expanding the use of geographic information systems (GIS) and other technologies: HSS funds.
- Implementing innovative strategies to identify and reach zero-dose children and missed communities: Equity Accelerator Fund (EAF), also available through Operational Cost (Ops) grants.
- Technical assistance funding and support from the Vaccine Alliance and extended in-country partners: Targeted Country Assistance (TCA) and Partners' Engagement Framework (PEF) funds.

These funds are also accessible through the Full Portfolio Planning (FPP) process.

2.4 Required considerations for countries requesting campaign support

While routine vaccination is the core of the immunisation programme, campaigns are valuable in three main ways:

1. To accelerate disease control and fill immunity gaps where people are missed by routine immunisation services or for diseases where there is no routine vaccine in use, thus decreasing the risk of outbreaks (preventive campaigns).
2. To build population immunity rapidly for certain vaccines during introduction (catch-up campaigns).
3. To respond to an outbreak (reactive campaigns).

Within the specificities of the different types of campaigns and other supplementary immunisation activities (SIAs), all efforts should be made to reach zero-dose children being consistently missed by routine immunisation, strengthen equitable routine immunisation and increase overall coverage to reduce reliance on follow-up campaigns.

Requirements for countries requesting support to conduct a campaign

(1) Countries should ensure that campaigns:

- are well-targeted and **designed to reach zero-dose and under-immunised children and underserved communities**;
- are designed to **integrate zero-dose and under-immunised children into the routine system** and to generate demand for a full course of vaccines;
- identify opportunities to **strengthen health delivery systems**; and
- **mitigate any adverse impact** the campaign may have on routine services.

(2) Countries should **make use of opportunities for integration** with other campaigns (as collaboration or co-delivery), vaccine-related activities or health interventions at any stage, either fully or partially in the planning, preparatory, implementation, delivery, and/or monitoring and reporting phases of the campaign, to reduce the adverse impact on routine immunisation and increase cost-efficiencies.

(3) Countries should **consider how campaign support will be complemented** with targeted and tailored approaches **to raise routine immunisation coverage on an ongoing basis** (e.g. enhanced routine immunisation activities, child health days). Please refer to the *Programme Funding Guidelines* for additional information on mobilising Gavi support.

(4) Countries should consider **targeted delivery approaches** as an alternative to nationwide activities in cases where campaigns aim to fill specific immunity gaps. Section 3.6 on measles and MR provides additional information on this.

Other examples of targeted delivery approaches include:

- periodic intensification of routine immunisation (PIRIs);
- expanding, introducing and re-introducing regular outreach sessions; and
- child health days, during which administered doses are recorded on a child's routine vaccination card.

(5) Funding for **operational costs should be used in a differentiated manner,** as reaching zero-dose children is likely to involve higher operational costs than those already receiving services.

Importance of robust campaign planning, implementation and monitoring

Countries must use the WHO SIA Planning and Implementation Guide and the accompanying SIA Readiness Assessment Tool (as is or adapted to country needs) to ensure high-quality planning, preparation, implementation and monitoring.

The SIA Readiness Assessment Tool allows countries to assess preparedness and ensure that all preliminary activities have been conducted before the campaign. Countries must indicate in their campaign plan of action how the tool will be used and report on the assessment results to the Gavi Secretariat and partners at the recommended intervals. If required, technical assistance on using the tool can be requested from WHO.

Countries are recommended to consider using **digital technologies for real-time monitoring of immunisation campaigns**. Real-time monitoring includes activities that employ digital technologies to accelerate the sharing, analysis and use of data to improve campaign efficiency. It can enhance the quality of campaigns by helping implementers review progress against targets promptly, identify issues and gaps quickly, track supplies, human resources and vaccine sessions, and make prompt decisions about corrective actions.

Key resources and references

- WHO guidance on Campaign Integration (forthcoming)
- Health Campaign Effectiveness Coalition
- Health Campaign Effectiveness Coalition: *Decision Guidance Toolkit for People-Centered Integration of Health Campaigns*
- WHO: SIA Planning and Implementation Guide (EN I FR)
- WHO: SIA Readiness Assessment Tool (EN I FR)
- WHO: SIA Readiness Dashboard (EN I FR)
- Gavi: Using digital technologies for real-time monitoring of supplementary immunisation activities
- Gavi/UNICEF: *Leveraging Geospatial Technologies and Data to Strengthen Immunisation Programmes* (rapid guidance for investment planning)

Campaign reporting requirements

Countries benefiting from Gavi support for campaigns must provide the following reporting elements to the Gavi Secretariat:

- **SIA technical report:** within three months after the campaign was implemented
- **Post-campaign coverage survey (PCCS)**: conducted within three months and submitted within six months
- **Reporting against agreed indicators in the monitoring and learning plan:** in line with agreed reporting timelines

Key resources and references

- WHO SIA technical report template (EN I FR)
- WHO Vaccination Coverage Cluster Surveys Reference Manual
- WHO vaccination coverage survey methods
- Checklist for PCCS report template, using measles as an example (to be adapted for other vaccines)[2]
- Gavi's Country Monitoring and Learning (M&L) Guidelines

Annex 2 of these guidelines highlights points to consider for PCCS supported by Gavi.

[2] F.T. Cutts, M.C. Danovaro-Holliday, D.A. Rhoda; Challenges in Measuring Supplemental Immunization Activity Coverage Among Measles Zero-Dose Children, *Vaccine*, Volume 39, Issue 9, 2021, Supplementary material; https://doi.org/10.1016/j.vaccine.2020.11.050.

2.5 Gavi support for vaccines optimisation and switches

Eligibility and requirements for vaccine switch requests (including compulsory vaccine switches)

Context and definitions

Several new vaccine options and alternative schedules have become available to Gavi-supported countries, and more are in the pipeline. **Vaccine portfolio optimisation** refers to the opportunity or requirement for a Gavi country to switch from the current vaccine product, presentation, schedule or use to more opportune one(s) containing the same antigen.[3] Several of the vaccine programmes that Gavi supports offer a variety of optimisation options.

This guidance is applicable to Gavi-eligible countries that have already introduced the Gavi-supported vaccine(s), as well as to countries planning new introductions or campaigns supported by Gavi. It is also applicable to Gavi-funded vaccines that might not be specifically funded in that country if the switch is programmatically justified.[4]

Vaccine options and potential optimisation impact for country programmes (2022)

Vaccine optimisation options		Potential benefits					
		Reduce programmatic complexity	Reduce cold chain space	Improve efficacy, effectiveness or safety	Improve coverage	Reduce cost	Secure vaccine availability
Rota	12	✓	✓		✓	✓	✓
PCV	5 2		✓	✓	✓	✓	✓
IPV	3 2 2	✓	✓	✓		✓	✓
HPV	3 2**	✓	✓		✓	✓	
Penta	4						✓
MCV	2				✓		
YF	2				✓	✓	
Mixed*	2+				✓		✓

Products or presentations Schedules Use

* A country can choose to combine options, e.g. India using two Rota products

** SAGE one dose permissive recommendation

Note: Numbers indicated in the bars illustrate the number of different vaccine options available by-products or presentation (green), schedules (blue) or use (yellow). For definitions of products or presentations, schedules and use, please refer to the table in the subsequent section.

[3] This definition excludes the case of interchangeable vaccines (e.g. pentavalent). Countries may receive the same presentation from different suppliers and this would not constitute a switch.

[4] For example, switching from measles-containing vaccine (MCV) in ten-dose vials to MCV in five-dose vials is supported also for countries that fully self-finance MCV.

Available vaccine presentations are described in the detailed product profiles on the Gavi website.

Definitions of vaccine programme prioritisation versus optimisation

Prioritisation

The need for countries to assess ***which vaccine programme(s) to invest in first*** when limited by constrained country capacity, resources or supply scarcity.

For some countries, savings from optimisation can expand prioritisation

Optimisation

The opportunity for countries to assess new/alternative vaccine product(s), presentation(s) or schedule(s) or use(s) for their vaccine programmes and ***switch to more opportune one(s)*** based on the country and market context.

Vaccine switch types and impact on countries and to market

Gavi support is offered for vaccines and dose schedules supported by WHO position papers and Gavi Board decisions. There are several types of vaccine switches:

Vaccine switch types

Product switch	Presentation switch	Schedule switch	Use switch
Changing to a vaccine manufactured by a different supplier, and/ or with a different combination or strain composition	Changing to a different primary presentation – vial size, blow-fill-seal – and/ or a different formulation (liquid versus lyophilised), or delivery technology (pre-filled syringes, patches)	Changing the dose schedule of the same vaccine	Changing how the same vaccine in the same formulation is administered

Gavi aims to provide countries with the information and resources to enable evidence-based assessments of optimisations in their vaccine programme while seeking to mitigate potential negative impacts on market health. This can mean optimisation options may be constrained, in some situations, to preserve broader market health.

Potential impact of vaccine switches on countries, market, Gavi partners and the Secretariat

Country

- Financial sustainability
- Programmatic ease
- Cold chain capacity and costs
- Disease burden
- Coverage
- Supply security

Market health

- Supply availability
- Prices increase/ decrease
- Increase/decrease investment in new presentations
- Increase/decrease investment in local manufacturing capacities

Gavi partners

- Pandemic readiness
- Strategic disease agendas
- Return on investment in innovations for low- and middle-income countries (LMICs)
- Advocacy and fundraising

Gavi Secretariat

- Vaccine cost
- Forecast accuracy
- Penalty payments (volume agreements)
- Risk mitigation

Timing

Countries can assess alternative vaccine options and submit switch requests at any time. Typically, new vaccine options become relevant when:

- countries update their national immunisation strategy;
- countries engage in Gavi's Full Portfolio Planning (FPP);
- countries move closer to transitioning out of Gavi or change phases within Gavi support;
- countries apply for new vaccine introduction or campaign support;
- changes in country context (new epidemiological data, fiscal space changes);
- supply availability changes;
- a new vaccine product/presentation prequalified by WHO offers advantages;
- changes in prices or wastage rates of available vaccines; and
- WHO publishes new SAGE recommendations/position papers on dose schedules or use.

Depending on the context, a country's change could either be elective (country's choice, e.g. switches requested to lower cost or to improve coverage) or non-elective (imposed by circumstances external to the country[5]).

Regardless of the reason driving a switch, the country is invited to share what rationale drove the decision to change product, presentation, schedule or use. Gavi will use this information to observe emerging trends in country preferences and to inform current and future supply or product innovations.

Guiding principles

The first set of these principles applies to every switch decision, including compulsory ones mandated by the Alliance to the country due to circumstances outside the country's control. The second set applies to elective switches only.

[5] A country introducing with their second-preferred option will retain the possibility to switch to the first preferred option later.

Principles applicable to all vaccine switches:

- The vaccines chosen must **fit within the existing cold chain infrastructure**. If multiple equivalent options are available, the country is expected to select an option that can be accommodated without substantial expansion of cold chain capacity. For example, a country with limited negative temperature capacity should not choose a frozen vaccine unless it is the only option.

- To minimise the number of children missing doses of a recommended vaccine, country choices are expected to **align with product availability** and to prioritise rapid implementation over "waiting for the ideal product".[6] For example, countries are encouraged to pick the second option if there is a supply shortage of the most preferred option.

- To mitigate the risk of stock-out, **wastage rate assumptions** for the first year should align with WHO estimates reflected in Gavi's detailed product profiles. If otherwise, adequate evidence should be provided.

Principles applicable to elective switches:

- Elective switches are expected to **result in a net benefit** for the country. Countries should demonstrate a positive impact on programme outcomes and/or programme sustainability and/or supply availability and are asked to provide the evidence that underpinned their decision.

- To minimise disruptions to routine immunisation, Gavi recommends an **interval of a minimum of 12 months** between introduction and switch, or between two switches of the same antigen, and bundling together multiple switches to enable implementation synergies (e.g. run a single training event rather than multiple). Requests for multiple switches of different vaccines to happen at the same time are encouraged (for example, a simultaneous switch of rotavirus vaccine and pneumococcal conjugate vaccine), noting the need for aligned process timelines and supply availability.

- In exceptional circumstances, countries may choose to **switch only a part of the nationwide vaccine volume** to add a presentation type of the same vaccine product used in routine (for example, to overcome HCWs' hesitancy to open a multi-dose vial with several doses, a country can request a single-dose presentation to use in peripheral sites with low population density while keeping a multi-dose presentation for high-density areas) or a second product with the same antigen.[7]

The above principles aim to strike a balance between being responsive to countries' preferences, ensuring that a switch's inherent risks are sufficiently addressed and keeping the request and review processes lean.

Requirements

All elective or compulsory switch requests must be **submitted via email to proposals@gavi.org** with the Gavi Senior Country Manager in copy. Switch requests can be submitted at any time.

[6] A country introducing with their second-preferred option will retain the possibility to switch to the first preferred option later.

[7] For example, India uses both Rotavac and Rotasiil in its national programme.

Documents to provide:

1 A Gavi switch request form
One form for each switch request,[8] including the following documents:

- **An assessment of the switch impact:** the benefits and trade-offs resulting from the switch across financial, cold chain, disease burden, supply and programme implementation aspects must be summarised in the **"switch impact assessment"** table on the form (see the "Forms, examples and technical references" section at the end of this section for examples).
- **Stock data to inform switch timing:** the most suitable time to switch needs to factor in the consumption of the old vaccine, if available, to ensure full use.
- **Cold chain readiness:** to confirm the availability of adequate cold chain capacity for switches with a cold chain impact, such as increasing doses, changing vaccine presentations or changing vaccines.
- **Financial sustainability:** for all requests:
  - submit a five-year scenario of how the switch will impact co-financing[9]; and
  - inform the Ministry of Finance and copy them into the submission.

The Ministry of Health (or delegate) must sign the switch request form. If the switch increases the co-financing amount(s), then the switch request form must also be signed by the Ministry of Finance.

2 NITAG (or ICC) supportive recommendation
Required if the switch changes one or more of the following:

- dose schedule;
- target population; and
- vaccine composition that can affect effectiveness (strains/serotypes) or safety (e.g. live vaccine or addition of preservative).

Optional for changes in:

- primary container (e.g. from ten-dose vial to five-dose vial);
- formulation (e.g. from lyophilised to liquid);
- cost factors (e.g. wastage rate, price per dose); and
- vaccines that are considered interchangeable in the Gavi detailed product profiles (e.g. pentavalent).

3 A switch implementation plan, including a short **chronogram of key activities** for the proposed switch.

As per WHO guidance, the main areas that countries will need to plan for include:

- selecting the vaccine product, presentation, formulation, schedule and use;
- updating the national immunisation policy and schedule (if applicable);

[8] For two independent switches requested at the same time, please submit two independent switch forms, one for each, and a single switch budget form encompassing both the Switch Grants, if requested.

[9] For switches of PCV, rotavirus and HPV vaccines, PATH's Vaccine Cost Calculators can be used.

- estimating and upgrading storage and cold chain capacity;
- updating the logistics management information system (LMIS);
- updating health information systems, including recording/reporting materials;
- consideration of catch-up immunisation strategy (if applicable);
- training and supervision of health personnel; and
- communicating with caregivers and communities.

4. **For switches that impact the vaccine schedule:** a copy of the current child vaccination card or Expanded Programme on Immunization (EPI) calendar to inform independent reviewers about the schedule changes a switch might trigger the need for additional visits.

5. **If the country requests a Switch Grant, the country must submit a budget in the standard Gavi template** (EN | FR).

Countries' switch requests will be reviewed by the Gavi Secretariat in consultation with technical partners and potentially with independent experts. The country will be notified of the updated implementation timeline and/or dose calculations, and eligible grant amounts through a decision letter. **Elective switch requests should be submitted at least eight months before planned implementation** to account for supply planning notification.

Requesting additional technical assistance

In many cases, when a country needs to or chooses to change to a different option(s) or to integrate a second option, Gavi offers support in the form of technical assistance and a Switch Grant. Technical assistance from WHO, UNICEF and extended partners can be requested through Gavi, preferably in the year before the switch decision-making.

Through the participation of Gavi/Targeted Country Assistance partners, Gavi funds tailored and differentiated technical assistance in response to specific country needs. Please review your approved technical assistance plan to assess whether the support required to implement a new vaccine is included.

Financial support for switches (Switch Grant)

For the implementation of the switch to be successful, countries will need to ensure that the required funding is available. Planning for and securing these funds in advance will help to facilitate the process. Depending on what option a country switches from, the implications of implementation complexity and resources needed can vary considerably. Some switches may require less funding than others, depending on country-specific opportunities for synergies with other planned events and how the switch can be feasibly integrated into routine services.

Gavi may provide support through a Switch Grant to facilitate the safe and effective transition to a new product, presentation, schedule or use, and intends to cover a portion of its one-time investments.

As per WHO's *Vaccine portfolio optimization guide: Assessing vaccine switch opportunities and planning for implementation*, possible costs to consider when estimating funding needs for the switch include the following:

1. Workshop to review/adapt the existing training modules, guides and communication support.
2. National-level kick-off meeting to ensure all government departments are informed, involve stakeholders to support the switch, update the national policy, etc.
3. Revision, production and distribution of tools, including printing child health cards, immunisation forms, vaccine stock forms, guidelines and procedures.
4. Briefing of national and regional level facilitators.
5. Updating logistics/health management information systems (LMIS/HMIS) electronic tools, systems and registries with the new product information.
6. Training and supervising all relevant health personnel at all levels for each switch, including refresher training.
7. Social mobilisation and communication. For example, a schedule change requires informing mothers to bring back their children later than the recent norm.
8. Programme monitoring and evaluation, including immediate post-switch supervisory or monitoring visits to identify and resolve issues affecting the switch.

Further guidance on the eligibility of support is provided in Gavi's *Budget Eligibility Guide* (EN | FR).

Switch Grant requests should be submitted jointly to the switch request form using the standard Gavi template (EN | FR). All Switch Grant requests will be subject to review.

The Switch Grant is not intended for investments that take longer than approximately six months to implement.

In the case of a compulsory switch with delayed introduction due to supply scarcity, a Switch Grant will be limited to cover unrecoverable expenses from the VIG. For example, if a country has printed training materials for one presentation that has become unavailable, the country may access a Switch Grant to finance the printing of materials for the new vaccine presentation.

Switch follow-up requirements

1. Countries should plan to use the full stock of the current presentation before implementing the switch to the new one to minimise waste as far as feasible (except for partial switches).
2. Countries must report the actual switch date to the Gavi Senior Country Manager within a year of the approval of the switch request.
3. Countries should implement the approved switch to different vaccine products, presentations, schedules or use in a timely fashion and no later than two years after approval.

Checklist of required documents to submit (check off prepared documents)

- ☐ Switch request form, signed by the Ministry of Health
- ☐ NITAG recommendation or ICC endorsement supporting the switch
- ☐ Switch implementation plan with a chronogram of key activities
- ☐ Budget for Switch Grant (if this financial support is requested)
- ☐ Five-year co-financing scenario[10] (only if co-financing changes)

A tailored checklist of required documents can be found at the top of each vaccine section.

Forms, examples and technical references

- Gavi switch request form
- Example of Gavi switch request form
- Example of Gavi switch implementation plan[11]
- Framework to inform vaccine selection or switch impact assessment, with examples

2.6 Support to middle-income countries (MICs)

In December 2020, the Gavi Board approved a new approach to engaging with middle-income countries (MICs) in the Gavi 5.0 strategic period: the "MICs Approach". Serving as a key tool for addressing threats to the equity and sustainability of routine immunisation programmes, the MICs Approach contributes to Gavi's overall vision of leaving no one behind with immunisation and has two overarching objectives:

1. to prevent backsliding in vaccine coverage in former Gavi-eligible countries; and

2. to drive the sustainable introduction of key missing vaccines in both former and select never Gavi-eligible countries.

Countries eligible under the MICs Approach include all former Gavi-eligible countries, never Gavi-eligible lower middle-income countries and additional International Development Agency (IDA)-eligible economies. Through the MICs Approach, Gavi provides support at a regional and global level to address the systemic issues that stand in the way of sustainable and equitable new vaccine introductions, alongside tailored support in response to country-specific needs in line with the MICs Approach objectives. This includes support to mitigate backsliding in a select group of former Gavi-eligible countries that have seen significant and sustained reductions in vaccine coverage as well as country-specific support to drive the sustainable and equitable introduction of pneumococcal conjugate vaccine, rotavirus vaccine and human papillomavirus vaccine.

[10] As per PATH's Vaccine Cost Calculators, available for human papillomavirus vaccine, pneumococcal conjugate vaccine and rotavirus vaccine.

[11] Adapted from the action plan developed by EPI Cameroon in 2022.

3 Vaccine programme guidelines

3.1 Oral cholera vaccine

→ PREVENTIVE CAMPAIGNS

Vaccine-specific mandatory application attachments

- ☐ Multi-year plan of action
- ☐ Hotspot analysis (workbook and report)
- ☐ National cholera plan (strongly recommended for first application, required for subsequent applications)
- ☐ Reports from three most recent preventive and/or reactive campaigns (if applicable)

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Detailed product profiles

WHO recommendations

The Global Task Force on Cholera Control's (GTFCC) *Ending Cholera: A Global Roadmap to 2030* relies on a multi-sectoral approach, including the use of oral cholera vaccine (OCV), surveillance and reporting; community engagement; health systems strengthening (HSS); leadership and coordination; and water, sanitation and hygiene (WASH).

Cholera vaccination is a cholera prevention and control measure that can be implemented in the short to medium term, while complementary interventions focused on expanding sustainable access to other primary prevention measures, including safe water and sanitation, are put in place.

WHO recommends that OCV be used in areas with endemic cholera; in humanitarian emergencies with a high risk of cholera; and during cholera outbreaks. The vaccines should always be used in conjunction with other cholera prevention and control strategies.

Key resources and references

- *Cholera vaccines: WHO position paper – August 2017*
- GTFCC guidance on OCV use
- GTFCC: *National Cholera Plan Development*
- GTFCC: *Guidance and tool for countries to identify priority areas for intervention*
- GTFCC: Key indicators reporting tool
- *World Health Organization vaccination coverage cluster surveys: reference manual*

Available Gavi support

Gavi provides support for the preventive and reactive (emergency) use of OCV, including vaccine and operational costs. Preventive cholera vaccination campaigns are supported in areas with a high and persistent cholera disease burden.

The following guidance pertains only to preventive OCV campaigns.

Preventive campaigns

- **Target population:** All persons at least one year of age are eligible to be included in preventive OCV vaccination campaigns. Pregnant and lactating women and HIV-infected individuals should be included, as per the detailed recommendations on vaccination of special populations (HIV-infected persons, pregnant and lactating women, and prison and other closed institutions) provided in the WHO cholera position paper.

This guideline does not cover reactive campaigns for outbreak response: Gavi provides support for the OCV stockpile managed by the ICG. Emergency requests for outbreak response vaccination campaigns can be submitted to the ICG. To access outbreak response support for cholera, countries should contact the ICG Secretariat (email: ICGSecretariat@who.int).

- Gavi supports the provision of two doses of OCV per targeted individual, in line with WHO guidance.

Key considerations for preventive campaigns

- **Dose spacing and campaign scheduling:** Gavi supports the provision of two doses of cholera vaccine following the SAGE recommendation, which is normally administered with a spacing of 14 days. However, programmatic variations in campaign scheduling may occur, resulting in a longer interval of time before the administration of the second dose (e.g. as a result of logistical constraints to organise the delivery of the second dose). Countries should include the rationale for the proposed scheduling in the plan submitted to Gavi, which should follow SAGE recommendations.

- **Co-administration:** As cholera vaccines can be co-administered with other injectable or orally administered vaccines (e.g. polio vaccines), capitalising on opportunities to integrate OCV with other immunisation activities with overlapping target populations is recommended.

- **Strengthening routine immunisation and reaching missed communities and zero-dose children:** OCV campaigns inherently target vulnerable populations and those who may not easily access routine health services. It is strongly recommended to use OCV campaigns to identify, refer and/or reach zero-dose and under-immunised children, adolescents and adults with other vaccines, especially in the second vaccination round (see illustrative activities below). The identify, reach, monitor, measure and advocate (IRMMA) framework provides further guidance on approaches and interventions that can be used to increase vaccination coverage among these groups.

- **Water, sanitation and hygiene (WASH) and other health intervention integration:** Opportunities to integrate short-term WASH interventions and/or other health activities and campaigns should be described in the application (see the following illustrative activities), including specific activities that will be conducted concurrently with OCV campaigns. Other funding sources to support the implementation of these activities should be identified in the detailed budget submitted as part of the application.

Opportunities to integrate other immunisation and health activities into OCV campaigns

First OCV dose

- Check routine immunisation (RI) vaccination status.
- Enumerate missed populations.
- Assess the reasons for non-vaccination and barriers to immunisation.

Inter-dose period

- Plan for integrating other vaccines or public health interventions into second round of campaign.
- Plan delivery strategies to reach missed communities and individuals.
- Plan for bringing zero-dose children reached through campaigns into RI.

Second OCV dose

- Deliver other vaccines and/or other public health interventions (e.g. PIRI and integrated outreach activities, WASH, malnutrition screening, integration of other campaigns such as vitamin A or bed-net delivery).
- Link missed communities to RI systems.

Post-campaign and RI

- Use surveys to identify populations missing vaccines, reasons for non-vaccination and barriers to immunisation.
- Integrate delivery strategies used for reaching missed communities and learnings into regular budgeted immunisation activities for the geographical region.

Oral cholera vaccine preventive use guidance and requirements

- **Hotspot assessment report:** For all applications, a report detailing the hotspot analysis (i.e. risk assessment) that was conducted using the GTFCC guidance to identify priority areas for cholera control interventions, and its findings, is required. The Excel file, including targeted areas and sequencing of vaccination campaigns, should also be attached. The report should include a description of the methodology, presentation of results, and the rationale for the selection of hotspots to be prioritised for cholera control interventions. The report should also describe why certain hotspots were selected to receive OCV, and the rationale for the sequencing of these hotspots for vaccination.

- **National cholera control plan:** It is strongly recommended that the multi-year vaccination plan be based on the *National Cholera Plan*, which demonstrates complementary multi-sectoral cholera control interventions, including long-term WASH investments and is endorsed by the GTFCC. The National Cholera Plan, if available, should be submitted as an attachment to the first multi-year preventive vaccination application. A fully endorsed National Cholera Control Plan will be required for subsequent applications.

- **Multi-year planning:** The primary document in the OCV application is the multi-year plan of action, which includes a preventive vaccination plan for up to five years. The multi-year plan of action should detail the rationale for selecting areas for preventive vaccination based on the hotspot analysis and

the rationale for the proposed timing of vaccination in these hotspots, as well as a description of the implementation strategies. A macro plan and budget for the entire time period of the plan is required at the time of application.

- **Annual adjustments:** On an annual basis, small changes to the following year's detailed operational plan and budget may be requested as long as these changes remain within the overall dose and budget ceilings approved. This annual review and approval process can include changes required to the detailed plan that do not substantially change the scope of the plan, for example, the need to shift the timing of preventive vaccination activities due to a cholera outbreak.

- **Co-financing requirements:** There is no co-financing requirement for preventive campaigns implemented in a specific geographic area for the first time. Co-financing requirements for periodic preventive vaccination, subject to Gavi Board approval, will only apply if and when a country over-relies on vaccination as a cholera control strategy and frequent, periodic, preventive vaccination campaigns are implemented in the same geographic area in a narrow window of time (i.e. less than three years from the previous preventive campaign). At the time of application, further flexibilities and requirements for co-financing may apply, per Gavi's co-financing policy.

Planning for Gavi support

Campaign Operational Cost grants (Ops): Gavi provides financial support for preventive cholera vaccine campaigns through Ops. Countries are eligible to apply for **up to US$ 0.65/0.55/0.45 per dose** based on transition status.

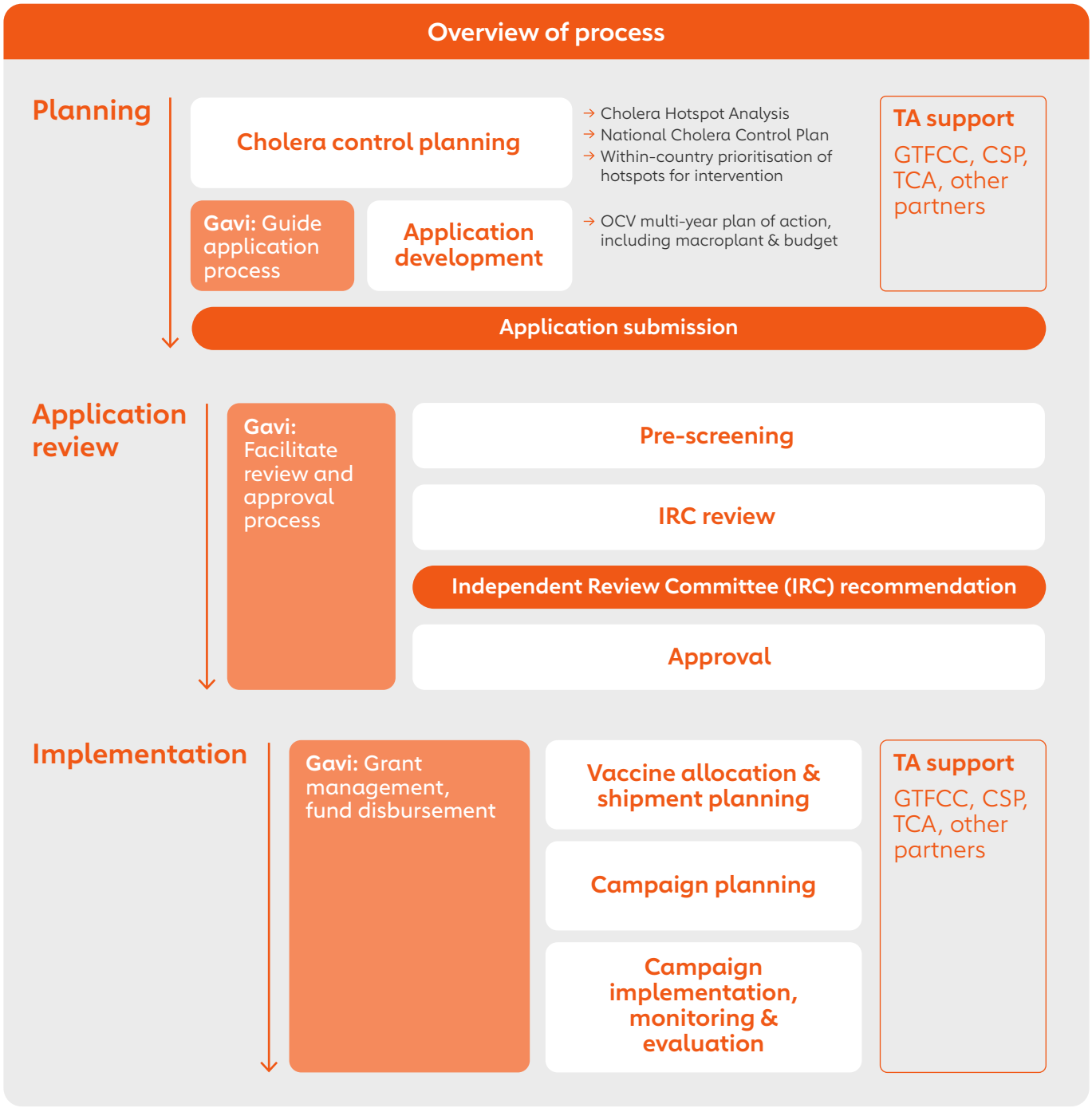
Sources of technical and financial support beyond the Ops grant

Technical assistance:

- The **GTFCC** and its member institutions can provide technical assistance to countries according to their needs for hotspot analysis, application development, and campaign planning and implementation. For further information, please contact the GTFCC OCV Focal Point (GTFCCsecretariat@who.int).

- In addition, the **Country Support Platform (CSP)**, hosted by the International Federation of the Red Cross, has been established to support cholera-affected countries: in the development of a national cholera plan and a multisectoral coordination mechanism to align government, national actors, GTFCC partners and key stakeholders towards a shared strategy; to mobilise resources towards the funding needs identified in their national cholera plans; and, in the provision of multisectoral technical support and capacity building for the formulation and the implementation of their national cholera plans and cholera vaccination plans. For further information, please contact the CSP (countrysupportplatform@ifrc.org) or the Gavi Cholera Programme Manager.

- Countries are also eligible to request **Targeted Country Assistance (TCA)** under Gavi's **Partners' Engagement Framework (PEF)** through the multi-year planning process to support cholera campaign planning, implementation and monitoring. For further information, please contact your Gavi Senior Country Manager.



Guidance and recommendations

Reporting requirements

- Please refer to reporting requirements detailed in section 2.4 "Campaign reporting requirements". Note that a post-campaign coverage survey (PCCS) is **required** for all campaigns.
- In addition, countries are requested to submit a GTFCC Key Indicators Reporting Tool within one month after each round of the campaign.

3.2 Human papillomavirus vaccine

→ NEW ROUTINE INTRODUCTION

→ NEW ROUTINE INTRODUCTION WITH ADDITIONAL MULTI-AGE COHORT (MAC)

Vaccine-specific mandatory application attachments

- ☐ Human papillomavirus (HPV) vaccine implementation plan
- ☐ HPV vaccine workplan
- ☐ Ministry of Education signature for school-based strategies
- ☐ HPV vaccine introduction budget

Access full library of Gavi guidelines

Detailed product profiles

→ EXISTING PROGRAMMES, DELAYED MAC

Vaccine-specific mandatory application attachments

- ☐ Updated estimates of target population/supply needs
- ☐ Updated HPV MAC workplan
- ☐ Updated HPV MAC budget
- ☐ Abbreviated HPV MAC implementation plan*

** Only countries with a delayed MAC that was pre-approved for the age range 9–14 years and are currently vaccinating a routine cohort at age 9 or 10 years but wish to extend the MAC to age 18 years on a single-dose schedule will need to submit an abbreviated HPV MAC implementation plan*

→ EXISTING PROGRAMMES, DOSING SCHEDULE SWITCH

Vaccine-specific mandatory application attachments

Notification of dosing switch only:

- ☐ NITAG or its equivalent supportive recommendation including Ministry of Health signature

If applying for Switch Grant, the above document and:

- ☐ Gavi switch request form
- ☐ Switch implementation plan
- ☐ Chronogram of key activities
- ☐ Copy of HPV vaccination card or EPI calendar
- ☐ HPV vaccine switch budget

→ EXISTING PROGRAMMES, VACCINATION COVERAGE IMPROVEMENTS

Vaccine-specific mandatory application attachments

For reallocation of existing health systems strengthening (HSS) grant:

- ☐ Narrative description of the activities
- ☐ Updated HSS budget reflecting the HPV vaccine activities

To request additional HSS funding:

- ☐ Formal request required
- ☐ Budget for the additional funds

WHO recommendations

The Global Strategy to Accelerate the Elimination of Cervical Cancer, adopted by the World Health Assembly in 2020, includes three main pillars: prevention through vaccination, screening and treatment of precancerous lesions, treatment and palliative care for invasive cervical cancer.

For cervical cancer prevention, the WHO-recommended primary target population for human papillomavirus (HPV) vaccination is girls aged 9–14 years. Current evidence suggests that either a single-dose or two-dose schedule may be used among the primary target population for HPV vaccination with comparable efficacy and duration of protection. A single-dose schedule is off-label and may offer programme and financial advantages.

In line with WHO recommendations for the primary target population, for countries applying to Gavi for a new HPV vaccine introduction Gavi provides support for HPV vaccination in girls aged 9–14 years[12] with either a two-dose schedule or single-dose off-label alternative schedule.

WHO recommends at least two doses and optimally three doses for immunocompromised populations, including HIV+ girls.

Off-label single dose considerations:

- Programmatic fit
- Ministry if Health approves
- NITAG (or equivalent) endorses
- National Regulatory Authority informed and allows
- Country understands implications

Key resources and references

- Human papillomavirus vaccines: WHO position paper, December 2022
- Resources for designing, implementing and scaling up HPV vaccination programmes, WHO Clearing House

Information on the selection of the HPV vaccine delivery strategy:

- WHO: *Guide to Introducing HPV Vaccine into National Immunization Programmes*
- Lessons learnt from human papillomavirus (HPV) vaccination in 45 low- and middle-income countries
- JSI: *HPV Vaccination in Malawi: Lessons Learned from JSI's Experience Supporting Vaccine Introduction and Routinization*
- WHO: Considerations regarding consent in vaccinating children and adolescents between 6 and 17 years old
- *Options for linking health interventions for adolescents with HPV vaccination*
- Lessons from post-introduction evaluations of national HPV vaccination programmes
- HPV vaccine technical partners: HPV Vaccine Schedule Optimization

WHO/PATH Information on financial planning, costing and budgeting HPV vaccination programmes:

- Financial planning tool for delivery strategies: *WHO Cervical Cancer Prevention and Control Costing tool: human papillomavirus vaccination module (C4P-HPV tool)*

[12] Countries that may be interested in vaccinating other populations (e.g. girls ≥ 15 years or boys) as a part of a new introduction of HPV vaccines should note that the government will have to bear the full operational and vaccine costs to reach these additional populations.

Key resources and references (continued)

- WHO tool to assess the cost-effectiveness of HPV vaccination
- PATH: HPV vaccine cost calculator

Further information on developing communication and social mobilisation plans:

- UNICEF lessons learned and field guides on HPV vaccine communication
- LSHTM/PATH HPV vaccine communications lessons learned
- WHO: *HPV vaccine communication: special considerations for a unique vaccine*
- JSI: *The Vital Role of Communities: Experience from Human Papillomavirus Vaccination in Tanzania*
- Girl Focus Toolkit for HPV vaccine

Information on switching to a single-dose HPV vaccination schedule:

- WHO: *CAPACITI decision support tool manual*
- PATH summaries of HPV vaccine single-dose evidence

Available Gavi support

As a part of revitalising country HPV vaccination efforts in response to a wider effort for immunisation programmes to recover from the global COVID-19 pandemic, in 2022, the Gavi Board approved an enhanced investment for HPV vaccines. Besides co-financing for vaccines, countries have five types of cash support from Gavi for HPV vaccination:

1. Vaccine Introduction Grant (VIG)
2. Operational Cost grant (Ops)
3. Switch Grant
4. Health systems strengthening grants (HSS)
5. Targeted Country Assistance (TCA)

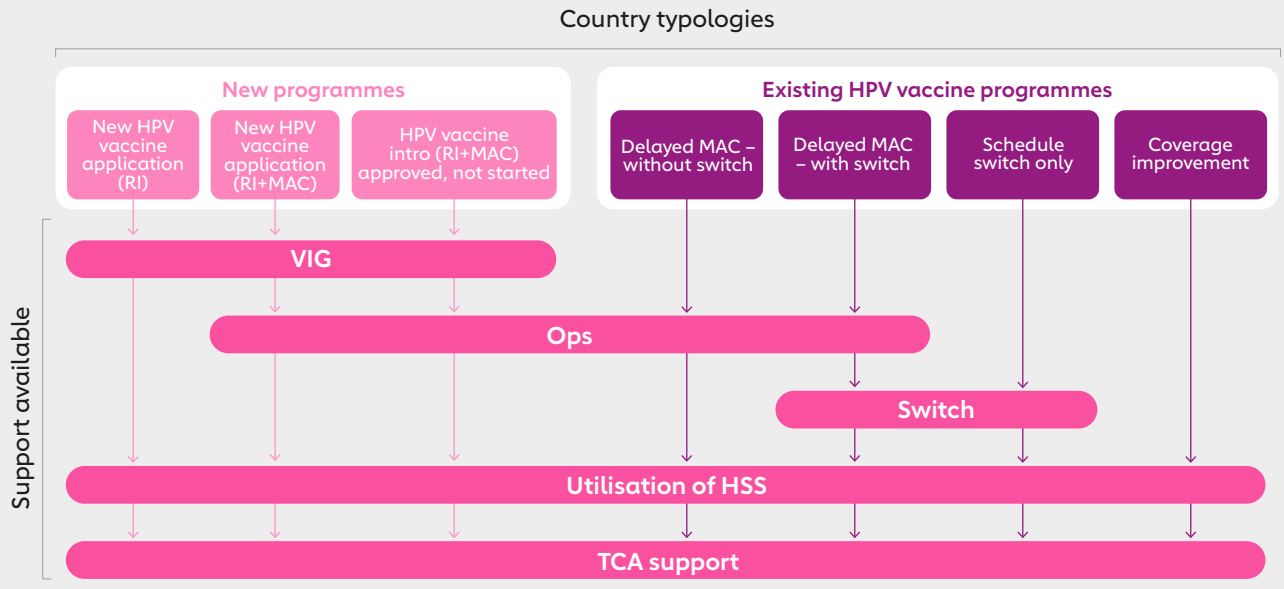
Countries can apply to Gavi for different types of support depending upon whether the support is for a new HPV vaccine introduction or supporting an existing HPV vaccination programme. The different types of support are summarised in the table below. For existing HPV vaccination programmes, countries may be eligible for different types of support based on programme characteristics, such as a delayed multi-age cohort (MAC), switching dosing schedules, and/or improving HPV vaccination coverage. The categories are not mutually exclusive. Countries are strongly encouraged to combine requests for multiple supports, i.e. prepare and submit them jointly.

Country typology	Types of support available*	VFG/PFG section
Countries with no existing HPV vaccination programme		
A HPV vaccine introduction • Single-age cohort only (routine) • Single-age cohort with MAC • Either one- or two-dose schedule	VIG VIG + Ops HSS	See section 2.3 (VIG, Ops) See *Programme Funding Guidelines* (PFG)
Countries with an existing HPV vaccination programme		
B Delayed MAC • MAC for routine at age 9 or 10 • MAC for routine at age 14 • Switch to a single-dose schedule, if concurrent with delayed MAC	Ops, up through age 18** Ops Switch Grant HSS	See section 2.3 (Ops, Switch) See *PFG*
C Dosing schedule switch only (introduction in routine programme and MAC completed) • Switch to a single-dose schedule	Switch Grant HSS	See section 2.3 (Switch) See *PFG*
D Improving HPV vaccine coverage • HPV1 coverage ≥70% (2021) • HPV1 coverage 40–69% (2021) • HPV1 coverage <40% (2021)	HSS	

* TCA is allocated through a separate process, not covered in these guidelines and is available to all countries, regardless of the type of support requested from Gavi.

** Delayed MAC for routine at age 9 or 10 that requests MAC to age 18 have additional requirements (see section B4 below)

Pathways for Gavi support



NO EXISTING HPV VACCINATION PROGRAMMES

A HPV vaccine introductions

A.1 Eligibility

Countries that have yet to introduce HPV vaccine into the national immunisation schedule may request Gavi support for only a routine single-age cohort within the age range of 9–14 years to be vaccinated annually in routine immunisation or as a combined introduction with a one-time vaccination for additional MAC up through age 14 years to maximise the impact during the introduction year.[13] Countries can select either a one-dose or two-dose HPV vaccination schedule.

HPV vaccine introductions with a single-dose schedule for introduction are not eligible for a Switch Grant.

A.2 Type of support available

- **Routine support:** VIG at US$ 2.40 per target girl in the routine single-age cohort and standard country co-financing for vaccine supply, regardless of the dosing schedule.
- **MAC support:** Additional one-time Ops grant at US$ 0.65/0.55/0.45 (as per country co-financing phase) per target girl in the MAC and vaccine supply at no cost, regardless of the dosing schedule.
- **HSS support:** Countries are encouraged to use their HSS grant to complement introduction support provided through the VIG to help build an HPV vaccine programme that is sustainable after the introduction year. Further information on allowable and encouraged HSS support is detailed in the *Programme Funding Guidelines*.
- **TCA support:** Targeted Country Assistance from in-country, regional and/or global partners to support the application and introduction activities is available. Countries are encouraged to contact their Gavi Senior Country Manager for guidance and instructions.

A.3 Planning for Gavi support

Countries are recommended to plan for a lead time of 15–18 months from the application submission to the planned HPV vaccine introduction. For instance, a country applying in April 2023 should plan for an introduction starting from Q3 or Q4 2024. This lead time will allow sufficient time for the Independent Review Committee (IRC) review processes, confirmation of supply, distribution of VIG with or without Ops grants, vaccine order and distribution and nine months of country-level planning suggested for a successful HPV vaccine introduction.

HPV vaccine supply

Information on supply availability of the different HPV vaccines that can be accessed with Gavi support can be found in the HPV vaccine product profile slide deck.

HPV-related supply documents:

- HPV vaccine product profile slide deck
- UNICEF Supply Division HPV vaccine tender 2021–2025

[13] Annex 1 indicates countries already receiving HPV vaccine support from Gavi and countries eligible to request new support.

Planning for HPV vaccine introduction

In line with WHO recommendations, countries are strongly encouraged to introduce the HPV vaccine for routine and MAC at the same time in the initial year of introduction.

Countries are required to identify a routine single cohort of girls (within ages 9–14 years) to be immunised on an annual basis (e.g. girls aged 9 years or a single grade: Primary 4) and additional girls who are older than the routine (or MAC) who will be immunised on a one-off basis in the initial year of introduction.

Countries opting to introduce **only** a single routine cohort will not be eligible for an Ops grant.

Planning for a phased introduction

Countries that cannot afford or implement an initial country-wide introduction of HPV vaccine may adopt a phased introduction approach by region, province or district. In such case, the following additional aspects should be taken into account:

- **Full vaccination within three years:** Countries will be required to expand the vaccination nationwide within three years of introduction.
- **VIGs and Ops for a phased introduction:** Vaccines and complementary financial support (i.e. VIG for routine and Ops for MAC) will be based on the size of the total target population and disbursed according to the year of each new phased introduction (as outlined in the HPV vaccine implementation plan).

Identify learning opportunities in the first phase of phased introduction: When a country decides on a phased introduction, it should include areas (i.e. districts, provinces, zones, etc) that provide the greatest learning opportunities in the first phase. These are likely to include challenging districts (i.e. that have been achieving consistently low vaccine coverage); for example, due to geographical factors (rural/urban), social and cultural factors (religion), including gender-related barriers (child, early and forced marriages, and low school enrolment), health system factors (low human resources, quality of health facilities) and behavioural factors, as well as strong performing areas. At all stages of planning for a phased introduction, countries are encouraged to review, analyse and revise strategies based on experience from earlier phases.

A.4 Guidance and requirements

To apply for the introduction of HPV vaccine through Gavi support, the country is required to fill out an **HPV vaccine implementation plan**, using the template available. The HPV vaccine implementation plan should be completed as thoroughly as possible and covers all the elements that countries need to consider carefully for a successful HPV vaccination introduction and sustainable programme.

Countries are strongly encouraged to reach out to neighbouring countries with existing HPV vaccination programmes and technical partners (in-country, regional and global) for learning and guidance about the successes and challenges of introducing HPV vaccines.

Specific guidance on programme components and structure can be found in the HPV vaccine implementation plan template. The following list provides the key programmatic considerations that all countries applying for HPV vaccine support should describe in their implementation plan.

Components of a comprehensive HPV vaccine implementation plan

- Description of prior experience with HPV vaccine delivery, such as a prior pilot or HPV vaccine demonstration programme;
- Target population for HPV vaccine, routine (the cohort to be reached year-on-year) and MAC (to be reached in the introduction year), if applicable, at national and subnational levels, including estimates of the population and source(s) of data for those estimates;
- Dosing schedule, routine and MAC, if applicable, and the reasons for selecting the proposed schedule;
- Minutes from the NITAG (or equivalent body) meeting endorsing the HPV vaccine introduction and the selected dosing schedule;
- Delivery strategies for both routine and MAC populations, including multiple opportunities for HPV vaccination;
- Coverage and equity considerations, including plans to reach vulnerable, hard-to-reach, and out-of-school girls, as well as areas of the country with high levels of zero-dose and under-immunised children for infant vaccines;
- Description of gender or equity issues and possible barriers to HPV vaccination, as well as interventions to address these;
- Social mobilisation and demand generation plans, including communication messages, materials and channels;
- Crisis communication and response plans;
- Description of how HPV vaccine and vaccinations will be integrated into the routine structures, processes and activities of the EPI, and any proposal for wider integration of HPV vaccination with other health services or interventions;
- Community Support Organisation/Community-Based Organisation/Faith-Based Organisation engagement, as applicable for country setting;
- Adverse events following immunisation (AEFI) monitoring and surveillance plans;
- Training and orientation plans;
- Vaccine logistics and waste management plans; and
- Synergies with any other new vaccine introductions planned for the same year as the HPV vaccine, if applicable.

Countries should refer to available technical guidance, such as the resources for designing, implementing and scaling up HPV vaccination programmes.

Additional information on the selection of the HPV vaccine delivery strategy: *Guide to Introducing HPV Vaccine into National Immunization Programmes*

1 Budget considerations

Countries applying for the HPV vaccine will be eligible to receive two grants: a **VIG** for the routine/single-age cohort and an **Ops grant** for the multi-age cohort. Countries are also encouraged to use their HSS grant to support the sustained implementation of the HPV vaccine programme after the first year. Further information on allowable and encouraged HSS support is detailed in the *Programme Funding Guidelines*. Please note, per the table below, the synergies between the VIGs and Ops grant programming. Below are the budget eligibility considerations under VIGs and Ops, including cost projections.

- HR-related costs should be aligned with Gavi's *Budget Eligibility Guide*.
- Countries are requested, where possible, to show a five-year budget, including the first year of introduction, with funding sources described (e.g. use of HSS, domestic resources, other donors) and secured for the initial two years.
- Countries can spend the VIG funds over multiple years for long-term strengthening of the programme, such as through continued advocacy, demand generation and communication strategies to improve sustainability.[14]

Eligible/not-eligible cost components under VIGs and Ops for the HPV vaccine programme

Cost components	Resources needed	Five-year budget				
		Year 1: intro	Year 2	Year 3	Year 4	Year 5
Eligible for Gavi's VIG and Ops funding						
Service delivery (microplanning)	• Per diems and travel allowances • Venue rental • Transport	✓				
Training	• Development and production of training materials • Per diems and travel allowances • Venue rental • Transport • Stationery	✓				
Demand generation, social mobilisation and information, education and communication	• Facilitator in meetings • Per diems and travel allowances • Stationery • Production of TV/radios spots, posters, leaflets	✓	✓	✓	✓	✓
Cold chain and waste management	• Cold chain carriers • Transport and fuel for waste management	✓				
Monitoring and evaluation	• Travel allowances • Transport fuel and maintenance • Stationery • Tally sheets and registers • Vaccination cards • Supervision and post-introduction evaluation (PIE) materials	✓				
Not eligible for Gavi's VIG funding (therefore, must be paid by governments)						
Service delivery (provision of immunisation in fixed and outreach strategies, PIRI*, campaigns and other strategies)	• Transport fuel and maintenance • Per diems and travel allowances • Supplies (e.g. cotton, PPE)	✓	✓	✓	✓	✓

*Periodic intensification of routine immunisation

✓ Assumes routine cohort and MAC to be introduced at the same time. The VIG and Ops budget should be developed with synergies in cost components between these two grants.

[14] Report to the Board 7-8 December 2016: Review of Gavi Support for HPV vaccine, 2016, https://www.gavi.org/sites/default/files/board/minutes/2016/7-dec/12%20-%20Review%20of%20Gavi%20support%20for%20HPV%20vaccine%20document.pdf

2 Evaluation requirements

Countries are recommended, but not required, to conduct a post-introduction evaluation (PIE) to evaluate the impact of the HPV vaccine introduction on the country's immunisation programme.[15] If a country is planning to conduct a PIE after the HPV vaccine introduction and wants to use part of the VIG funding to support this activity, the PIE activity should be listed in the VIG budget submitted to Gavi.

A.5 HPV vaccine application requirements

In addition to standard new vaccine support materials, HPV vaccine-specific documents to provide:

- ☐ HPV vaccine implementation plan in the Gavi template, including embedded communication and social mobilisation plan and crisis communication plan.
- ☐ HPV vaccine workplan in the Gavi template.
- ☐ NITAG or equivalent body endorsement of the HPV vaccine introduction and further endorsement if electing for a single-dose vaccination schedule, evidenced by meeting minutes, authoritative email with endorsement or other documentation, as relevant.
- ☐ Budget on the Gavi template with clear demarcations of the use of the funds from the VIG and Ops grant (if applicable) in the introduction year, and an indication of the use of domestic resources, HSS funding, additional financing from donors or partners, and indications of financial sustainability for ongoing vaccination costs particularly in outer years.
- ☐ Signature from the Ministry of Education if implementing HPV vaccinations at schools.

EXISTING HPV VACCINATION PROGRAMMES

B Delayed multi-age cohort (MAC) HPV vaccination

B.1 Eligibility

Countries that are currently providing HPV vaccination as part of their routine immunisation programme and have previously been approved for a MAC but have yet to implement the MAC are eligible.

- If the current single-age cohort is aged 9 or 10 years, MAC support is available through the age of 18, to catch-up missed opportunities. If electing to expand the delayed MAC age above 14 years, the country must switch to a single-dose schedule.
- If the current single-age cohort is aged 14, MAC support is available through the age of 14, per standard Gavi policies.

[15] Given the experience countries have in introducing new vaccines, WHO does not recommend that all countries should conduct a PIE 6–12 months after their national introduction. WHO now recommends combining the evaluation of any new vaccine introduction with the next scheduled EPI Programme Review.

B.2 Type of support available

- **MAC support:** An adjustment to the previous Ops support and vaccine allocation reviewed and approved by Gavi, with additional one-time Ops at US$ 0.65/0.55/0.45 (as per country co-financing phase) per additionally targeted girls in the MAC, and vaccine supply at no cost.

- **HSS support:** Countries are encouraged to use the Ops grant for primary activities related to delayed MAC implementation. If the need arises, countries may request to use HSS funds to complement the Ops grant to support the implementation of the delayed MAC. However, countries must demonstrate extenuating circumstances justifying the request and contact their Gavi Senior Country Manager for further guidance. Further information on allowable and encouraged HSS support is detailed in the *Programme Funding Guidelines*.

- **TCA support:** Targeted Country Assistance from in-country, regional and/or global partners to support the planning and implementation of a delayed MAC is available. Countries are encouraged to contact their Gavi Senior Country Manager for guidance and instructions.

B.3 Planning for Gavi support

Once a country is notified of available supply and confirms to conduct their delayed MAC, countries with a delayed MAC are recommended to plan for a lead time of at least nine months from their planned date of MAC implementation. For instance, a country applying in May 2023 should plan for a MAC in late Q2 2024. This lead time will allow sufficient time for Gavi review processes, confirmation of supply, distribution of Ops, vaccine order and distribution, and country-level planning.

HPV vaccine supply

Information on the supply availability of the different HPV vaccines that can be accessed with Gavi support can be found in the HPV vaccine product profile slide deck. Multiple products at different price points exist, each requiring different lead times for procurement from UNICEF and shipment by the manufacturer.

HPV-related supply documents:

- HPV vaccine product profile slide deck
- UNICEF Supply Division HPV vaccine tender 2021–2025

B.4 Guidance and requirements

Countries that have already been approved for a MAC and only vaccinating within the 9–14 age group are required to submit the following documents for Gavi's review:

- revised estimates of the target population;

- an updated workplan of key activities; and

- a revised budget for the use of the Ops grant.

Countries that have already been approved for a MAC and want to extend HPV vaccination to up to 18-year-old girls are required to submit the following documents for reconsideration of the implementation plan by Gavi:

- a revised HPV MAC implementation plan;
- revised estimates of the target population;
- an updated workplan of key activities; and
- a revised budget for the use of the Ops grant.

Key considerations for resubmission of estimates of the MAC target population, workplan and budget revisions are below.

1 Target population

- **Estimates of MAC population:** Countries should calculate an estimate of the MAC target population in line with the dosing schedule selected and adjust for cohorts that have been previously vaccinated and those that have been missed.
- The revised estimates should also factor in any change in the HPV vaccine dosing schedule per revised WHO recommendations.
  - **WHO recommended dose schedule for HPV vaccine:** Current evidence supports either a one- or two-dose schedule to be used in the primary target population, with comparable efficacy and duration of protection.

WHO recommends at least two doses and optimally three doses for immunocompromised populations, including HIV+ girls.

2 Workplan

- Ensure workplan revisions include assumptions for refresher training, enhanced community sensitisation and/or social mobilisation and demand generation, and activities for the dosing schedule change, if applicable.

3 Budget considerations

- Countries applying for delayed MAC will be eligible to receive an adjustment of their **Ops grant** (see section 2.3 Gavi support for new vaccines and campaigns).
- Countries switching the ongoing HPV routine vaccination schedule to a single dose while implementing the MAC vaccinations are eligible for a Switch Grant to support the switch in the routine immunisation schedule (see section 2.5). Ops and Switch Grants cannot be used to cover the same activities, and budgets should clearly indicate the source of funding used for planned activities.
- Budgets submitted should summarise all planned activities and expenditures, identifying the source of funds, those from Gavi and domestic resources or other funds, and the synergistic use of all funds identified.
- The same budget guidance provided for new HPV vaccine introductions should be applied for delayed MAC budgets.

C HPV vaccination schedule switch

C.1 Eligibility

Countries that have already introduced HPV into their routine programme are eligible.

New HPV vaccine introductions that are using a single-dose schedule are not eligible for a Switch Grant.

C.2 Type of support available

- **Switch Grant:** Switching product or presentation of the HPV vaccine, Gavi provides US$ 0.80 per targeted girl in the routine cohort or a lump sum of US$ 30,000, whichever is higher.
- **HSS support:** Countries are encouraged to use their HSS grants to complement the funds provided under the Switch Grant to support the sustained implementation of the HPV vaccine programme. Further information on allowable and encouraged HSS support is detailed in the *Programme Funding Guidelines*.
- **TCA support:** Targeted Country Assistance from in-country, regional and/or global partners to support the planning and implementation of an HPV vaccination schedule switch is available. Countries are encouraged to contact their Gavi Senior Country Manager for guidance and instructions.

C.3 Planning for Gavi support

Countries that currently have the HPV vaccine on the national immunisation schedule and considering switching the HPV vaccination schedule from two doses to a single dose should review the "Gavi support for vaccines optimisation and switches" section of this document for the detail on planning considerations.

In brief, the switch must be supported by the country NITAG or its equivalent, the timing should minimise disruptions to the activities of the current HPV vaccination programme, and the switch should provide a positive impact on programme outcomes (such as increased coverage), programme sustainability (easing health system burden and reducing costs), and vaccine use and supply.

All countries planning a switch to their HPV vaccine dosing schedule are required to notify Gavi of their intention, regardless of whether they are seeking a Switch Grant for financial support. Countries should contact their Gavi Senior Country Manager for guidance and instructions.

D HPV vaccination coverage improvement

D.1 Eligibility

Countries currently providing the HPV vaccine as a part of the national immunisation programme are eligible.

D.2 Types of support available

- **HSS support:** Countries currently providing HPV vaccine as a part of the national immunisation programme are encouraged to use Gavi HSS funds to support coverage improvement and strengthen sustainable delivery of HPV vaccines.

  Countries should consult the HPV Annex of the *Programme Funding Guidelines* for further detail on recommended and allowable activities and contact their Gavi Senior Country Manager for further detail on available HSS funding.

- **TCA support:** Targeted Country Assistance from in-country, regional and/or global partners to support the planning and implementation of HPV vaccine coverage improvement activities switch is available. Countries are encouraged to contact their Gavi Senior Country Manager for guidance and instructions.

3.3 Inactivated polio vaccine

→ CATCH-UP VACCINATION FOR MISSED CHILDREN DUE TO GLOBAL SUPPLY CONSTRAINTS

→ ADDITION OF SECOND DOSE IPV INTO ROUTINE SCHEDULE

Vaccine-specific mandatory application attachments

For catch-up vaccination

- ☐ Letter from Ministry of Health
- ☐ Campaign Plan of Action for second dose introduction
- ☐ Inactivated polio vaccine (IPV) switch form

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends that countries with delayed inactivated polio vaccine (IPV) introduction or stock-outs should prepare for the catch-up vaccination of children who could not receive IPV in the routine schedule due to supply constraints from 2016 to 2019. SAGE emphasised that IPV catch-up vaccination activities are necessary, should be conducted as soon as the supply allows and should be prioritised according to the risk criteria developed by the programme.

WHO recommends introducing a second IPV dose in all countries that currently administer one IPV dose and bivalent oral polio vaccine (bOPV) in their routine immunisation schedules. The preferred schedule is to administer the first IPV dose at 14 weeks of age (with diphtheria, tetanus toxoid and pertussis (DTP3)/ pentavalent3) and to administer the second IPV dose at least four months later (possibly coinciding with other vaccines administered at nine months of age). This schedule provides the highest immunogenicity and may be carried out using full-dose IPV or fractional intradermal IPV (fIPV) without loss of immunogenicity.

SAGE added that countries might consider alternative schedules based on local epidemiology, programmatic implications and feasibility of delivery. As an alternative to the preferred schedule, countries may choose an early IPV schedule starting with the first dose at 6 weeks of age (with DTP1/Penta1) and the second dose at 14 weeks (with DTP3/Penta3). This alternative schedule offers the advantage of providing early-in-life protection; however, there is a lower total immunogenicity achieved. If this schedule is chosen, full-dose IPV should be used rather than fIPV due to the lower immunogenicity of fIPV at early ages. Regardless of the two-dose IPV schedule used, the introduction of the second IPV dose would not reduce the number of bOPV doses used in the routine immunisation schedule.

Key resources and references

Polio and inactivated polio vaccine

- WHO website on poliomyelitis
- Global Polio Eradication Initiative (GPEI)
- GPEI gender equality strategy
- IPV support page on Gavi website

Key resources and references (continued)

Routine vaccination and IPV2

- WHO SAGE recommendation on IPV second dose (October 2020)
- WHO FAQ on IPV2 (April 2021)
- IPV switch request form (EN I FR I RU) (April 2021)
- WHO Use of fractional dose IPV in routine immunization programmes (April 2017)

IPV catch-up vaccination

- WHO SAGE recommendation on catch-up vaccination (October 2016)

Available Gavi support

As part of the Global Polio Eradication Initiative (GPEI), the Vaccine Alliance supports the introduction of IPV in Gavi-supported countries. Initially, Gavi provided support for the introduction of one dose of IPV into routine immunisation schedules starting in 2014.

Gavi continues to provide support for **catch-up vaccination of missed children linked to the global IPV supply situation** and **the introduction of a second dose of IPV (IPV2) into routine schedules**. Gavi currently supports IPV in 70 eligible and transitioned countries until the certification of polio eradication. These countries continue to be exempt from the co-financing obligation of IPV.

1 Catch-up vaccination of missed children:

- **Target population:** In line with SAGE recommendations, Gavi supports the vaccination of children missed due to global supply constraints from 2016 to 2019. Between the switch from trivalent to bivalent oral poliovirus vaccines (OPV) and the delayed introduction of one dose of IPV in routine schedules, an estimated 42 million children missed their first dose of IPV and remained unprotected against poliovirus type 2.

- Countries are recommended to vaccinate these children and are eligible to receive appropriate quantities of vaccines for the administration of one full dose or two fractional doses of IPV, as well as operational cost support to cover some of the costs associated with the activity.

2 Introduction of IPV2 into routine schedules:

- **Target population:** All children should receive IPV2 at 14 weeks or 9 months.

- Countries are eligible for a schedule switch grant of up to US$ 0.25 per infant in the birth cohort in the year of introduction (or a lump sum of US$ 30,000, whichever is higher).

Planning for Gavi support

Catch-up vaccination of missed children due to global IPV supply constraints:

For the Gavi Secretariat to approve the additional quantities of doses intended to catch-up with the missed cohort and for the UNICEF Supply Division to start delivering them, countries are requested to discuss the approach with WHO and UNICEF counterparts in country and inform the focal points at the Gavi Secretariat and UNICEF Supply Division of the approach and number of children targeted as soon as possible.

In addition, the following should be considered:

- The request should be made by submitting an official letter concerning the country's decision to vaccinate missed children. Gavi supports all appropriate strategies, from vaccination of missed cohorts through routine immunisation systems to campaigns as per country decisions and in consultation with technical partners. Irrespective of the delivery strategy, Gavi strongly encourages countries to integrate this activity with other health interventions.

- A plan of action must be submitted, highlighting the key activities and addressing the approach and ability to reach missed children. Include the following information:

    - a clear definition and estimation of the target population of children missed, determined by the effective date of introduction of IPV first dose. The planned start date should be at least 12 months after submission;
    - selected delivery strategy to vaccinate the missed cohorts, including the rationale for integration or lack thereof with other health interventions, such as other Gavi-supported immunisation activities. This needs to describe how these children will be identified and reached;
    - choice of dosing (full or fractional) and preferred presentation; and
    - any other relevant recommendation from National Immunisation Technical Advisory Groups (NITAGs) or similar authority and consultation with WHO and other partners, such as an inter-agency coordinating committee (ICC).

- Send documents to your Gavi Senior Country Manager.

Introduction of IPV2 into routine schedules:

The country should first inform the Gavi Secretariat and UNICEF Supply Division of its intention to add IPV2 to the routine schedule. Preferably, the approach to introducing IPV2 has previously been discussed with WHO and UNICEF counterparts. In addition, please consider the following specific guidance:

- The country should consult the WHO FAQ on IPV2 and complete the IPV switch form for submission to the Gavi Secretariat.
- The planned date of IPV2 introduction into the routine immunisation schedule should be carefully considered (at least 12 months after the date of the application).
- The estimated target population for IPV2 should align with that of other vaccines administered during the same contact and based on SAGE recommendations and historical evidence.
- The NITAG should provide contextual information such as local epidemiology, programmatic implications and feasibility of delivery to justify the selected IPV2 schedule.

3.4 Japanese encephalitis vaccine

→ ROUTINE INTRODUCTION

→ ROUTINE INTRODUCTION WITH CATCH-UP CAMPAIGN

Vaccine-specific mandatory application attachments

- [ ] New vaccine introduction plan and campaign plan of action (merged into one document)

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends 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 incorporating JE vaccines into the national routine immunisation schedule.

Key resources and references

Japanese Encephalitis Vaccines: WHO position paper

Available Gavi support

Gavi provides support for the **introduction of the JE vaccine into the routine immunisation schedule, with an initial catch-up campaign** for at-risk countries that have not yet applied for JE vaccine support. Countries that have previously conducted campaigns may also apply for support under the following circumstances:

Gavi does **not** provide support for JE outbreaks or epidemic responses.

- if surveillance data identify a new area of risk not previously targeted by a campaign (with or without Gavi support);
- if the previous campaign was conducted without incorporating JE vaccination into the routine programme afterwards. In such instances, the country may apply for Gavi support for unreached cohorts between 9 months and 14 years old; and
- if the previous campaign was conducted for a portion of the population over 14 years old. This includes campaigns done using donated vaccines. The country may apply for the remaining target age group up to 14 years.

Countries establishing surveillance systems with sufficient data to warrant the introduction or expansion of JE vaccination are encouraged to apply even though new at-risk areas may be identified in the future.

Introduction in routine, with catch-up campaign

- **Target population guidance for Gavi support**
  - For routine: surviving infants 12 months of age in the year of introduction
  - For catch-up campaign: 9 months to 14 years

Planning for Gavi support

Key considerations:

- Focus on routine immunisation
  - Introduction of the vaccine into the routine immunisation schedule may be nationwide or subnational/regional as warranted by the epidemiological context.
  - Countries will need to provide plans to introduce JE vaccination into the routine immunisation schedule following the completion of the catch-up campaign to ensure good coordination between the campaign and routine introduction planning. These plans should be reflected in the new vaccine introduction plan (NVIP) and/or plan of action. These documents may be combined to minimise duplication.
- Targeting considerations
  - Countries must describe the target population for the Gavi-supported campaign and routine introduction based on the epidemiological information (see guidance and requirements section below).
  - Reference should be made to a country's target population for the measles vaccine first dose, as the JE vaccine is usually co-administered at the same age.
  - The geographical areas identified for introducing the JE vaccine in the routine should be, at the minimum, the same areas as for the Gavi-supported campaign.
  - For countries that previously conducted campaigns in geographical areas and/or age groups other than those identified in the request for new support, evidence of such campaign areas, targets and coverage must be provided.

Guidance and requirements

1 Epidemiology and disease burden and description of the target population

Countries must provide the rationale for introducing the JE vaccine 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. These activities should be reflected in the JE vaccine introduction plan. The epidemiological rationale 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 outbreaks or clustering of cases in the past three years; or
- in the absence of data from JE/AES surveillance, data from rapid assessments and/or argumentation on environmental and biological plausibility.

2 JE surveillance indicators

If available, countries should provide information on the following indicators of the quality of JE surveillance for at least two years before requesting new support for JE:

- reporting rate at the national level: (number of reported AES cases per 100,000 population); and
- laboratory confirmation rate (% of tested AES cases that were JE IgM-positive).

3 JE vaccine-related key information to be captured in the NVIP and/or campaign plan of action

To ensure good coordination between the JE vaccine catch-up campaign and routine introduction planning, the NVIP and/or plan of action should include the following:

- **Vaccination strategy:** A comprehensive vaccination strategy for the introduction of the JE vaccine, including a description of:
  - the initial JE vaccination campaign, including the planning process and plans to reach missed communities; and
  - an implementation plan for the smooth transition to the routine immunisation programme, which specifies geographical extent, the timing of routine introduction and projected coverage.
- **Surveillance:** A description of the following surveillance activities:
  - AES/JE surveillance: status of reporting system, the existence of a national laboratory for confirmation of JE, data management, or, if not in place, plans to establish AES surveillance; and
  - adverse event following immunisation (AEFI) surveillance: status of the reporting system, awareness of health care workers on AEFI reporting, AEFI data management, the status of AEFI expert committee.
- **Communication strategy:** The communication strategy for the introduction of the JE vaccine and conducting the campaign.
- **Vaccine coverage monitoring and reporting:** This should include a description of plans to track individual vaccination status.
- **Estimated date for introduction:** Under the NVIP, countries must provide the estimated date for the introduction into the routine programme, with appropriate plans to ensure no cohorts are missed.

3.5 Malaria vaccine

→ ROUTINE INTRODUCTION

Vaccine-specific mandatory application attachments

New introductions of malaria vaccine:

- ☐ New vaccine introduction plan, with details on phased approach and subnational areas with highest burden and need

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends the use of malaria vaccine for the prevention of *Plasmodium falciparum* malaria in children living in regions with moderate to high *P. falciparum* malaria transmission as defined by WHO. The currently available RTS,S/AS01 (RTS,S) malaria vaccine should be provided as part of a comprehensive malaria control strategy, in a four-dose schedule in children from five months of age.

Countries may consider providing the malaria vaccine seasonally, with a five-dose strategy, in areas with highly seasonal malaria or with perennial malaria transmission with seasonal peaks. Countries should note that the seasonal deployment of the RTS,S vaccine constitutes off-label use. Due to little experience providing childhood vaccines seasonally in malaria-endemic areas, countries that choose the seasonal deployment of the vaccine are strongly encouraged to document their experience, including vaccine effectiveness, feasibility and occurrence of any adverse events, to inform future guidance updates.

Key resources and references

- Malaria vaccine: WHO position paper – March 2022
- WHO Guidelines for malaria
- Framework for the allocation of limited malaria vaccine supply

Additional information and guidance on vaccine use:

- WHO guide to introducing a malaria vaccine (document under development by WHO)

Available Gavi support

Introduction in routine:

Target population guidance

- Routine introduction, as a four-dose schedule in children from five months of age.
- Vaccine introduction through a five-dose schedule in areas with highly seasonal malaria or perennial malaria transmission with seasonal peaks. **Note:** While the vaccine supply constrains subsist, countries applying for support for a five-dose schedule may need to target a smaller population in order to provide five doses with the available doses.

Key information

WHO's *Malaria Vaccine Global Market Study* indicates supply constraints in the first four to six years from the expected introduction in 2023. The supply constraints will affect available Gavi support and the access and allocation of vaccines, as further described below.

The **global supply of malaria vaccine doses will likely not be sufficient to meet the total demand** between 2023 and 2026/2027. To this end, the vaccine roll-out is expected in phases, in line with the guidance of the allocation framework:

- Allocation of vaccine doses will first prioritise the continuation of immunisation in the malaria vaccine implementation programme (MVIP) pilot areas of Ghana, Kenya and Malawi that have already introduced the malaria vaccine.
- Allocation beyond the MVIP pilot countries to additional countries will be phased, starting with subnational areas with the greatest need as defined in the allocation framework.

The Gavi Board approved a new, time-limited co-financing policy for the malaria vaccine.[16] This new co-financing policy will guide co-financing commitment by countries for the 2023–2025 period.

For initial self-financing countries: country contributes US$ 0.20 per dose (no annual increase).

For preparatory transition countries: country co-financing starts at US$ 0.20 per dose in the first year of introduction, and the price fraction increases by 15% annually.

For accelerated transition countries: country contributes 20% of the price fraction in the first year of introduction and increases co-financing by 10 percentage points annually. Country should reach 100% co-financing after eight years.

Countries planning to newly introduce the malaria vaccine

Available vaccine support and phased roll-out

Gavi's support aims to facilitate introducing malaria vaccines into national routine immunisation schedules in areas with moderate to high *P. falciparum* malaria transmission as part of a country's comprehensive plan for the control of malaria.

In light of the **limited global supply of malaria vaccine doses** and following the guidance provided in the WHO framework for allocating limited malaria vaccine supply, the **malaria vaccine will be rolled out in subnational phases starting in areas with the greatest need**. Countries must present a stratification of subnational areas according to the categories of need in the framework (based on best available local data on *P. falciparum* parasite prevalence in children and under-five all-cause mortality, or alternative indicators of malaria risk, such as malaria incidence or severe malaria data).

To increase equity in initial access to vaccine doses for areas of greatest need across many countries, there may be a need to rationalise the number of vaccine doses delivered to each country for each prioritisation phase.

[16] This is as per the December 2022 Gavi Board approval of Decision 19, which can be found in the Review of Decisions. This is to be reviewed by the Programme and Policy Committee no later than 2027.

Gavi partners are committed to finding approaches and taking actions to accelerate and increase the malaria vaccine supply, increase access and reduce child illness and deaths.

Available financial support: Vaccine Introduction Grants (VIGs)

Gavi provides Vaccine Introduction Grants (VIGs) to facilitate the timely and effective introduction of a vaccine into the routine vaccination programme. Considering the expected phased roll-out of the malaria vaccine, the VIG amount will be calculated and provided as follows:

Vaccine Introduction Grants (VIGs)	
Roll-out phase	**VIG amounts**
Phase one The first introduction of the malaria vaccine into a country's routine immunisation programme, which is occurring at a subnational level	Lump sum of US$ 100,000 or an amount calculated on the targeted subnational birth cohort, whichever is higher. The calculated VIG amount is, depending on the country's transition status, US$ 0.80/0.70/0.60 per infant in the birth cohort of the subnational area covered in phase one. For example, for a country in the initial transition phase, it is US$ 0.80 per infant in the birth cohort (live births in the year of introduction) of the subnational area covered.
Subsequent phases Expanding provision of the malaria vaccine into additional areas, including the expansion of immunisation beyond the MVIP areas (implementation and comparator areas) in MVIP countries	Calculated VIG amount is, depending on the country's transition status, US$ 0.80/0.70/0.60 per infant in the birth cohort of the subnational area covered in the phase.

Technical assistance

For countries that will introduce the malaria vaccine by December 2025, Gavi has made available a dedicated envelope to provide technical assistance. The assistance will be provided in two phases, with phase one supporting the development of high-quality applications that meet the criteria for approval by the Independent Review Committee (IRC). Phase two technical assistance support will be provided through Gavi partners, who will support programme implementation activities within the countries. The assistance for the malaria vaccine programme is additional to the Targeted Country Assistance (TCA) overall ceiling communicated to countries. Countries should contact their Gavi Senior Country Manager if in need of technical assistance.

Planning for Gavi support

Allocation considerations

Until supply constraints are resolved, the framework for allocating limited malaria vaccine supply will guide Gavi support for malaria vaccine doses. The priority allocation principle is to allocate the malaria vaccine to countries with areas of greatest need, that is, areas where the malaria disease burden in children is highest and the risk of death is also highest. Given the expected supply level, firm allocation decisions will initially be limited to requests from countries with areas of greatest need ("category one" areas). In addition, the

solidarity principle that no single country should initially receive more than 20% of the total available supply will be applied if needed. If vaccine requests from multiple countries for areas within the same category of need cannot be fully satisfied, the second allocation principle (maximise health impact) will be applied to establish the order of priority.

Countries applying for malaria vaccine support from Gavi, including countries participating in the MVIP, are invited to present the full scope of desired vaccine roll-out in regions with moderate to high transmission (i.e. supply-unconstrained) alongside the stratification of subnational areas according to the categories of need in the framework (including the number of children in the target population of each category, see the following guidance and requirements section). As part of this comprehensive application, the country should provide more details on the proposed scope of the first phase of vaccine roll-out that would be implemented in greatest need areas while there is limited supply.

Some of the requirements in the following section will help Gavi apply the allocation framework principles consistently across country applications. Countries are encouraged to use the framework principles when developing their malaria vaccine introduction plan.

Guidance and requirements

Countries must pay attention to the guidance and considerations outlined to apply for the introduction of malaria vaccine through Gavi support.

Overarching requirements

Applications need to demonstrate:

- confirmation of the country's decision to introduce the malaria vaccine, for example Minister of Health sign-off, as well as NITAG meeting minutes, immunisation inter-agency coordination committee (ICC) minutes;
- existence of a joint immunisation-malaria coordination mechanism, e.g. establishment of a working group with a joint Expanded Programme on Immunisation (EPI)/National Malaria Control Programme (NMCP) participation;
- plans to use the malaria vaccine together with other appropriate malaria interventions based on local data and context;
- integrated and multi-sectoral approaches where, as much as possible, the deployment of the malaria vaccine uses existing health systems, including the existing routine immunisation systems;
- strong community engagement to ensure vaccine acceptance and resilient demand; and
- country readiness and commitment to meet co-financing obligations by having their applications signed off by:
    - Minister of Health (or their delegated authority); and
    - Minister of Finance (or their delegated authority).

Epidemiological rationale for and information on target populations and areas selected to introduce the vaccine

Countries should present the full scope of desired vaccine roll-out in line with the WHO recommendation for the malaria vaccine to be used in children living in regions with moderate to high *P. falciparum* transmission.

Countries are requested to present a subnational stratification of areas according to the categories of need in the framework based on the best available local evidence (see "Subnational stratification of need" table). There are instances where the available *Plasmodium falciparum* parasite rate (PfPR) data may not be recent or sufficient for reliable subnational stratification into categories of need, and countries may prefer to use their malaria incidence or severe malaria data instead. WHO and other partners are available to provide support for this stratification if needed.

Based on the subnational stratification and categories of need, the geographic scope and target population for the first phase of vaccine roll-out should be described in more detail.

Subnational stratification of need

Category	Possible combinations of parasite prevalence and all-cause under-five mortality	
	***Plasmodium falciparum* parasite rate**	**All-cause under-five mortality rate**
Category one *(greatest need)*	20–<40%	>=9.5%
	>=40%	>=9.5%
	>=40%	7.5–<9.5%
Category two	10–<20%	>=9.5%
	20–<40%	7.5–<9.5%
	>=40%	6–<7.5%
Category three	10–<20%	7.5–<9.5%
	20–<40%	6–<7.5%
	>=40%	<6%
Category four	10–<20%	6–<7.5%
	20–<40%	<6%
Category five	10–<20%	<6%

Programmatic requirements

Applications need to demonstrate/provide the following, which is typically articulated in the new vaccine introduction plan:

- A detailed introduction strategy also outlines a phased introduction of the vaccine at the subnational level and alignment with principles of the framework for allocating limited vaccine supply.
- Implementation plan/approach, i.e. timing, projected coverage and geography for a phased introduction.
- Description of preparatory activities required to enable vaccine introduction, e.g. training, social mobilisation, etc.
- Explanation of schedule choice and delivery modalities. Countries need to specifically demonstrate what plans and systems they have (or will develop) to deliver the vaccine, given that the vaccination time points for the four doses of the malaria vaccine may fall outside of the time points provided in the existing EPI schedule.
- Strategies that will be implemented to minimise suboptimal vaccine use and wastage (using the proxy of national drop-out rate between DTP3 and MCV1) and reduce drop-out rates between the third and fourth dose.
- Additional interventions that would be integrated with vaccine delivery (e.g. MCV2 and vitamin A administration).
- Description of the country's technical assistance needs for vaccine introduction and implementation.
- Confirmation of cold chain readiness. Countries need to provide analysis of their cold chain capacity and describe how that capacity will (or will be enhanced to) accommodate the malaria vaccine introduction. This analysis should consider the entire phased vaccine roll-out (and not just the first phase) that the country proposes to adopt.
- Description of how the routine immunisation programme and health system will be strengthened to accommodate the additional work that malaria vaccine introduction will create, including the need to provide the malaria vaccine at touch points (time points) not currently used in routine immunisation.
- Description of how the potential impact of the vaccine introduction and additional vaccination time points on the workload of the human resources for health will be mitigated.
- Description of plans/strategies to minimise vaccine wastage especially given the four-dose (or five-dose) vaccine schedule.
- Description of the country's risk communication and community engagement (RCCE) strategy to ensure vaccine acceptance and resilient demand. The country's community engagement strategy should include community education on the vaccine, including its efficacy, and the need to continue using other malaria control interventions even after the roll-out of the vaccine. The RCCE strategy should outline measures to mitigate the potential risk that introducing the vaccine in specific subnational areas and not others (in line with the allocation framework) may create the impression that the vaccine introduction is selective and inequitable.
- Description of country plans on development of training materials for health workers and information, education and communication materials; adaptation, printing and distribution of revised routine monitoring and reporting tools for use in facilities; distribution method of vaccines and injection supplies; training of health officials and health care workers; and information, communication and social mobilisation of malaria vaccination activities.

- A post-introduction monitoring and learning plan. This needs to describe how the introduction of the malaria vaccine will be monitored and how lessons from the introduction will be curated and used to inform the future roll-out of the vaccine.

- How the malaria vaccine is integrated as a complementary tool to existing malaria control interventions and as part of the country's immunisation strategy. In demonstrating this integration, countries may provide an updated comprehensive multi-year plan for immunisation, national immunisation strategy or national malaria strategy or addenda to these documents if these exist and are updated to demonstrate this integration. Countries that do not have these documents must describe how the malaria vaccine is integrated as a complementary tool to existing malaria control interventions and as part of the country's immunisation strategy.

Zero-dose and missed communities considerations

Applications need to reflect the following:

- consideration of differentiated delivery strategies to reach missed communities and zero-dose children. Countries need to describe how they plan to introduce the malaria vaccine to reach zero-dose children with vaccines available through EPI;

- reference the identify, reach, monitor, measure and advocate (IRMMA) framework to reach missed communities and zero-dose children;

- identify gender-related barriers to immunisation and demonstrate gender-responsive interventions to address these barriers; and

- role of the vaccine in extending the reach of current health services (e.g. using the demand for malaria vaccine to offer other health services and support catch-up vaccination).

The support covers vaccines, i.e. vaccine dose procurement and associated supplies (e.g. injection safety devices) and financial support to facilitate the introduction (VIG).

Gavi does **not** provide support for malaria vaccine campaigns or catch-up vaccination. Countries can use Gavi health systems strengthening (HSS) funds to support outreach activities and periodic intensification of routine immunisation (PIRI) to support seasonal delivery strategies.

3.6 Measles vaccine and measles-rubella vaccine

→ RUBELLA-CONTAINING VACCINE (RCV) ROUTINE INTRODUCTION AS MEASLES-RUBELLA (MR) WITH MR CATCH-UP CAMPAIGN

→ MEASLES OR MR SECOND DOSE (MCV2) ROUTINE INTRODUCTION

→ MEASLES OR MR FOLLOW-UP CAMPAIGN

Vaccine-specific mandatory application attachments

RCV introduction with MR catch-up campaign:

- ☐ New vaccine introduction plan
- ☐ Campaign plan of action (can be merged)

Measles or MR second dose routine introduction:

- ☐ New vaccine introduction plan

Measles or MR follow-up campaign:

- ☐ Campaign plan of action

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Detailed product profiles

WHO recommendations

WHO recommends[17] that all children are reached with **two doses of measles-containing vaccine (MCV) through routine immunisation** to obtain high population immunity and thus achieve the high immunity threshold required for measles (i.e. more than 95% coverage with two doses).

- All countries should thus include a **second routine dose of MCV (MCV2)** in their national vaccination schedules, regardless of the level of the first routine dose of MCV (MCV1) coverage. The introduction of MCV2 aims to reduce the accumulation of susceptible children by immunising those who did not respond to MCV1, thereby reducing the risk of outbreaks.
- As it takes time to achieve high rates of population-wide coverage with two doses of MCV, countries should use available good-quality data on **population immunity** (i.e. MCV1 and MCV2 vaccination coverage, surveillance, serological studies) to (a) monitor the **accumulation of susceptible people**, and (b) plan **additional immunisation activities**, including follow-up campaigns, to target these susceptible people.

Furthermore, WHO recommends[18] that countries take advantage of the measles platform to **introduce the measles-rubella (MR) vaccine**.

- When introducing the MR vaccine, countries are recommended to conduct a **wide age-range MR vaccination catch-up campaign**, followed immediately by introducing the MR vaccine into the national routine immunisation schedule. The timing of any subsequent follow-up campaigns should be determined by measles epidemiology.
- In addition, countries should make efforts to immunise adolescent girls and women of childbearing age through routine services or campaigns.
- Countries should also monitor rubella (integrated with measles) and congenital rubella syndrome (CRS).

[17] Measles vaccines: WHO Position Paper, Weekly Epidemiological Record, No 17, 2017, 92, 205-228

[18] Rubella vaccines: WHO Position Paper, Weekly Epidemiological Record, No. 27, 2020, 95, 301–324

SAGE[19] endorsed the following guiding principles to support countries in identifying and **addressing gaps in immunity to measles and rubella**, according to a "continuous quality improvement" approach that entails the following steps in regular cyclical review:

- Review all available national and subnational data on the epidemiology of measles and rubella or CRS and potential immunity gaps; identify, prioritise and implement interventions and assess the outcomes of interventions.
- Strengthen routine vaccination as the primary strategy for increasing population immunity.
- Conduct campaigns (as rescue measures) when routine vaccination with two doses is suboptimal and to address specific gaps in immunity.
- During and after campaigns, quickly prioritise activities to strengthen routine vaccination.

SAGE stresses that vaccination campaigns are resource intensive and are not sustainable as a strategy. Countries should therefore **prioritise routine immunisation strengthening to become less reliant on campaigns.** The primary goal of campaigns should be to reach unvaccinated or "measles zero-dose" (i.e. has not received MCV1) and under-vaccinated children (i.e. has not received MCV2). Unvaccinated and under-vaccinated children should be identified, monitored and documented to be given other vaccines and health interventions through routine immunisation. Therefore, Gavi expects country proposals to target measles zero-dose children and make differentiated use of funding available for operational costs. Campaigns should be used as opportunities to **integrate other vaccines and/or health interventions** to the extent that additional interventions or activities do not compromise the quality of the campaign.

Key resources and references

WHO position papers:

- *Measles vaccines: WHO position paper – April 2017*
- *Rubella vaccines: WHO position paper – July 2020*

Introducing new vaccines and strengthening routine immunisation:

- WHO: *Principles and considerations for adding a vaccine to a national immunization programme*
- WHO: *Establishing and strengthening immunization in the second year of life*
- Missed Opportunities for Vaccination
- *Leave no one behind: guidance for planning and implementing catch-up vaccination*

Implementing high-quality campaigns and reporting coverage:

- WHO SIA Planning and Implementation Guide (EN I FR)
- SIA Readiness Assessment Tool (EN I FR)
- SIA Readiness Dashboard (EN I FR)
- *Decision Guidance Toolkit for People-Centered Integration of Health Campaigns*
- Checklist for MR campaign post-campaign coverage survey (PCCS) report template

[19] Meeting of the SAGE on Immunization, October 2018, Weekly Epidemiological Record, No. 49, 2018, 93, 661–680

Available Gavi support

Gavi's measles and rubella strategy provides a **single comprehensive approach to measles and rubella control**. Gavi support strongly focuses on strengthening routine immunisation as the primary intervention to improve MCV coverage, complemented by well-planned, high-quality and independently monitored campaigns that focus on measles-unvaccinated and under-immunised children and reach at least 95% coverage (as per an independent and statistically sound survey). Long-term programmatic and financial sustainability for recipient countries should underpin requests for Gavi support by providing a rolling five-year plan for measles and rubella – either with the vaccine application or as part of the Full Portfolio Planning (FPP) process.

Please refer to Annex 3 for a framework of Gavi support for measles and rubella control.

Under the comprehensive measles and rubella strategy, Gavi provides vaccine support for the following:

1. **introduction of rubella-containing vaccine into routine as MR with MR catch-up campaign;**
2. **introduction of a second dose of MCV into routine, as measles or MR;**
3. **measles or MR follow-up campaigns; and**
4. **outbreak response fund (managed by the Measles & Rubella Partnership).**

The types of vaccine support available depend on a country's current MCV presentation and immunisation schedule.

Types of vaccine support				
MCV schedule & presentation at time of application	Type of Gavi support available			
	Introduction of RCV into routine as MR with MR catch-up campaign	Introduction of a second dose of MCV into routine, as measles or MR	Measles or MR follow-up campaigns	Outbreak response
Country not yet using rubella-containing vaccine				
Measles, one-dose schedule	✓	✓	✓	✓
Measles, two-dose schedule	✓	✓ (as MR)	✓	✓
Country already using rubella-containing vaccine				
MR, one-dose schedule	✗	✓	✓	✓
MR, two-dose schedule	✗	✗	✓	✓

Planning for Gavi support

Comprehensive five-year plan and budget for measles and rubella and annual planning

- As per the Board-approved measles and rubella strategy, countries must develop a **rolling measles and rubella five-year plan and budget**. The plan should be based on a comprehensive situation analysis for measles and rubella and reflect on high-level coherent, integrated measles and rubella disease control activities and budget for the coming five years. The plan should be submitted as part of the Gavi FPP process and updated annually as part of the joint appraisal.

- Countries must also include all measles and rubella-related activities in the annual EPI plan, to be submitted annually as part of the joint appraisal.

- Please refer to the FPP and joint appraisal guidelines for additional information on these requirements.

Requirement to co-finance the equivalent to the measles vaccine component of MCV1 with domestic funds

- To be eligible to receive any type of measles and rubella vaccine support, countries must co-finance the equivalent of the measles vaccine component of MCV1 with domestic funds. For example, in 2021, countries are required to domestically co-finance at least US$ 0.287 from the total co-financing requirement (US$ 0.40/child if using a two-dose measles schedule; US$ 0.30/child if using a one-dose MR schedule; US$ 0.60/child if using a two-dose MR schedule – for a fully immunised child) with the remaining co-financing amounts to be financed from domestic sources or by other partners or donors if needed. If the country is not yet financing MCV1 with domestic funds at the time of application for Gavi support, the country must provide a written commitment to do so, with a letter signed by the Minister of Health and Minister of Finance.

- Countries that fall under Gavi's fragility, emergency and refugees policy do not have to meet this requirement before applying, as long as there is written commitment from another donor to continue financing the equivalent to MCV1 moving forward (at least for the years of Gavi approval).

Planning timelines

- Countries are strongly encouraged to ensure that the application for Gavi support is submitted at least 12 months before the start date of the activities and ideally **15–18 months before** the implementation date. Applications submitted within 12 months of the start date will require countries to defer the date of the campaign and/or routine introduction. Please note that the procurement of measles and MR vaccines and injection devices have approximately six months lead times from issuing a decision letter to delivery. Countries should keep in mind their measles high transmission season, the accumulation of measles-susceptible individuals and the risk of measles outbreaks, other planned activities on the national calendar and other seasonal considerations, and any implications this may have when deferring planned campaigns.

- For **routine introductions**, preparatory activities should start **6–12 months** before the introduction, following the guidance in the WHO principles and considerations for adding a vaccine to a national immunisation programme.

- For **campaigns**, preparatory activities should start **at least 15 months** before the campaign, following the guidance in the WHO supplementary immunisation activities (SIA) Planning and Implementation Guide.

Guidance and requirements

1 Introduction of rubella-containing vaccine as MR, with MR catch-up campaign

Summary of support

- This support is available to countries currently using measles vaccine in a one- or two-dose schedule wishing to introduce RCV as MR into the routine immunisation schedule (i.e. transitioning from one/two doses of monovalent vaccine to one/two doses of MR vaccine), accompanied by a one-off MR catch-up campaign. For countries newly introducing MCV2 as MR as part of the MR routine, please refer to the "Introduction of MCV2" section.
- As per WHO recommendations, Gavi provides support for a one-off wide age range (9 months to <15 years) nationwide non-selective MR catch-up campaign targeting both sexes in preparation for the introduction of MR into the routine immunisation schedule. Support for the wide age-range catch-up campaign can only be requested in combination with an MR routine introduction.
- To be eligible to receive Gavi support for the introduction of the MR vaccine, countries must meet the following criterion:
  - routine MCV1 coverage, as determined by WUENIC, must be ≥80% in 2019 **OR** coverage of the most recent nationwide measles preventive campaign must be ≥80%, as determined by a high-quality coverage survey using WHO's latest methodology.
- For countries wishing to introduce RCV as measles-mumps-rubella (MMR), the mumps component will be fully country-funded; Gavi does not support the mumps component.

Introduction of rubella-containing vaccine as MR		
	MR routine introduction (one- or two-dose schedule)	**MR catch-up campaign**
Target population guidance	• Recommended schedule: first dose of MR at either 9 or 12 months; second dose of MR at 15–18 months. The minimal interval between MR1 and MR2 is 4 weeks. • There should be no upper age limit for administration of MR (i.e. routine delivery of MR1 should not be limited to infants aged 9–12 months, and routine delivery of MR2 should not be limited to infants aged 15–18 months). Every opportunity should be taken to vaccinate all children who missed one or both MCV doses as per WHO catch-up guidance.	• 9 months to <15 years, both sexes • Any expansion of the target population beyond 15 years of age will need to be financed by the country or other partners.
Co-financing	Countries are required to co-finance the MR vaccines in the routine immunisation schedule depending on transition status. • Initial self-financing: US$ 0.30/dose • Preparatory transition: In the introduction year, country pays a co-financing of US$ 0.30 per dose. The co-financing amount per dose increases by 15% every subsequent year (e.g. from US$ 0.30 to US$ 0.345, then US$ 0.397 etc). • Accelerated transition: In the introduction year, country pays US$ 0.30 per dose. Co-financing ramps up linearly in the remaining years of transition up to 100% of vaccine cost (US$ 0.72 in 2021).	There is no co-financing requirement for the one-off wide age range MR catch-up campaign at the time of RCV introduction.

Key requirements for the MR catch-up campaign

- MR catch-up campaigns must be well planned and implemented to reach the recommended ≥95% coverage. Countries are requested to follow the guidance in the WHO SIA Planning and Implementation Guide to ensure that best practices for preparatory activities and implementation are described in the application. Particular attention should be paid to:
  - how the campaign is designed to achieve the expected results, incorporating comprehensive data analysis, lessons learned from previous campaigns and innovative approaches being employed;
  - the use of the WHO SIA Readiness Assessment Tool;
  - microplanning to identify the best strategies to reach the unvaccinated;
  - rapid convenience monitoring during and immediately after the campaign to take immediate corrective action in low-performing areas; and
  - the post-campaign coverage survey.
- Countries may consider targeting school-aged children within the target age range through school-based vaccination. If so, close coordination with the Ministry of Education and educational authorities will be required at all levels from the outset of application development to assess how and when to conduct vaccinations at the school (e.g. ensuring representation from the Ministry of Education in the technical committees).
- Other **considerations for countries requesting campaign support** apply. For detailed guidance on information to provide as part of the MR routine introduction with the MR catch-up campaign application, please refer to the MR new vaccine introduction plan and plan of action.

2 Introduction of MCV2

Summary of support

- This support is available to countries currently using the measles or MR vaccine in a one-dose schedule that wish to introduce a second dose of measles or MR in the routine immunisation schedule.
- Countries introducing MCV2 into the routine immunisation schedule should use the same vaccine (either measles or MR) for both doses. This is to simplify procurement, logistics, recording, reporting and vaccine wastage, with the benefits outweighing the marginal increase in vaccine cost.
- The introduction of MCV2 should be used:
  - to establish a well-child visit during the second year of life; and
  - as a platform to strengthen vaccine coverage through the administration of MCV2, a catch-up of missed doses of MCV1 and other routine doses, and other health interventions in this age group (second year of life).
- The introduction of MCV2 should accompany immunisation policy changes that allow for the vaccination of children older than 12 months who have not completed their vaccination schedule and the adoption of a **catch-up immunisation schedule** with no upper age limit for MCV vaccination. These delayed doses should be recorded and reported through the health management information systems.

MCV2 routine introduction	
Target population guidance	• The recommended schedule for MCV2: 15–18 months. • The minimal interval between MCV1 and MCV2 is four weeks. • There should be no upper age limit for the administration of MCV (i.e. routine delivery of MCV1 should not be limited to infants aged 9–12 months, and routine delivery of MCV2 should not be limited to infants aged 15–18 months of age) and every opportunity should be taken to vaccinate all children who missed one or both MCV routine doses (e.g. second year of life well-child visit, school entry, etc).
Co-financing	Countries are required to co-finance the Gavi-supported measles and MR vaccines in the routine immunisation schedule. If applying for MCV2 support, both doses (MCV1 and MCV2) become co-financed. • Initial self-financing: measles: US$ 0.20 per dose; MR: US$ 0.30 per dose. • Preparatory transition: in the introduction year, the country pays a co-financing of US$ 0.20 and US$ 0.30 per dose, respectively. The co-financing per dose increases by 15% every subsequent year (e.g. from US$ 0.30 to US$ 0.345, then US$ 0.397 etc). • Accelerated transition: in the introduction year, the country pays US$ 0.20 and US$ 0.30 per dose, respectively and ramps up linearly in the remaining years.

Key requirements for MCV2 introduction

- MCV2 introductions must be well-planned and implemented to reach the desired objectives. Countries are requested to follow the guidance in the WHO *Principles and considerations for adding a vaccine to a national immunization programme* to ensure that best practices for preparatory activities and implementation are described in the application. Particular attention should be paid to:
  - updating immunisation policies to allow for immunisation of children older than 12 months;
  - the adoption of a catch-up immunisation schedule (ideally with no upper age limit for MCV vaccination); and
  - advocacy, communications and social mobilisation of children in the second year of life.
- For detailed guidance on information to provide as part of the MCV2 routine introduction, please refer to the MR new vaccine implementation plan template.

3 Measles or measles-rubella follow-up campaign

- Gavi funding for operational costs must be used in a differentiated manner to ensure zero-dose children are prioritised.
- Measles and MR follow-up campaigns must be well planned and implemented to reach the recommended ≥95% coverage. The request for Gavi support must provide details of how the campaign is designed to achieve the expected results, incorporating comprehensive data analysis, lessons learned from previous campaigns and innovative approaches that are being employed.
- Countries will be required to conduct a post-campaign coverage survey to determine campaign coverage and to measure the proportion of measles zero-dose children reached as part of the campaign.

- Gavi provides flexibility for countries requesting follow-up campaign support to apply for operational cost support calculated based on the national 9–59 months population for **national campaigns**, **subnational campaigns** or **enhanced routine immunisation activities** to reach missed children. Differentiated use of funding for operational costs to reach zero-dose children is expected.

Measles or measles-rubella follow-up campaign	
Target population guidance	• 9–59 months • The focus of Gavi support is 9–59 months, but there is flexibility to support a wider age group if countries provide strong epidemiological evidence to justify this for measles control.
Co-financing	Countries are required to **co-finance** a portion of the vaccines for measles or MR follow-up campaigns according to their transition status. • Initial self-financing phase: country pays 2% of each dose of vaccine • Preparatory transition phase: country pays 5% of each dose of vaccine • Accelerated transition phase: country pays 5% of each dose of vaccine

Differentiated delivery strategies and differentiated use of campaign operational costs to reach measles-unvaccinated and under-vaccinated children in measles/MR follow-up campaigns

The principle of developing differentiated delivery strategies for different intra-country contexts aims to ensure that all children, particularly those consistently missed in vaccination efforts, are reached as part of the Gavi-supported follow-up campaign. As reaching consistently missed children and communities will require more resources, a greater share of the operational cost budget should be allocated compared to more readily available ones.

Countries are encouraged to use Gavi's **zero-dose guidelines** and **IRMMA framework** when developing the measles/MR follow-up campaign plan of action and budget with differentiated strategies and operational costs.

Key requirements for measles/MR follow-up campaign plans of action and budgets

A successful measles/MR follow-up campaign application is expected to:

1. be epidemiologically and programmatically **justified;**
2. be well tailored to **identify and reach measles-unvaccinated and under-vaccinated children** and missed communities, by **employing differentiated delivery strategies** and **differentiated use of operational cost support**; this includes considering more targeted and tailored alternatives to nationwide non-selective campaigns (e.g. enhanced routine immunisation activities, subnational campaigns);
3. be designed to serve as an **entry point** for children and missed communities **into the routine immunisation system**, and to generate demand for a full course of vaccines;
4. leverage opportunities for **integration** with other health campaigns (immunisation or other health interventions) or with **catch-up vaccination** of routine vaccines; and
5. identify opportunities for Gavi support to **strengthen the routine delivery systems** before, during and post-campaign and mitigate any adverse impact on routine services.

Countries are requested to follow the guidance in the WHO SIA Planning and Guide to ensure that best practices for preparatory activities and implementation are described in the application. For detailed guidance on information to provide as part of the measles/MR follow-up campaign application, please refer to the MR plan of action template.

① Campaign justification

- The measles/MR follow-up campaign application should strongly justify the activity and the main campaign parameters (target age group, timing, geographical scope and delivery strategies).
- The campaign justification should contain a comprehensive analysis of the following information:
  - measles immunity profile;
  - national and subnational vaccination coverage;
  - disease surveillance data;
  - outbreak investigations and root causes analyses;
  - serological studies (where feasible); and
  - modelling (where feasible).

② Differentiated delivery strategies and flexibilities in using campaign operational costs to reach measles-unvaccinated and under-vaccinated children

- All countries should follow the guidance on differentiated delivery strategies and differentiated use of campaign operational costs to reach measles-unvaccinated and under-vaccinated children in measles/MR follow-up campaigns to develop the campaign plan and budget. The data elements used for campaign justification will be particularly critical in the "identify" and "reach" steps of campaign planning.
- Lower-performing countries likely need to rely on a **nationwide non-selective approach** to reach the highest proportion of measles-unvaccinated and under-vaccinated children in a cost-effective way.
- However, in certain settings, nationwide non-selective campaigns may not be cost-effective or required. Based on available data, alternative strategies should be considered to differentiate between high- and low-risk areas or communities. Leveraging the board-approved operational cost flexibilities for measles/MR follow-up campaigns, Gavi strongly recommends that higher-performing countries **prioritise tailored and targeted campaign delivery strategies and/or enhanced routine immunisation activities** as an alternative to nationwide non-selective follow-up campaigns, with a focus on reaching measles-unvaccinated and under-vaccinated children.
  - The choice of strategy or strategies should consider country context, immunisation coverage, disease surveillance data and programme capacity.
  - Examples of tailored and targeted delivery strategies include:
    - subnational non-selective campaigns; and
    - national or subnational selective campaigns (i.e. checking immunisation records as part of campaign with the administration of other vaccines and/or health interventions, where feasible).

- Examples of enhanced routine immunisation activities include:
  - bolstered mobile and outreach services;
  - periodic intensification of routine immunisation (PIRI) and child health days; and
  - catch-up vaccination at school entry.
- Delivery strategies and activities can be mixed and matched depending on intra-country context (e.g. subnational non-selective campaigns in higher-risk regions and PIRIs in lower-risk regions).
- Please refer to **Annex 4** for guidance on targeted and tailored campaign delivery strategies and enhanced routine immunisation activities that can be supported through flexibilities in programming operational support for measles/MR follow-up campaigns.

③ Campaigns as a routine immunisation entry point for children and missed communities

- Please refer to the section above on key requirements for countries requesting support to conduct a campaign for additional details.

④ Integration

- Countries must describe how the Gavi-supported follow-up campaigns will be used as an opportunity to integrate with other health campaigns (as collaboration or co-delivery) and/or to conduct catch-up vaccination of missed vaccines linked to the effects of COVID-19 routine immunisation-related interruptions. Strong justification needs to be provided if the country decides not to use the delivery of measles/MR vaccines in the campaign for integration.

⑤ Strengthening the routine system before, during and post-campaign

- Please refer to the WHO SIA field guide for considerations on how the routine immunisation system can be strengthened before, during and post-campaign.

- Countries must describe which **enhanced routine immunisation activities** will be implemented to address measles immunity gaps between follow-up campaigns and, in the long term, decrease reliance on these campaigns. Annex 4 provides some examples of the activities that can be conducted to raise routine MCV coverage (e.g. PIRIs, school entry checks, etc). Countries should ensure that the selection of routine immunisation activities is aligned with investments already planned or budgeted for within the Gavi portfolio, for example, through health systems strengthening (HSS).

4 Outbreak Response Fund (managed by the Measles & Rubella Partnership)

Countries experiencing a significant measles and/or rubella disease outbreak of national public health importance that are unable to respond fast enough with local funding (domestic epidemic response funds or donor funding) should consider applying to the Measles & Rubella Partnership's Outbreak Response Fund (ORF) for support for vaccines and operational costs. As per the ORF standard operating procedures, they are required to investigate root causes of the outbreak and initiate mitigation strategies.

Further details including eligibility requirements are available in the Measles & Rubella Partnership's Outbreak Response Fund.

3.7 Meningococcal A vaccine

→ ROUTINE INTRODUCTION WITH CATCH-UP CAMPAIGN

→ ROUTINE INTRODUCTION WITH PREVENTIVE MASS CAMPAIGN

Vaccine-specific mandatory application attachments

For routine introduction:

- ☐ New vaccine introduction plan

For campaigns:

- ☐ Campaign plan of action (can be merged)
- ☐ Risk assessment report and district prioritisation tool (if applicable)
- ☐ Catch-up campaign targeting

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends the following strategies in the 26 countries where meningococcal meningitis is endemic ("meningitis belt"):

- a single-dose preventive mass campaign with meningococcal A vaccine in the population aged 1–29 years;
- introduction of meningococcal A vaccine into the routine vaccination schedule should be done as soon as possible and within no more than five years following the preventive mass campaign completion, along with a one-time catch-up campaign;
- the catch-up campaign targets birth cohorts born since the initial mass vaccination, outside the age range targeted by the routine immunisation programme. The exact age range for the catch-up campaign will depend on the time between the preventive mass campaign and the introduction into the routine immunisation schedule; and
- for countries that have not yet conducted preventive mass campaigns, introduction into the routine immunisation schedule should be concurrent with the mass preventive campaign unless a strong justification for the delay and plans for introduction are outlined.

The 26 meningococcal meningitis endemic countries are: Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Mali, Mauritania, Niger, Nigeria, Rwanda, Senegal, South Sudan, Sudan, Tanzania, Togo and Uganda.

Key resources and references

- WHO: *Guide to introducing meningococcal A: conjugate vaccine into the routine immunization programme*
- WHO guidance on use of meningitis A vaccine in a controlled temperature chain during campaigns

Available Gavi support

Gavi provides support for introducing the meningococcal A vaccine into the routine immunisation schedule, either combined with support for an initial preventive mass campaign or a catch-up campaign (sometimes referred to as a one-time mini catch-up campaign). Please find below details on these two support types:

To access outbreak response support for meningitis countries should contact the International Coordinating Group (ICG) on Vaccine Provision Secretariat

Introduction in routine, including preventive mass campaign:

Target population guidance

- For routine: one dose at 9 months or 15–18 months, depending on specific country situation and epidemiology.
- For the preventive mass campaign: 1–29 years.

Introduction in routine with catch-up campaign:

Target population guidance

- Routine: one dose at 9 or 15–18 months, depending on specific country situation and epidemiology.
- Catch-up campaign: target susceptible children ≥12 months of age born less than one year before the initial mass campaign up to the routine introduction.

Planning for Gavi support

For both types of support, the following apply:

- **Focus on raising routine coverage:** Guidance is above on using campaigns to strengthen routine immunisation.
- **Considerations for subnational introductions:** For the introduction of the vaccine into the routine immunisation schedule, a nationwide introduction is encouraged. However, some countries, particularly large countries with relatively small endemic areas, may consider regional introductions. When making decisions regarding the scope of the introduction into the routine schedule – i.e. nationwide versus in high-risk areas/districts only, additional elements may be considered. These include the following:
  - the complexity of implementing different vaccination programmes in the same country could be a challenge;
  - public perceptions of inequity could arise about vaccination in different parts of the country;
  - climate variability could result in the evolution of at-high-risk areas in the country (i.e. extension of the meningitis belt) since the epidemic risk is highly related to climatic conditions; and
  - nationwide introduction might also benefit neighbouring countries (e.g. building geographic herd protection and maintaining the benefits of the initial mass campaigns).

- **Reference measles target population:** Countries should also reference their target population for measles vaccines' first and second doses in their request since meningococcal A vaccines are usually co-administered at the same age as measles.

- **Targeting of catch-up campaigns:** The geographical areas identified to conduct meningococcal A vaccine catch-up campaigns should be the same areas as for the Gavi-supported preventive mass campaigns (i.e. targeting endemic areas as defined through the risk assessment) unless appropriate justification to proceed otherwise is provided.

- **Using a controlled temperature chain (CTC) strategy:** Additional technical guidance through WHO is also available for countries planning to use a CTC strategy when implementing a preventive mass or mini catch-up campaign. Countries wishing to use a CTC strategy should summarise how they will use CTC, when they plan to start using it and how they will comply with the WHO guidelines during implementation in their request for Gavi support.

Guidance and requirements

1 Timing and coordination for the delivery strategies

- **Requests for routine introduction and campaigns should be prepared together.**
  - Requests for routine introduction with catch-up or preventive mass campaign should be prepared together and include a detailed new vaccine introduction plan (NVIP) for the routine introduction and a plan of action for the campaign.
  - The NVIP and campaign plan of action can also be combined into one document to minimise duplication.

- **Timing for the campaign**: The catch-up and mass campaign timing depends on the age at routine introduction, aiming to avoid duplication or missing children.

Target age of child for RI* dose	Timing of catch-up/mass campaign
9 months of age	3 months [3–4 months] **after** RI introduction
15 months of age	3 months [2–3 months] **before** RI introduction
18 months of age	6 months [3–6 months] **before** RI introduction.

*Routine immunisation

- **Identify synergies across delivery strategies:** Countries are strongly encouraged to identify cross-cutting communications and training across the different delivery strategies. These should be reflected in the budgets for each component of the support requested (i.e. routine programme, catch-up or preventive mass campaign, including any use of a CTC strategy during campaigns).

2 Epidemiology and target identification

Countries requesting support **must** submit an analysis of epidemiological information on meningococcal A circulation and relevant data on disease burden and the target population at risk. The choice of

national or subnational introduction into a routine should be explained (see "Considerations for subnational introductions" under "Planning for Gavi support" above).

- **For countries requesting support for mass preventive campaigns:** These countries must submit a risk assessment report to determine the epidemiological information on meningococcal A circulation and relevant data, disease burden and the target population at risk. The report should be endorsed by WHO, and a consensus meeting report may be submitted together with the report. If a district prioritisation tool exercise was conducted, the resulting report should be submitted as part of the risk assessment materials.

- **For countries requesting support for catch-up campaigns:** Countries are **required** to submit the following as applicable:
  - the main conclusions of the initial risk assessment (that informed decision-making for the mass preventive campaigns) should be reminded in the application;
  - areas and the target population per district or region where the catch-up will be conducted, including the source and ideally disaggregated by year since the preventive mass campaign. This information is typically included in the risk assessment report; and
  - if the geographical area for the catch-up campaign is different from the target area for the initial mass preventive campaign, **appropriate justification** should be provided.

3 Meningococcal A vaccine-related key information to be captured in implementation plans

The following aspects should be considered when developing a plan specific to meningococcal A vaccination:

- **Lessons learned:** For countries requesting support for routine introductions and catch-up campaigns, the plan should include how some of the lessons learned from past preventive campaigns will be integrated into the implementation.

- **National communication strategy and communication plan:** A comprehensive national communication strategy and communication plan, including introducing the meningococcal A vaccine into the routine immunisation system and the campaign (catch-up or preventive mass campaign).

- **Meningitis surveillance:** A description of the meningitis surveillance system: either a meningitis-specific system or, preferably, an integrated surveillance system that includes meningococcal meningitis with other diseases. Details of the status of the reporting system, data management processes, the national laboratory and other systems for handling and confirming meningitis cases related to all serogroups should be provided (or indicate that these are not in place).

3.8 Pneumococcal conjugate vaccine

→ ROUTINE INTRODUCTION

→ ROUTINE INTRODUCTION WITH CATCH-UP VACCINATION

Vaccine-specific mandatory application attachments

- ☐ New vaccine introduction plan (NVIP)
- ☐ Campaign plan of action if requesting support for catch-up (can be merged with NVIP)

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends prioritising pneumococcal conjugate vaccine (PCV) in childhood immunisation programmes, especially in countries with under-five mortality greater than 50 per 1,000 live births.

In 2017, SAGE recommended catch-up vaccination during PCV introduction in children aged 1–5 years. This is reflected in the WHO pneumococcal conjugate vaccine position paper (2019).

Key resources and references

- WHO pneumococcal vaccine information
- WHO position paper on Pneumococcal conjugate vaccines in infants and children under 5 years of age (2019)

On PCV vaccines and supply

- WHO *Considerations for pneumococcal conjugate vaccine (PCV) product choice*
- *Gavi-supported PCV profiles to support country decision making* (2020)
- *Evidence Dossier Pneumococcal Conjugate Vaccine (PCV) Interchangeability* (2019)
- PCV Product Assessment (April 2017)
- *Global Market Study: Pneumococcal Conjugate (PCV) and Polysaccharide (PPV) Vaccines*
- Pneumococcal conjugate vaccine cost calculator

On implementation:

- *Introduction of pneumococcal vaccine: A handbook for district and health facility staff*
  - For PCV13
  - For PCV10
- SAGE recommendation on multiple injectable vaccines in a single vaccination visit

On integration:

- *The integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD)*

Available Gavi support

Gavi provides support for the introduction of PCV into the routine immunisation schedule. Countries may request support for introducing PCV in routine vaccination, choosing among two support options (vaccinate routine cohort with or without catch-up vaccination) and five introduction modalities.

Planning for Gavi support

Five modalities of PCV introduction in routine vaccination are supported.

Support option	Vaccinate routine cohort with catch-up			Vaccinate routine cohort only	
Introduction modality	**PCV routine with simultaneous catch-up[20]**	**PCV routine, phased, with catch-up nationwide**	**PCV routine, phased, with phased catch-up** (over 2+ years)	**PCV routine (no phasing)**	**PCV routine, phased** (over 2+ years)
Impact of each option in the first five years					
Support in year of launch	VIG* + Ops** + vaccines for routine and catch-up cohorts	VIG + Ops + vaccines for routine and catch-up cohorts	VIG + Ops + vaccines for routine and catch-up cohorts (phase-specific target group)	VIG + vaccines for routine cohort	VIG + vaccines for routine cohort (phase-specific target group)
Target population	Routine: <12 months	Routine: <12 m (phase-specific target group)	Routine: <12 m (phase-specific target group)	<12 months	<12 months
	Catch-up: 1–5 years	Catch-up: 1–5 years	Catch-up: 1–5 years		

*Vaccine Introduction Grant

**Operational Cost grant

Countries may choose to introduce the vaccine into their routine immunisation schedule via a phased introduction based on feasibility considerations or a subnational introduction based on risk (e.g. in certain geographical zones, districts or provinces). Countries that cannot operationally implement an initial country-wide introduction of PCV may adopt a phased introduction approach.

[20] In exceptional cases when feasibility of catch-up vaccination at launch is limited, the catch-up can be deferred up to 11 months after launch.

Support provided to PCV routine and catch-up vaccination		
	PCV routine cohort	**PCV catch-up cohort**
Target population	Children up to 12 months of age	Children from 12–59 months of age, to be immunised on a one-off basis within 12 months from introduction
Dose schedule	Three-dose schedule (either 3+0 or 2+1)	A single dose only
Vaccines support	Standard co-financing applies	All doses financed by Gavi
Cash grant	A one-time VIG at US$ 0.80/0.70/0.60 (as per country co-financing phase) per target child in the birth cohort of the year of introduction	A one-time Ops grant (in addition to the VIG) at US$ 0.65/0.55/0.45 (as per country co-financing phase) per target child in the catch-up cohort

Guidance and requirements

1 Requirements for routine vaccination

- Most recent **disease burden assessment** (burden of all-cause pneumonia, meningitis or hospitalisations for entities caused by *Streptococcus pneumoniae*, and data regarding serotype prevalence, even from the carriage, if available).

- **National Immunisation Technical Advisory Group (NITAG) recommendation** supporting the introduction and the choice of PCV product, the presentation and the dosing schedule. The document should state the reasons why those are recommended. Where a NITAG does not exist, Gavi recommends that countries include plans to establish one and submit such plans with their request for new vaccine support.

- **New vaccine introduction plan including:**
  - an implementation plan for the routine immunisation programme, which specifies geographical extent, the timing of routine introduction and projected coverage. The plan should also include a catch-up vaccination policy and address missed opportunities for vaccination. More guidance can be found in WHO's *Leave no one behind: guidance for planning and implementing catch-up vaccination*;
  - the challenges or opportunities for the introduction of PCV based on previous vaccine introductions;
  - a clear description of preparatory activities, such as social mobilisation and communication strategy, training of health workers, community resources persons and coordination of activities;
  - confirmation of cold chain readiness;
  - strengthened vaccine safety monitoring; and
  - integrated disease prevention, control and linkage to existing health interventions. 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 required to provide the following information in line with GAPPD objectives:

- a high-level description of any existing interventions for preventing and treating pneumonia and diarrhoea and the implementation status;
- a description of how pneumococcal vaccination could strengthen joint delivery of services and communication about healthy actions such as exclusive breastfeeding and handwashing with soap, safe drinking water and sanitation, and guidance around care-seeking behaviours; and
- a description of potential barriers to integrating 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).

❷ Additional requirements for catch-up vaccination:

- Requests for routine introduction with catch-up should be prepared and submitted together.
- **Catch-up cohort target population** description and number estimate.
- **NITAG recommendation** supporting the catch-up.
- **Catch-up vaccination plan of action,** including checklist and activity list and chronogram (unless the information is included in the NVIP already), and the PCV catch-up plans for specific populations where coverage is low or inequitable. The NVIP and/or plan of action can be combined to avoid duplication and ensure strong coordination between the routine introduction and catch-up campaign. The following elements need to be captured in the countries' catch-up plan of action and budget:
  - Detailed **strategies for reaching all eligible children**, including an increased focus on identifying and reaching zero-dose children and missed communities.
  - Detailed description of **preparatory and implementation activities,** including:
    - capacity building and training;
    - microplanning;
    - advocacy, communication and social mobilisation;
    - adverse events following immunisation (AEFI) monitoring and preparation for crisis communication; and
    - operation of vaccination posts.
  - **Monitoring and measuring** children reached in the campaign, including a post-campaign coverage survey. Countries receiving support for PCV catch-up may conduct a high-quality, nationally representative survey using probability sampling to assess coverage. This is to have an independent estimation of coverage of the completed vaccination and hold in-country key stakeholders accountable for the campaign.
  - Opportunities to **strengthen routine immunisation**, including establishing long-term plans for reaching under-vaccinated children through routine immunisation.
  - **Chronogram** of activities, with campaign planning and preparations.
  - Use of the **WHO supplementary immunisation activities (SIA) Readiness Assessment Tool** to track the implementation of preparatory activities for the campaign.
  - Within three months of catch-up implementation:
    - submit an SIA technical report; and
    - conduct independent, statistically and technically sound **post-campaign coverage survey**, and submit it within six months post-implementation.

- Countries should follow the guidance in the **WHO SIA Planning and Implementation Guide** to ensure that best practices for preparatory activities and implementation are considered. This guide provides comprehensive information on planning and implementing a high-quality campaign, including critical activities and proposed timelines (Annex 6 of the SIA guide) and highlights the opportunities to strengthen routine immunisation and surveillance (see section 3.1 of the SIA guide).

3 Key considerations of catch-up vaccination

- Countries should **assess the option to introduce with catch-up**: evidence suggests that PCV immunisation for children outside the birth cohort at the time of national introduction accelerates both direct and indirect protection and thereby hastens the impact of PCV. If logistically feasible, catch-up campaigns at PCV introduction can enhance the benefit per dose of the PCV programme in settings with high vaccine-type carriage and disease beyond infancy.
    - If there is limited availability or capacity for catch-up immunisation, the youngest children should be prioritised to receive catch-up doses of PCV because of the higher pneumococcal disease risk.
- **Countries should provide justification if they do not request catch-up support.**
- Countries should demonstrate how the operational support for the catch-up implementation will be used to strengthen vaccine delivery through the routine immunisation programme.
- **Timing:** The catch-up vaccination should aim to cover the largest number of children possible. If this is not feasible, a catch-up campaign can start 11 months after the routine introduction and target three cohorts. Countries must run catch-up vaccination within 12 months of routine launch to receive catch-up support.
- Countries are encouraged to leverage implementation synergies and **budget efficiencies:**
    - where campaigns for other vaccines are planned within the same year; and
    - if the catch-up is scheduled to launch at the same time as the routine introduction.

4 Schedule choice

- For countries that have yet to introduce PCV, decisions regarding the choice of schedule should consider operational and programmatic issues, including timeliness of vaccination, the coverage expected to be achieved at the third dose, and pneumococcal disease age distribution patterns, if known. Low population vaccine coverage at visits between 9–12 months of age or later may warrant using a three primary doses without a booster (3p+0) schedule.
- Once a programme has been initiated, schedule switching is only recommended if one or more factors that led to the original choice of schedule change substantially.
- A dosing interval of eight weeks between the first two doses of a two primary doses with one booster (2p+1) schedule and a dosing interval of at least four weeks for a 3p+0 schedule is recommended. However, the eight-week interval recommended for the 2p+1 schedule may be shortened if there is compelling reason, such as timeliness in receipt of the second dose and/or higher coverage that may be achieved with the schedule. The dosing interval between primary doses within each schedule should not be shorter than four weeks.

- The timing of the booster dose in the 2p+1 schedule should be selected to maximise coverage. The selected age for administering the booster dose in most programmes is 9, 12, 15 or 18 months, depending on operational and programmatic factors, including the timing of vaccination contacts in the national immunisation schedule for other vaccines. There is insufficient evidence to suggest the optimal timing of the booster dose.

5 Procurement of vaccines

- PCV must be procured through UNICEF due to the terms and conditions of the Pneumococcal Advance Market Commitment (AMC). Countries procuring vaccines through UNICEF can still self-procure vaccine devices.

- Currently, three different vaccines are offered in the PCV portfolio. Consult Gavi's detailed product profiles for the most up-to-date vaccine information.

6 Product choice recommendations

- Three WHO-prequalified vaccines are available: PCV10GSK (Synflorix, GSK), PCV10SII (PNEUMOSIL, Serum Institute of India) and PCV13 (Prevenar 13, Pfizer). PCV13 and PCV10SII may have additional benefits in settings where disease attributable to serotype 19A (ST19A) or serotype 6C (ST6C) constitutes a significant public health problem. However, there is currently no supportive evidence of different net impacts on overall disease burden between products. The country-level product choice should consider programmatic characteristics, vaccine supply, vaccine price, local/regional vaccine serotype prevalence and antimicrobial resistance patterns among vaccine serotypes.

- Of note, PCV10SII is prequalified up to two years of age. It has been tested in toddlers up to 15 months of age and adults but not in children between 2–5 years of age. A catch-up programme up to the age of five would be off-label. Countries may consider strengthening post-introduction safety surveillance.

7 Budget

- Countries applying for routine with catch-up vaccination will be eligible to receive two grants: a Vaccine Introduction Grant (VIG) for the routine cohort and an Operational Cost grant (Ops) for the catch-up cohort. The two grants and funded activities are expected to complement and build on each other.

3.9 Rotavirus vaccine

→ ROUTINE INTRODUCTION

Vaccine-specific mandatory application attachments

- ☐ New vaccine introduction plan

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends that rotavirus vaccines be included in all national immunisation programmes and considered a priority, particularly in countries with high rotavirus gastroenteritis (RVGE)-associated fatality rates.

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases.

Rotavirus vaccination has consistently been cost-effective and even cost-saving in most low- and middle-income countries compared to no vaccination. Cost-effectiveness results also remain generally favourable, though not universally, for countries undergoing transition from Gavi support, as well as for non-Gavi-eligible countries.[21]

Key resources and references

- WHO rotavirus vaccine information
- *Rotavirus vaccines: WHO position paper – January 2013*
- SAGE recommendations during meeting on October 2020
- WHO: *Introduction of Rotavirus Vaccines: Information for Policy Makers, Programme Managers, and Health Workers*
- PATH: Rotavirus Vaccine Cost Calculator
- Recent articles on rotavirus vaccination impact and cost-effectiveness
  - *The Lancet:* Re-evaluating the potential impact and cost-effectiveness of rotavirus vaccination in 73 Gavi countries: a modelling study
  - *The Lancet:* Evaluating the potential economic and health impact of rotavirus vaccination in 63 middle-income countries not eligible for Gavi funding: a modelling study
- *The integrated Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea (GAPPD)*

[21] Sage recommendations during meeting on October 2020: https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf?ua=1.

Available Gavi support

Gavi provides support for the introduction of rotavirus vaccine into the routine immunisation schedule.

Countries that cannot operationally implement an initial country-wide introduction may adopt a phased introduction approach. Countries may introduce the vaccine into their routine immunisation schedule via a phased introduction based on feasibility considerations (e.g. in certain geographical zones, districts or provinces).

Introduction to routine systems

- **Target population guidance**
  - Children up to 12 months of age
- **Dose schedule**
  - Full vaccination, with either two or three doses, depending on the choice of vaccine product
- **Vaccine Introduction Grant (VIG) and co-financing**
  - A one-time VIG at US$ 0.80/0.70/0.60 (as per country co-financing phase) per target child in the birth cohort of the year of introduction
  - Standard country co-financing applies

Guidance and requirements

1 Dose administration considerations

- WHO recommends that the first dose of rotavirus vaccine be administered as soon as possible after six weeks of age. WHO recommends that rotavirus vaccine be administered at the same time as **diphtheria, tetanus and pertussis (DTP)-containing vaccine**. By allowing infants to receive rotavirus vaccine together with DTP regardless of the time of vaccination, immunisation programmes will be able to reach children who were previously excluded from the benefits of rotavirus vaccines.
- Rotavirus vaccines are given orally with an interval of at least four weeks between doses.
- Vaccinations can be administered simultaneously with other routine infant vaccines.
- Because of the typical age distribution of RVGE, rotavirus vaccination of children over 24 months of age is not recommended.

2 Monitoring adverse events following immunisation (AEFI)

For rotavirus vaccines, countries should:

- provide proper planning and training of staff for vaccine-pharmacovigilance before 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;

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

- train and encourage health staff to detect, report and investigate intussusception cases and RVGE cases so that risks and benefits of this vaccine can be further assessed. A plan for monitoring AEFIs and staff training should be implemented before introducing the vaccine.

3 Rotavirus-related key information to be captured in the implementation plans

The following elements should be captured in the plans for the introduction of the rotavirus vaccine to the routine immunisation programme:

- most recent **disease burden assessment;**

- **National Immunisation Technical Advisory Group (NITAG) recommendation** supporting the introduction and the choice of rotavirus vaccine product and presentation. The document should state the reasons why those are recommended. Where a NITAG does not exist, Gavi recommends that countries include plans to establish one and submit such plans with their request for new vaccine support; and

- **new vaccine introduction plan** including:
  - the implementation plan for the routine immunisation programme. This should specify the geographical extent, the timing of routine introduction and projected coverage. The plan should also include a late vaccination policy and address missed opportunities for vaccination. Guidance can be found in WHO's *Leave no one behind: guidance for planning and implementing catch-up vaccination*;
  - challenges or opportunities for the introduction of rotavirus based on previous vaccine introductions;
  - clear description of preparatory activities, such as social mobilisation and communication strategy, training of health workers, community resources persons and coordination of activities;
  - confirmation of cold chain readiness;
  - clear description of vaccine safety monitoring; and
  - WHO recommends that plans for introducing rotavirus vaccines consider the disease's epidemiology by age, the coverage and actual age at vaccination. Plans should also include an evaluation of the estimated public health impact and potential risks. It is important to establish the baseline incidence of intussusception. Proper planning and staff training to conduct vaccine-pharmacovigilance should occur before the vaccine is introduced. Caregivers should be adequately counselled to recognise danger signs of dehydration or intussusception.

4 Product choice considerations

- The country-level product choice should consider programmatic characteristics, vaccine supply and price.

- In their application, countries are requested to choose their preferred presentation and are strongly recommended to identify a second preferred one. A NITAG recommendation should be provided to support the choice of product and presentation.

- Countries should consult Gavi's rotavirus vaccine profiles for the latest information, noting multiple WHO-prequalified vaccine products and presentations are available. Additional presentations have been submitted for WHO prequalification and might become available in the future.

5 Integrated disease prevention, control and linkage to existing health interventions

As highlighted in the WHO/UNICEF integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD), the use of rotavirus 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 required to provide the following information in line with GAPPD objectives:

- a high-level description of any existing interventions for preventing and treating pneumonia and diarrhoea and the implementation status;
- a description of how rotavirus vaccination could strengthen joint delivery of services and communication about healthy actions such as exclusive breastfeeding and handwashing with soap, safe drinking water and sanitation, and guidance around care-seeking behaviours; and
- a description of potential barriers to integrating 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).

3.10 Typhoid conjugate vaccine

→ ROUTINE INTRODUCTION

→ ROUTINE INTRODUCTION WITH CATCH-UP CAMPAIGN

Vaccine-specific mandatory application attachments

For routine introduction:

- ☐ New vaccine introduction plan (NVIP)

For catch-up campaign:

- ☐ Campaign plan of action (can be merged with NVIP)
- ☐ Typhoid Data Guidance (tables 1 and 2)

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

WHO recommends introducing typhoid conjugate vaccine (TCV) for infants and children over six months of age as a single dose in countries where the disease is endemic and, where feasible and supported by epidemiological data, a one-time single dose catch-up of children up to 15 years of age.[22]

Catch-up vaccination of multiple age cohorts at the time of vaccine introduction is likely to accelerate the impact of vaccine use. This strategy may also increase indirect (herd) protection of unvaccinated individuals.

Countries should explore existing immunisation schedules to identify where TCV may be co-administered with other vaccines to ensure synergies and cost-effectiveness, such as at nine months of age or in the second year of life.

Key resources and references

- WHO Surveillance Standards for Typhoid and other invasive salmonellosis
- *Typhoid Data Guidance for Gavi Applications*
- WHO Guidance on Co-Administration of Typhoid Vaccine with Measles-containing vaccines
- Typhoid vaccines: WHO position paper – March 2018 (2018)

Available Gavi support

- **Gavi support:** Gavi provides support for nationwide introduction of TCV into the routine immunisation schedule and, depending on country context, a one-time catch-up immunisation of up to 15 years of age.

[22] Typhoid Vaccines: WHO Position Paper, Weekly Epidemiological Record, No 13, 2018, 93, 153–172.

- **Phased introduction:** Large countries (e.g. Nigeria, Pakistan) may choose to introduce the vaccine into their routine immunisation schedule via a phased introduction based on feasibility considerations or a subnational introduction based on risk (e.g. in certain geographical zones, districts or provinces). These large countries might also conduct TCV catch-up campaigns to accelerate the impact of vaccine use in all districts or in some selected districts among those where TCV will be introduced in routine immunisation. TCV should be introduced into routine immunisation as a minimum in all areas covered by a catch-up campaign as part of each introduction phase.

- **Outbreak response:** Gavi does not currently provide support for a TCV stockpile. However, Gavi support can be requested to respond to typhoid fever outbreaks. Given the limited data on TCV use in emergencies, countries should contact their Gavi Senior Country Manager, who can liaise with appropriate technical experts if needed.

Planning for Gavi support

Introduction in routine systems with or without catch-up campaign

- **Target population guidance**
  - **For routine:** surviving infants at nine months or in the second year of life.
  - **For catch-up campaign:** 9 months up to 15 years of age.

Key considerations for the selection of immunisation strategy

- **Implementation feasibility and epidemiologic rationale: Countries are strongly encouraged to consider implementation feasibility in choosing a specific immunisation strategy**. Countries must justify the selected strategy, and all necessary data should be captured in the completed forms included in the *Typhoid Data Guidance for Gavi Applications*. At a minimum, countries should introduce TCV into the routine system in all areas targeted with a one-time catch-up campaign.
  - **Catch-up campaigns:** If choosing a strategy of a catch-up campaign followed by introduction into the routine immunisation schedule, countries will need to demonstrate plans to introduce TCV into the routine immunisation schedule following the completion of the catch-up campaign to ensure coordination between the two activities. These plans must be reflected in the new vaccine introduction plan (NVIP) and/or plan of action (these documents may be combined to minimise duplication).
  - **Target population**
    - Countries must describe the target population for the catch-up and/or routine introduction and provide any available information on the typhoid epidemiological situation. If already using the vaccine, evidence of such vaccine use, targets and coverage must be provided.
    - Based on the timing of routine vaccination, countries should reference their TCV target population against a relevant existing national reference (e.g. measles first dose) if TCV is co-administered at the same age. Countries should also consider integrating TCV catch-up immunisation with other planned supplemental immunisation activities.

Guidance and requirements

1 Epidemiology and disease burden

Countries must provide the rationale for introducing TCV into the immunisation schedule (including if it will be national or risk-based) using typhoid disease burden data. Such rationale is strengthened by providing national or sentinel typhoid fever data (e.g. records of laboratory-confirmed typhoid cases). The WHO recommends that typhoid cases be confirmed by blood culture or molecular methods of *Salmonella* Typhi (S. Typhi) or detection of S. Typhi DNA from a normally sterile site. Widal tests are not sufficient to confirm cases of typhoid fever. If such data are unavailable, countries should consider using data from rapid assessments, modelling analyses, typhoid risk factors (e.g. access to sanitation or clean water) or environmental sampling. See Gavi's guidance on data for TCV introduction for more details.

Countries should consider establishing surveillance systems to estimate and/or monitor typhoid incidence after vaccine introduction. Gavi support for surveillance activities is available through technical assistance provided through the Partners' Engagement Framework-Targeted Country Assistance (PEF-TCA) or health system strengthening (HSS) support.

For further guidance, consult the WHO Surveillance standards for Typhoid and other invasive salmonellosis.

Requests for TCV support must include the following:

- available data or modelling, an overview of the country's epidemiological situation, including but not limited to disease burden, communities most at-risk and geographic spread of typhoid disease and/or risk factors;
- reports on outbreaks or clustering of typhoid fever cases or other diseases with similar risk factors, such as cholera; and
- rationale for selected immunisation strategy (e.g. routine only versus routine plus catch-up, national versus subnational risk-based, one time versus phased).

Requests for TCV support may additionally include:

- data on inadequate sanitation and insecure access to safe water in an area;
- antimicrobial resistance data and trends for S. Typhi; and
- lab-confirmed disease data by age (years and/or months).

2 TCV-related key information to be captured in the new vaccine implementation plan and/or plan of action

Depending on the immunisation strategy chosen by the country, the NVIP and plan of action can be combined to avoid duplication and ensure strong coordination between the routine introduction and catch-up campaign.

A comprehensive vaccination strategy (NVIP or plan of action) for TCV introduction must include the following:

- **Routine immunisation**
  - An implementation plan for the routine immunisation programme, which specifies geographical extent, the timing of routine introduction and projected coverage.
  - Demonstration of understanding of challenges or opportunities for introducing TCV based on previous vaccine introductions to ensure appropriate measures are in place to avoid disruption or build on best practices.
  - Description of integration of TCV into the national health information system for routine tracking of vaccination coverage.

- **Catch-up campaign**
  - An implementation plan to quantify the target population, and to reach high coverage of the targeted age group, using lessons learned from previous campaigns targeting in-school and out-of-school children.
  - The catch-up campaign needs to reach specific populations where routine immunisation coverage is low and inequitable. These populations are often socially and economically marginalized communities, geographically difficult-to-reach communities, and/or racially and ethnically discriminated communities. The campaign design therefore needs to include explicit initiatives to reach such populations.
  - Plans for monitoring coverage during the campaign to identify gaps in real time, tracking individual vaccination status and conducting a post-campaign coverage survey.
  - Implementation plan for the smooth transition to the routine immunisation programme.

- **Surveillance**
  - **Typhoid fever surveillance:** status and scope of reporting system, the existence of access to laboratory confirmation testing for typhoid fever and testing for antimicrobial resistance in typhoid fever cases, data management. If there is no surveillance in place, countries should provide plans to establish typhoid fever surveillance, but this is optional to apply for Gavi support.
  - **Adverse events following immunisation (AEFI) surveillance:** status of the reporting system, awareness of health care workers on AEFI reporting, AEFI data management and the status of the AEFI expert committee.

- **Preparatory activities:** clear description of governance and coordination, and preparatory activities, including the social mobilisation and communication strategy, training of health workers and community resource persons.

- **Water, sanitation and hygiene (WASH):** description of or reference to country plans and process to improve WASH in identified high-burden areas. Countries should consider approaches for integrated disease prevention, control and linkage of immunisation programmes to existing health interventions (e.g. WASH and/or leveraging opportunities across vaccine programmes).

3.11 Yellow fever vaccine

→ ROUTINE INTRODUCTION

→ PREVENTIVE MASS CAMPAIGN

Vaccine-specific mandatory application attachments

For routine introduction:

- ☐ New vaccine introduction plan

For preventive mass campaign:

- ☐ Campaign plan of action
- ☐ Risk assessment report
- ☐ EYE strategy implementation plan (recommended)

Access full library of Gavi guidelines

Detailed product profiles

WHO recommendations

Yellow fever (YF) cannot be eradicated, but epidemics can be eliminated if population immunity levels are raised through mass vaccination and sustained by routine infant immunisation. The risk of outbreaks can be substantially reduced by immunising at least 80% of the population in at-risk areas.

To achieve and maintain this high coverage rate in at-risk countries, the Eliminate yellow fever epidemics (EYE) strategy 2017-2026 outlines four potential ways to improve vaccination coverage in high-risk areas:

1. integration of YF in routine immunisation programmes when administering the measles-containing-vaccine first dose (MCV1) and strengthening coverage;
2. conducting preventive mass vaccination campaigns to rapidly increase population immunity in high-risk areas;
3. implementing catch-up activities as a risk mitigation measure to close immunisation gaps; and
4. maintaining a stockpile for reactive campaigns that ensures vaccine equity for YF outbreak response.

All countries should note that YF virus circulation and risk can change and/or expand to additional countries or regions not currently considered high-risk. WHO therefore recommends that countries:

- consult with the EYE Secretariat at WHO;
- refer to YF WHO guidance notes, which are revised annually. These documents can be found on the WHO YF webpage or from relevant WHO country offices; and
- refer to the Eliminate yellow fever epidemics (EYE) strategy 2017-2026.

Key resources and references

- WHO YF vaccine page
- Eliminate yellow fever epidemics (EYE) strategy 2017-2026
- WHO YF page including key publications and documents
- WHO Vaccination Coverage Cluster Survey Reference Manual

For WHO recommendations on the implementation of the eliminating YF epidemics strategy, please refer to the country toolkit and related guidance.

For more information on conducting a risk assessment, refer to the WHO African Region YF focal point and EYE Secretariat (EYE.Strategy@who.int).

Available Gavi support

Gavi provides support for routine introduction, a one-time preventive mass campaign for countries classified as at high risk of YF and support for YF diagnostics (see section 3.12).

Countries at moderate risk of YF virus circulation or at potential risk that have yet to conduct risk assessments are only expected to apply for support if the identified risk is validated in consultation with the EYE Secretariat.

Gavi channels funds for **rapid outbreak response** for YF through the International Coordinating Group. Details on accessing support for outbreak response are available on the YF vaccine stockpile website.

Introduction to routine systems

- **Target population guidance**
  - WHO recommendation for countries in sub-Saharan Africa: 9 months.
  - WHO recommendation for countries in the Americas: 12 months.
- **Key considerations**
  - **High-risk countries:** High-risk countries are recommended to:
    - introduce and sustain high YF vaccine coverage in their routine immunisation system; and
    - introduce the YF vaccine into the routine within nine months of the preventive mass campaign.
  - **Subnational introduction:** Introduction of the vaccine into the routine immunisation schedule will generally be nationwide. However, large countries with relatively small hyperendemic areas may consider subnational introduction depending on key findings and results of risk assessments.
  - **Co-administration with MCV1 and other vaccines:** It is recommended that the YF vaccine is given to children 9–12 months at the same time as measles, which often coincides with other vaccines (e.g. meningococcal A). Hence countries should also mention their target population for the measles vaccine first dose in their YF request.

Preventive mass campaigns

- **Target population guidance**
  - Population in high-risk areas, nine months and older, with a recommended upper limit of 60 years old. The exact target age range may vary depending on the existing specific immunity per country.

- **Key considerations**
  - **High vaccination coverage through routine immunisation is top priority:** Most high-risk countries already have the YF vaccine in their routine and should focus on raising routine vaccine coverage as a top priority. Guidance is provided in section 2 ("Gavi support to introduce and scale up vaccines") on using campaigns to strengthen routine immunisation.
  - **Countries must commit to introducing the YF vaccine routinely:** Countries that have not yet introduced the YF vaccine in their routine should apply for support to do so at the same time as the request for a preventive mass campaign or provide a statement committing to introduce the YF vaccine into the routine immunisation schedule within nine months after the campaign.

Guidance and requirements

1 Long-term planning and prioritisation

- To support a comprehensive approach to sustained YF control with proper prioritisation, countries are encouraged to have long-term YF prevention and control plans and attach them to the application. For example, a summary of all activities related to YF should be reflected in the annual Expanded Programme on Immunization (EPI) plan or the three-year EYE strategy implementation plan.

- Countries are expected to maintain high routine coverage rates following preventive mass campaigns. This is important to ensure that the benefits of a preventive campaign are sustained through the subsequent protection of newer cohorts. Countries should contact WHO for further guidance on planning preventive mass campaigns before requesting new Gavi support.

2 Risk assessments

- Countries must submit a subnational risk assessment prepared with the engagement of the EYE risk analysis working group when applying for Gavi support. In addition, countries are expected to consult with the EYE Secretariat at least 6–12 months before submitting a request for support to Gavi to receive technical assistance to:
  - prioritise for new YF vaccine routine introduction plans;
  - validate the level of country risk;
  - prioritise preventive mass campaign introductions; and
  - validate vaccine dose requirements per phase and year.

3.12 Yellow fever diagnostics support

Access full library of Gavi guidelines

In November 2018, the Gavi Board approved support for yellow fever (YF) diagnostic capacity strengthening by providing laboratory supplies, equipment and capacity building to countries.

This support aims to facilitate more reliable YF laboratory testing, which in turn should allow more effective and efficient YF vaccine usage, particularly in response to outbreaks and in addressing the gaps in routine immunisation coverage identified through the detection of YF cases.

Available Gavi support

Gavi support for YF vaccine procurement is focused on consumable supplies, including reagents, needed for tests to confirm YF infection in suspected YF cases and the equipment specifically needed to conduct those tests. Gavi may support the procurement of consumable YF vaccine laboratory supplies for a country without supporting the procurement of YF diagnostic equipment.

Types of reagents, supplies and equipment for YF diagnostic testing eligible for Gavi support

- **Enzyme-linked immunosorbent assay (ELISA) testing**
  - ELISA reagents or test kits
  - ELISA testing consumable supplies, including ELISA reaction plates and pipette tips.
- **Polymerase chain reaction (PCR) testing**
  - PCR test kits
  - PCR testing consumable supplies, including PCR testing tubes
- **Personal protective supplies, including eye protection and disposable gloves**
- **Equipment**
  - ELISA washer
  - ELISA reader
  - PCR machine
  - Biosafety cabinet

For purposes of Gavi funding for procurement of reagents, supplies and equipment for YF diagnostic testing, the specific amounts and types of consumable supplies procured for testing a given number of samples and the types of equipment procured for use in the YF laboratory network will be determined based on input from WHO and UNICEF.

Countries eligible to request YF diagnostics support

The support for YF diagnostic reagents, supplies and equipment is currently available to Gavi-eligible African countries classified as high or moderate risk for YF by WHO as part of the Eliminate YF epidemics (EYE) strategy.

- Approved: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, Guinea, Kenya, Liberia, Mali, Niger, Nigeria, Senegal, South Sudan, Sudan, Togo and Uganda.

- Eligible, not (yet) applied for: Burundi, Eritrea, Gambia, Guinea-Bissau, Mauritania, Rwanda, Sierra Leone, Somalia, United Republic of Tanzania and Zambia.

Planning for Gavi support

- The national government must submit requests to the Gavi Secretariat. In addition, this support is provided only to a country's national public health YF reference laboratory. To receive support, the national public health YF reference laboratory must have a solid basis for testing at least 50 YF samples a year to maintain adequate testing proficiency.

- Gavi-supported YF laboratory supplies and equipment will be procured via UNICEF Supply Division. Self-procurement or procurement via other mechanisms is not possible for Gavi-funded procurement of YF laboratory supplies and equipment.

Support for consumable supplies

Gavi will provide funding for purchasing consumable supplies from the categories described above to test up to 120% of samples expected to be received for ELISA testing and 120% of samples eligible for PCR testing through 2021. The additional 20% will serve as a reserve (buffer) if more samples are received than expected.

The initial country application will identify the number of samples expected to be tested in the first year, with subsequent annual renewals allowing revised estimates of sample testing volumes based on new experience and information. Gavi will also annually fund support for purchasing consumable supplies for testing approximately another 30 samples with ELISA and 20 samples with PCR for training and quality assurance purposes. The amounts and types of consumable supplies needed for testing a given number of samples will be determined based on input from the WHO and UNICEF.

Support for equipment

Gavi may also fund the procurement of some YF ELISA and PCR testing equipment identified above if the need for such equipment has been confirmed through a WHO-associated laboratory capacity assessment visit for Gavi to fund the procurement of that equipment. The available equipment types will be based on input from WHO and UNICEF.

Countries should explain in their application how installation and maintenance services for the equipment will be secured.

Limitations and other sources of support

Funding for basic laboratory infrastructure components such as staff, electricity, water, furniture, etc is not available as part of Gavi support for YF diagnostic capacity; such components should be funded through other means. Gavi health system and immunisation strengthening funding may be available to support surveillance and laboratory capacity in national plans focusing on achieving and maintaining high immunisation coverage and addressing underlying equity challenges. In addition, technical assistance, such as laboratory staff training and quality assurance/quality control testing, can be made available for YF national laboratories and WHO regional reference laboratories.

Guidance and requirements

Requirements

- Completed application form.
- Signatures required to endorse the request before submission to Gavi:
  - Minister of Health (or their delegated authorities);
  - Director of national YF laboratory (or their delegated authority); and
  - Director of Finance for the Ministry of Health (or their delegated authority).
- The coordination forum – the inter-agency coordinating committee (ICC), health systems coordinating committee (HSCC) or equivalent body – must endorse the request before submission to Gavi. This can also be done through the ICC/HSCC endorsement of the joint appraisal and should be reflected in ICC/HSCC minutes.

NOTE: The signature of the Minister of Finance (or their delegated authorities) is recommended but optional. To ensure long-term financial sustainability, countries will be expected to eventually contribute some of their resources and gradually assume full responsibility for funding YF laboratory materials. More information will be provided as it becomes available. The endorsement of this request by the Director of Finance for the Ministry of Health is required to ensure government awareness of its responsibility for the funding of YF laboratory reagents, supplies and equipment.

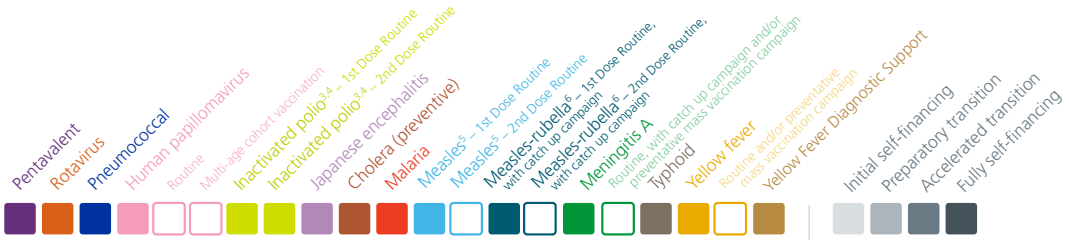
Annex 1: Available Gavi vaccine support and eligibility by country

The chart below provides an overview of a country's Gavi-supported vaccine portfolio (as of 2022) and transition phase for purposes of better understanding which vaccines a country is eligible for but has not yet introduced and country obligations for vaccine co-financing.

COUNTRY VACCINE INTRODUCTIONS, ELIGIBILITY, AND TRANSITION STATUS AS OF 2022

AFRICAN REGION	VACCINE INTRODUCTIONS FROM 2000 TO 2022 & ONGOING ELIGIBILITY																					TRANSITION STATUS AS OF 2022			
	Pentavalent	Rotavirus	Pneumococcal	Human papillomavirus	Routine	Multi-age cohort vaccination	Inactivated polio[3-4 – 1st Dose Routine]	Inactivated polio[3-4 – 2nd Dose Routine]	Japanese encephalitis	Cholera (preventive)	Malaria	Measles[5 – 1st Dose Routine]	Measles[5 – 2nd Dose Routine]	Measles-rubella[6 – 1st Dose Routine, with catch up campaign]	Measles-rubella[6 – 2nd Dose Routine, with catch up campaign]	Meningitis A	Routine, with catch up campaign and/or preventative mass vaccination campaign	Typhoid	Yellow fever	Routine and/or preventative mass vaccination campaign	Yellow Fever Diagnostic Support	Initial self-financing	Preparatory transition	Accelerated transition	Fully self-financing
Angola[1]	R	R	R				RC	R					RC												
Benin	R	R	R	D	E	E	R	E		E	A	R		RC	E	E	C	E	RC						
Burkina Faso	R	R	R	DR	R	A	RC	R		E	A	R		RC	RC	RC		E	RC						
Burundi	R	R	R	D	E	E	RC	E		E	A	R		RC	RC	C	E	E							
Cameroon	R	R	R	DR	R	A	R	A		E	A	R			RC	C	E	E	RC						
Central African Republic	R	A	R	E	E	E	R	E		E	E		E			RC		E	RC						
Chad	R	E	E	E	E	E	R	R		E	E		RC	E	E	RC		E	R	E					
Comoros	R	E	E	E	E	E	RC	E		E				RC	RC			E							
Congo	R	R	R	E	E	E	R	E		E				RC					RC	E					
Côte d'Ivoire	R	R	R	DR		A	RC	E		E	E		RC	RC	RC	RC		E	RC						
DR Congo	R	R	R	E	E	E	R	A		E	A		A	E	E	C	E	E	RC						
Eritrea	R	R	R	RC	R	C	RC	R		E	E	R		RC	RC	RC		E							
Ethiopia	R	R	R	DR	R	A	R	E		E	E	R	R	E	E	C	E	E	E	E					
Gambia	R	R	R	DRC			R	R		E	E	R	R	RC	RC	RC		E			E				
Ghana	R	R	R	D	E	E	RC	E		E	A	R	R	RC	RC	RC		E	RC						
Guinea	R	E	E	E	E	E	R	R		E	E	A	A			R	R	E	RC						
Guinea-Bissau	R	R	R	E	E	E	R	E		E	E		R	E	E		A	E	R	E	E				
Kenya	R	R	R	DR		A	R	E		E	A			RC	RC	C	E	E	R	E					
Lesotho	R	R	R	RC	R	C	R	E		E	E		R	RC	RC			E							
Liberia	R	R	R	DR		A	RC	E		E	A	R	R	E	E			RC	RC						
Madagascar	R	R	R	D	E	E	R	R		E	E	R	R					E							
Malawi	R	R	R	DR		A	RC	E		E	A	R		RC	RC			A							
Mali	R	R	R	D	A	E	R	R		E	E	R		E	E	RC		E	RC						
Mauritania	R	R	R	RC	R	C	R	E		E	E			RC	A	C	E	E							
Mozambique	R	R	R	D	R	A	R	A		E	A	R		RC	RC			E							
Niger	R	R	R	D	E	E	R	R		E	A			E	E	RC		E	R	E					
Nigeria	R	A	R	A	A	A	R	R		E	SE	RC	R	E	E	RC		E	RC						
Rwanda	R	R	R	R	R		R	R		E	E	R		RC	RC	E	E	E							
Sao Tome and Principe	R	R	R	D	R	C	RC	E		E	E	R		RC	RC			E	R						
Senegal	R	R	R	DR	R	A	RC	A		E	E	R		RC	RC	C	E	E	RC						
Sierra Leone	R	R	R	DR	R	A	RC	R		E	A	R		RC	RC			E	RC		E				
South Sudan	R	E	E	E	E	E	R	R		E	E		E			C	E	E	E	E					
Togo	R	R	R	D	A	A	R	R		E	E	R		RC	RC	RC		E	RC						
Uganda	R	R	R	R	R		R	R		E	A			RC	A	C	E	E	RC						
UR Tanzania	R	R	R	DR	R	A	RC	E		E	E	R		RC	RC	E	E	E							
Zambia	R	R	R	DR	R	A	RC	E		E	E	R		RC	RC			E							
Zimbabwe	R	R	R	DRC	R	C	RC	R		E	E	R		RC	RC			RC							

COUNTRY VACCINE INTRODUCTIONS, ELIGIBILITY, AND TRANSITION STATUS AS OF 2022



REGION OF THE AMERICAS	VACCINE INTRODUCTIONS FROM 2000 TO 2022 & ONGOING ELIGIBILITY	TRANSITION STATUS AS OF 2022
Bolivia (Plurinational State of)[1]	R R R R R R	
Cuba[1]	R E	
Guyana[1]	R R RC R E	
Haiti	R R R E E E R E E E	
Honduras[1]	R R R R R E	
Nicaragua[1]	R R R R	
EASTERN MEDITERRANEAN REGION		
Afghanistan	R R R E E E R R E C E E E	
Djibouti	R R R E E E R A E E R E E E	
Pakistan	R R R E E E R R E E RC RC RC	
Somalia	R E E E E E R R E E R E	
Sudan	R R R E E E RC R E A A A RC E RC	
Syria	R E E E E E R E E RC	
Yemen	R R R E E E R R E RC E	
EUROPEAN REGION		
Armenia[1]	R R R D R E	
Azerbaijan[1]	R R R R R	
Georgia[1]	R R R D E E	
Kyrgyzstan	R R R RC R C R R E E	
Republic of Moldova[1]	R R R D R E	
Tajikistan	R R R E E E RC R E E	
Uzbekistan[1]	R R R R C R R	
SOUTH-EAST ASIAN REGION		
Bangladesh	R A R D A A RC E E E R RC RC E	
Bhutan[1]	R R[2] R RC R	
DPR Korea	R E E E E E R E E E R RC E	
India	R R R E E R E RC C E	
Indonesia[1]	R A[2] D RC R RC C	
Myanmar	R R R R R A R A RC E R RC RC E	
Nepal	R R R D E E R E RC E R RC RC A	
Sri Lanka[1]	R R R R R E	
Timor-Leste[1]	R A[2] A R A	
WESTERN PACIFIC REGION		
Cambodia	R E R D A A R E RC E R RC RC E	
Kiribati[1]	R R R E	
Lao PDR	R A R DRC R C R E C E R C RC E	
Mongolia[1]	R R[2] R E	
Papua New Guinea	R R SE SE SE R R E R C E	
Solomon Islands	R R R DRC R C R E R C E	
Vietnam[1]	R A RC R R C	

Introduction type

R - Introduction of a routine programme **C** - Campaign **D** - Demonstration **A** - Approved, awaiting introduction

Eligibility type

Not yet introduced a routine or campaign **E** - Eligible **SE** - Requiring special board decision Not eligible

[1] These countries are fully self-financing.

[2] Supported to access the PCV AMC price.

[3] Approval for IPV catch-up campaign: Côte D'Ivoire, Eritrea, Kyrgyzstan, Malawi, Mongolia, Rwanda, Senegal, Sierra Leone, Togo, Uzbekistan, Zimbabwe

[4] Eligibility for IPV catch-up campaign: DPR Korea, Djibouti, Gambia, Guinea-Bissau, Lesotho, Nepal

[5] Second dose of M or MR vaccine as second dose of measles containing vaccine. The list excludes measles follow-up campaigns as they are not directly associated with routine introductions. They are supplementary immunisation activities to fill measles immunity gaps.

[6] MR vaccine as rubella containing vaccine. Eligibility in this list is based on WUENIC 2019 data and survey coverage of the last M/MR campaigns and may change based on latest available data. Please refer to the MR programme guidance for details of the eligibility criteria. The list excludes measles-rubella follow-up campaigns as they are not directly associated with routine introductions. They are supplementary immunisation activities to fill measles immunity gaps.

Annex 2: Post-campaign coverage survey (PCCS) requirements

Countries benefiting from campaign support must report results to the Gavi Secretariat.

PCCS requirements for Gavi-supported campaigns

- Following all Gavi-supported vaccination campaigns, **countries must conduct an independent, statistically and technically sound PCCS** with probability sampling to assess the national level of vaccination coverage[23] achieved during the campaign.[24] This requirement helps to ensure:
  - independent estimation of national coverage of the completed campaign supported by Gavi using probability sampling; and
  - accountability for the campaign by in-country leaders and other stakeholders.
- When applying for Gavi campaign support, countries must indicate the **scope and objectives** of a planned PCCS in the campaign plan of action. Countries must also include the **cost of the PCCS** as part of the detailed budget for the Operational Cost grant. The PCCS should ideally be funded by the Gavi grant to ensure there is no funding gap, but it can also be funded by a third party if the funding has been committed and mobilised.
- The **PCCS report** must be submitted to Gavi upon completion and no later than six months after implementing the campaign.

Planning for a PCCS

- **Roles and responsibilities:** Countries should clearly define the roles and responsibilities of key persons and agencies for planning, conducting, analysing and disseminating the post-campaign survey.
  - An independent, interdisciplinary team should conduct a post-campaign survey with inputs from the immunisation programme and its partners to ensure an objective campaign coverage assessment.
  - Countries are encouraged to work with the national statistical office or an equivalent government programme to obtain the best available sampling frame and to ensure continued engagement and local capacity strengthening.
- **Timing of survey:** A PCCS should be conducted as soon as feasible, within three months, after the completion of a campaign to reduce recall bias. This may mean conducting the PCCS at staggered intervals for campaigns that are implemented in phases.
- **Anticipate a 6–12 month planning period:** The technical and operational planning for a PCCS should start at least 6–12 months before the planned campaign.
- **Integrated campaigns:** If conducting an integrated campaign (e.g. MCV and meningococcal A vaccine), the PCCS should aim to measure the coverage of each intervention delivered during the campaign. This will require careful planning of the supplementary immunisation activities (SIA) (e.g. giving each vaccine in a different but consistent limb), use of different coloured finger marks for each vaccine, and recording each vaccine on the campaign card (or using a different coloured card for each vaccine given during the campaign). This will make it easier to collect data on which vaccine(s) were received when conducting the PCCS.

[23] For subnational campaigns, coverage in the population and geographic areas targeted by the campaign.

[24] If countries are faced with exceptional circumstances that do not allow the PCCS to be conducted (e.g. security issues), they must provide a written justification to Gavi.

- **Adapt SIA Readiness Assessment Tool:** Countries are encouraged to adapt WHO's SIA Readiness Assessment Tool (EN I FR) to capture key PCCS-related activities and milestones to adequately monitor the preparations and implementation of a high-quality PCCS.
- **Technical assistance:** Countries are encouraged to consider including technical support for a planned vaccination survey and PCCS. Close engagement and partner support are key, especially during the early planning and budget estimation process.

PCCS design

Refer to the WHO Vaccination Coverage Cluster Survey Reference Manual for Post Campaign Coverage Surveys for technical guidance to plan, design and conduct as PCCS.

- **Standardised questionnaires:** Standardised PCCS questionnaires – or questionnaires reviewed by an expert committee and validated for collecting data on vaccination – are strongly encouraged to ensure conformity with best practice. Questionnaires should be designed to facilitate accurate data collection and according to the methods used in the local setting to document doses received during the campaign and in routine vaccination services. Adequate pilot testing is encouraged, and practical training and supervision of interviewers is essential.
- **Standardised statistical analyses:** Conduct appropriate statistical analyses given the survey sampling design. This is facilitated by using vaccination coverage quality indicators (VCQI). Data analyses must be appropriately weighted following WHO guidelines; it is important to ensure that the information to calculate weights is well documented during survey planning and implementation.
- **Sample size and degree of precision for PCCS:** The survey needs to be of sufficient sample size relative to the target population of interest and the purpose of the survey. Technical experts recommend that countries aim for a national campaign coverage estimate with a precision of ±5% when coverage is expected to be at least 80%. Aiming for more or less precision may depend on the programmatic decisions expected from the survey. Special efforts are needed to ensure the most up-to-date and complete sampling frame and determine operating procedures for reaching special populations such as refugees, internally displaced populations and the urban poor.
    - **For integrated campaigns** (e.g. MCV and meningococcal A vaccine), which may have multiple age groups, the sample size needs to be calculated for each indicator in terms of the number of interviews to be completed, and then the required number of households to include in the survey needs to be calculated based on the local population demographics (see Annex B of *WHO vaccination coverage cluster survey reference manual for post campaign coverage surveys*).
- **Geocoordinates:** Collecting geo-coordinates of households (or, at a minimum, of clusters) to allow for geospatial analysis of data. This is strongly encouraged as geospatial analyses can help extrapolate information from the survey to areas not included in the survey and identify areas within the country where extra attention is needed to reach zero-dose children in future activities.[25]
- **Prioritising national-level coverage estimates:** Reliable **national-level** coverage estimates should be the priority of Gavi-supported PCCS. Aiming for precise estimates in each subnational unit is discouraged as this can hurt the process and quality.[26] Experiences in some countries showed that aiming to produce subnational estimates can delay the survey process, potentially increasing recall

[24] Geospatial variation in measles vaccine coverage through routine and campaign strategies in Nigeria: Analysis of recent household surveys. Utazi CE, Wagai J, Pannell O, Cutts FT, Rhoda DA, Ferrari MJ, Dieng B, Oteri J, Danovaro-Holliday MC, Adeniran A, Tatem AJ.Vaccine. 2020 Mar 23;38(14):3062-3071. doi: 10.1016/j.vaccine.2020.02.070. Epub 2020 Feb 29.

[26] The WHO coverage survey guidelines describe the implications and considerations for sample size, resources and quality control of stratifying surveys to different levels of the health system.

bias, significantly increasing the survey cost and potentially compromising the survey quality. If there are specific questions about certain **high-risk population sub-groups** based on existing evidence, countries may consider **oversampling** specific areas or target groups. Countries should discuss any considerations for subnational and/or specific population sub-groups with Gavi and technical partners, especially when conducting targeted or tailored subnational or selective activities.

- **Coverage among "measles zero-dose" children:** For MCV vaccination campaigns, the PCCS must also provide an estimate of the campaign coverage among **children younger than five years stratified by the number of previous MCV doses** (zero, one, at least two, or unknown), as per the PCCS report template checklist above and as calculated by vaccination coverage quality indicators (VCQI). This will allow estimation of campaign coverage among "measles zero-dose" children (i.e. children who had not previously received MCV).
- **Routine immunisation coverage:** To calculate coverage among measles zero-dose children, questions must be asked about prior receipt of MCV during routine vaccination (according to the vaccination record or caretaker recall) and/or during previous SIAs (according to an SIA card or caretaker recall). Adding questions on receipt of all routine vaccinations to a PCCS is generally discouraged, as it adds to the required time, cost and complexity and may jeopardise the data quality of the PCCS.[27] Routine vaccination questions may be integrated into PCCS in limited instances, provided that:
  - there is adequate planning time and funding;
  - the addition of routine vaccination questions does not add an unnecessary burden on data collection and does not hamper the quality or timeliness of a PCCS; and
  - countries and technical partners must agree on a small number of routine vaccination questions to be added based on the intended use of data.

PCCS reporting

- The PCCS report should have a detailed description of the rationale and purpose of the survey, the scope of the survey, the target population, sampling procedures, planned sample size, strategies used to minimise bias (e.g. revisits to target populations) and limitations to facilitate the interpretation of the results and replication of similar surveys in the future. It should also include a detailed description of the sample from which data was collected (e.g. areas excluded before or after the sample was taken due to security or other concerns). Please refer to the PCCS report template checklist referred to above.
- Countries may wish to encourage the agency conducting the survey to use the **WHO VCQI** tools for survey analysis.
- If possible, countries should also share the **raw data** from the PCCS with Gavi when submitting the PCCS report.

Using PCCS report for future planning

- The PCCS, if of high quality, can help to plan future campaigns and other strategies. Examples include lessons learned and improvements in the next campaign from triangulation of information from multiple sources, planning for strategies that could be used to improve routine immunisation based on results on the proportion of children reached for the first time by campaigns (and on geospatial analyses, if conducted), and improving strategies for a particular age group for next campaign if the analysis is stratified by age group.

[27] Monitoring vaccination coverage: Defining the role of surveys, Cutts F.T., Claquin P, Danovaro-Holliday MC, Rhoda DA, *Vaccine*, 2016 July 29;34(35):4103-4109. doi: 10.1016/j.vaccine.2016.06.053. Epub 2016 Jun 24.

Annex 3: Framework of Gavi support for measles and rubella control

Gavi support for measles and rubella uses the standard hierarchy of strategies for measles and rubella control:

1. Routine immunisation
2. Supplementary immunisation activities (SIA) (or campaigns)
3. Outbreak response

Measles and rubella control strategies

Strategy for measles control	Aim	Available Gavi support	Gavi guidance documents	Process to request support	Measles and rubella-specific requirements
1 **Routine immunisation**	Improving MCV1* and MCV2** coverage to protect individuals and achieve high population immunity on an ongoing basis and decrease reliance on SIA	Health system strengthening (HSS)	Programme Funding Guidelines	• Full Portfolio Planning (FPP) process • Joint appraisal process	• Measles and rubella five-year plan with FPP • Annual review of the five-year plan
	Reduce burden of rubella and congenital rubella syndrome, quickly build up population immunity against rubella and avoid paradoxical effect through MR catch-up campaign	New vaccine support (measles-rubella introduction and catch-up)	Vaccine guidelines	Vaccine application process, as part of FPP or standalone	• Campaign plan of action • Campaign budget
	Introduction of a second dose of MCV in routine immunisation	New vaccine support (MCV2)	Vaccine guidelines	Vaccine application process, as part of FPP or standalone	• New vaccine introduction plan • New vaccine introduction budget
2 **Supplementary immunisation activities (or campaigns)**	Supplement routine immunisation and quickly address measles immunity gaps to mitigate risk of outbreaks	New vaccine support (M/MR follow-up)	Vaccine guidelines	Vaccine application process, as part of FPP or standalone	• Campaign plan of action • Campaign budget
3 **Outbreak response**	Respond to measles outbreak	Outbreak Response Fund (ORF) through Measles & Rubella Partnership (M&RP)	M&RP guidelines	Ad-hoc	Please refer to *Measles & Rubella Partnership website*

*Measles-containing vaccine dose 1

**Measles-containing vaccine dose 2

Annex 4: New measles or measles-rubella follow-up campaign support information

Introduction

In line with the November 2018 Board decision, countries requesting new measles or measles-rubella follow-up campaign support may request operational support for national and subnational campaigns and enhanced routine immunisation activities to reach missed and zero-dose children identified by the campaigns. If countries decide to use this flexibility to conduct enhanced routine immunisation activities with their measles/measles-rubella (MR) supplementary immunisation activities (SIA) funding, the following guidelines provide additional information on what activities may be proposed as part of this flexibility.

Principles for selection of activities:

- improving measles-containing vaccine (MCV) coverage while strengthening routine immunisation overall;
- **strengthening routine immunisation** to increase the SIA intervals and, in the long term, decrease the reliance on SIAs; and
- **aligning with existing support** to ensure coherence with investments in the national expanded programme of immunisation (EPI) and those already planned and budgeted in existing Gavi health system strengthening (HSS) support. This alignment will be reviewed by the Independent Review Committee (IRC) during their review of the overall application. (See *Gavi Application Process Guidelines*).

Enhanced routine immunisation strengthening activities (illustrative)

SIA-related: before, during and after SIA

The following routine immunisation-strengthening activities are focused on short-term investments intended to occur around the timeline of the SIA. For additional details, see the SIA Field Guide and the accompanying SIA e-learning course. For additional strategies and activities, refer to the *Global Routine Immunisation Strategies and Practices (GRISP)* specifically to activities targeted at reaching universal immunisation coverage. Most of the following activities or guidance can and should already be incorporated into the pre-, intra- and post-SIA activities without requiring additional resources.

Before SIA

- **Training:** Conduct training needs assessment six months before the SIA to organise competency-based training accordingly. Include routine immunisation and surveillance topics during SIA training and reinforce skills for proper routine immunisation microplanning, vaccine handling, injection safety, adverse events following immunisation (AEFI) management and waste management. Identify training institutions (health training college, nursing schools, etc) in the SIA areas that can host training and possibly move towards providing this training support in the long term.
- **Advocacy, social mobilisation, communication:** Conduct the knowledge, attitudes, beliefs and practices (KABP) survey in the community to develop communication messages for routine immunisation and SIA.

- **Supervision, monitoring and evaluation:** Use routine supervisory visits and other relevant information before the SIA to assess routine immunisation performance, identify training needs and plan for targeting high-risk districts for additional routine immunisation supervisory support after the SIA.

During SIA

- **Training:** Use supervision checklists to review processes and address issues of the routine immunisation programme (e.g. injection safety and waste management, etc)
- **Vaccine safety surveillance:** Strengthen AEFI reporting, management and proper use of AEFI kits through supervision during the SIA.
- **Advocacy, social mobilisation, communication:** Emphasise the importance of the SIA and routine immunisation during media briefings, press releases and community education sessions. Have health care workers (HCWs) remind caregivers to bring children back to routine immunisation service for any missing routine immunisation doses and MCV2 in their second year of life (depending on vaccination schedule). Have health workers register under-immunised children and plan for defaulter tracking.
- **Supervision, monitoring and evaluation:** Review and address challenges to the routine immunisation programme. Use rapid convenience monitoring to identify communities with children being missed by the SIA or routine immunisation and the reasons for non-vaccination.

After SIA

- **Planning:** Update and revise routine immunisation micro plans, maps of catchment areas and routine immunisation strategies for communities with many under-vaccinated or unvaccinated children. Use SIA data and post-SIA review meetings to revise sites of routine immunisation outreach locations and plan in the short/medium term for periodic intensification of routine immunisation (PIRI) where needed.
- **Logistics, cold chain, vaccine handling and waste management:** Include cold chain equipment purchased for the SIA in the routine immunisation programme equipment inventory and maintenance plan.
- **Advocacy, social mobilisation, communication:** Use advocacy and social mobilisation activities with interested groups (e.g. women's and youth groups) to promote routine immunisation and recognition/reporting of suspected measles and rubella cases.
- **Supervision, monitoring and evaluation:** Conduct coverage surveys to assess SIA and routine immunisation coverage levels and identify high-risk and underserved populations, low-coverage districts and reasons for non-vaccination within the routine immunisation programme. Immediately use SIA data, including rapid convenience monitoring results in low coverage areas, to rapidly plan and execute vaccination sessions and PIRI as needed.

Enhanced routine immunisation-strengthening activities

Beyond SIA: Longer term interventions (see "Beyond SIA" table for illustrative activities)

The following routine immunisation-strengthening activities fall under five intervention areas: missed opportunities for vaccination, second year of life, reaching every district (RED/REC), school screening and PIRI. These areas have been selected for their relevance to routine immunisation-strengthening strategies identified in the GRISP and their ability to improve MCV coverage.

Missed opportunities for vaccination (MOV): Reducing missed opportunities for vaccination is a strategy to increase immunisation coverage simply by making better use of **existing** vaccination sites (at health centres, hospitals, outreach/mobile services etc). The MOV strategy answers questions about how many opportunities are missed, why and what can be done differently to address the missed opportunities.

Additional information

- MOV planning guide, assessment methodology and intervention guidebook (the intervention guidebook is in development and coming soon).
- The Service Provision Assessment (SPA) survey is a health facility assessment that provides a comprehensive overview of a country's health service delivery, including services delivered through non-governmental (private) providers.

Second year of life (2YL): An increasing number of vaccine doses are recommended to be given after one year of age, and most infant vaccination can be caught up in the 2YL (if missed earlier). A strong platform in the 2YL is the first important step in extending immunisation beyond infancy and encouraging the continuity of routine vaccination into preschool, school, adolescent and adult populations. For additional information, refer to WHO guidance, *Establishing and strengthening immunization in the second year of life.*

Reaching Every District/Reaching Every Community/Reaching Every Child (RED/ REC): Planning and implementing the five RED/REC approach components is fundamental to improving immunisation coverage and equity at national, district and health facility levels. This includes: 1) planning and managing resources, 2) engaging with communities, 3) supportive supervision, 4) monitoring and using data for action, and 5) reaching all eligible populations. The updated 2017 RED/REC guide also addresses strategies to improve access and use among urban populations.

Additional information

- Reaching Every District (RED) (2017)
- **Guidelines for coverage and equity assessments** that complement the RED structure (being developed by UNICEF, supported by working papers overseen by the Equity Reference Group) will increase focus on certain areas such as urban poor, remote rural, conflict and gender issues. This will help MR flexibilities target the most vulnerable/lowest coverage, with suggestions around strategies that can support improvement.

School screening: Checking the vaccination history upon entry to, or during, childcare, pre-school or primary school is one strategy countries can employ to identify and catch-up children who have missed previous doses of routine vaccinations. Rates of home-based record retention and school enrolment are important factors to consider when identifying populations that would benefit most from a school screening programme. High-level engagement with school health programmes and advocacy at the national and subnational levels are critical to the success of this approach. For additional information on school immunisation screening case studies, refer to WHO page, which includes case studies of effective school screening programmes.

Periodic intensification of routine immunisation (PIRI): PIRI is a descriptive term that refers to a range of activities that aim to increase coverage for routine immunisation, including doses of all vaccines. PIRI can include activities to augment service delivery, increase the support and demand for routine immunisation, or a combination of supply- and demand-related activities. To justify using resources and not inadvertently detract from routine immunisation services, PIRI service delivery activities should focus on reaching populations frequently underserved or missed by routine immunisation.

Beyond SIA: illustrative activities for enhanced routine immunisation strengthening

Gavi grant activity category	MOV and 2YL	PIRI	RED/REC	School screening
Service delivery	• Update supportive supervision checklists and other tools to include 2YL and MOV principles on screening and catch-up of missed vaccinations, recording/reporting of late doses, and monitoring MCV1-MCV2 dropout. **2YL:** Develop and disseminate 2YL guidelines (including promotion of screening and catch-up at all contacts). **MOV:** Update existing immunisation guidelines for MOV and disseminate (including promotion of screening and catch-up vaccination).	• Convene a technical working group and subcommittees to oversee detailed planning for PIRI. The technical working group should review subnational data to identify target populations that are perpetually underserved and establish the main parameters for the PIRI service delivery, including target age groups, vaccines and doses to be provided, geographic areas to be served, and service delivery strategies. • Plan for additional outreach or mobile sessions to provide immunisation plus other primary healthcare services as feasible to populations that are currently missed and which cannot be reached through fixed services. • Conduct microplanning considering the age groups to be vaccinated during the PIRI activity, the estimated numbers of unvaccinated or under-vaccinated children to be reached, and where they live.	• Support EPI (district) health management teams to identify immunisation opportunities for delivering additional PHC interventions. • Expand sessions (fixed, outreach, mobile) to reach targeted groups (e.g. urban, rural, pastoralist). • Arrange for the use of private sector facilities as outreach. • Develop systems to track children between visits (e.g. Tickler files) to reduce dropout. • Conduct community meetings and/or focus group discussions on demand generation and integration of services. • Convene policy-makers for discussion and alignment on policies for integrated delivery (e.g. school health and EPI). • Hold microplanning meetings at district level, particularly to address missed groups (e.g. urban slums). • Convene working group and/or meetings with relevant vaccine safety stakeholders.	• Convene working group and/or meetings from school and EPI to develop a country-tailored strategy for school immunisation screening. • Review data on school enrolment rates to identify potential geographic areas of focus. • Procure home-based records. • Conduct microplanning to include school screening and/or delivery of vaccines. • Pilot school screening programme in targeted district(s) or nationwide as appropriate. • Develop and distribute guidelines for school staff and health workers on vaccinating school-aged children.

Beyond SIA: illustrative activities for enhanced routine immunisation strengthening (continued)

Gavi grant activity category	MOV and 2YL	PIRI	RED/REC	School screening
Capacity building of human resources	• Support countries to develop a national continuous professional learning approach or integrated plan for in-service training and modules to complement/update pre-service training. • Develop and produce training materials (including e-material) for screening and eligibility criteria of both EPI and non-EPI staff. • Develop, field test and distribute (also in e-versions) job aids. • Training of trainers, with emphasis on those who can train others. • Identify training institutions able – or enable suitable institutions – to provide training (health training college, nursing schools, etc) for the long term. • Adapt/use existing innovative adult learning approaches and tools (e.g. web-based immunisation academy). • Assess HR/staffing to support implementation, change job description/ term of reference for existing positions to include 2YL/MOV work.	• Develop competency-based training, clearly identifying the parameters of the activity (i.e. objectives, location, timing and duration, activities, monitoring and evaluation aspects). Include screening, recording and reporting of doses to be administered. • Develop a schedule for training, including both training of trainers and training of all service delivery providers. Identify and budget for training, including materials needed during training. • Develop a schedule for supportive supervision visits during PIRI activities (designate supervisors for the PIRI activities and develop a supervision checklist).	• Develop and conduct supervisor trainings for integrated delivery. • Develop and distribute integrated supervisory checklists. • Develop and implement remote systems for supportive supervision. • Conduct trainings on interpersonal communication. • Explore capacity building innovations such as adult learning. • Identify training institutions able – or enable suitable institutions – to provide training (health training college, nursing schools, etc) for the long term.	• Train HCWs to communicate with parents about school screening and importance of home-based record retention. • Conduct workshops for school staff and proprietors to educate them about vaccinations and school screening procedures.
Procurement and supply chain management	• Update vaccine forecasting and order additional vaccines accordingly. • Calculate and order commodities for integrated interventions. • Assess and meet additional cold chain space requirements, if needed.	• Develop a detailed schedule and budget for distribution of vaccines and other commodities.	• Assess and procure devices for waste disposal and cold chain. • Calculate and order commodities for integrated interventions.	• Procure additional cold boxes as needed (if vaccines are to be transported to school).

Beyond SIA: illustrative activities for enhanced routine immunisation strengthening (continued)

Gavi grant activity category	MOV and 2YL	PIRI	RED/REC	School screening
Health information systems	• Modify information system and tools (including home-based records and registers) to reflect catch-up vaccination. • Field test and validate new tools. • Procure and distribute updated home-based records and registers. • Conduct health facility assessment.	• Develop and distribute tally sheets and registers to all service delivery points. • During training and supervision, include skills practice on screening, recording of doses given during PIRI and how to capture these doses in monthly summary reports to the health management information system. Training should include specific guidance on actions to take when children lack home-based records indicating their vaccination status. • Conduct evaluation on the extent to which the target populations were reached by PIRI service delivery activities.	• Revise/distribute tally sheets, registers and cards. • Pilot and assess electronic immunisation registries in urban areas. • Develop and implement monitoring systems for integrated service delivery. • Develop processes and tools to improve data monitoring and reporting (visual dashboards, charts, etc). • Conduct private sector assessment on quality of services and contribution to coverage. • Procure and distribute AEFI reporting forms. • Conduct equity analysis. • Conduct root cause analysis.	• Determine how to record and report doses given at older ages. Develop and procure necessary data collection and child tracking tools, e.g. school registers. • Field test and validate.
Advocacy, communication, and social mobilisation	• Develop, field test, order and disseminate communication materials. • Advocacy, sensitisation of professional societies, private practitioners, etc. • Pilot and finalise communication and social mobilisation messages. • Develop and distribute social mobilisation materials. **2YL:** Prepare for launching ceremony.	• Establish or convene a working group for advocacy, communication, and social mobilisation to address PIRI. The group should articulate the communication objectives for PIRI in a way that reinforces routine immunisation. • Develop a plan of action and budget that includes the development and testing of key messages on the importance of routine immunisation and where and when it is provided. • Conduct meetings with community leaders so they can convey the importance of routine immunisation and features of the PIRI activity, if it has a service delivery component.	• Create and pilot health messages to address demand (e.g. through use of TV/ radio, posters or other media). • Explore innovative methods of communication and demand generation such as SMS messaging reminders to caregivers. • Engage community health workers. • Conduct urban needs assessment to identify barriers to seeking care in urban areas and slums. • Conduct social mobilisation activities to generate demand for vaccination in areas with poor uptake of services (e.g. urban areas and slums). • Conduct stakeholder meetings with private providers.	• Conduct focus group discussions with parents to develop key messages around school immunisation screening and/or delivery. • Procure materials to educate parents and school staff about school immunisation/ screening programme. • Conduct social mobilisation activities to communicate school vaccination and/or screening activities with parents. • Inform, obtain and document parent consent for children to be vaccinated.

Beyond SIA: illustrative activities for enhanced routine immunisation strengthening (continued)

Gavi grant activity category	MOV and 2YL	PIRI	RED/REC	School screening
Legal, policy and regulatory environments	• Review and revise existing laws and develop policies on MOV or relating to vaccination in the 2YL. • To place emphasis on country leadership to reduce MOV, create MOV strategy team at the national or subnational level. • Consider transition to use of M/MR in five-dose vials for routine – especially in rural areas and settings with small session sizes. **2YL**: Develop and disseminate 2YL guidelines (including promotion of screening and catch-up at all contacts).	• Review existing policies and guidelines and remove any barriers to vaccinating children over the age of one year that would impede the provision of routine doses of vaccine to children over one year of age. • Develop and distribute operational guidelines for PIRI service delivery activities.	• Review and revise catch-up vaccination and multiple injection policies. • Review and revise laws for protection of health workers in case of AEFI. • Review and revise policies for school immunisation screening.	• Review and revise policies for school immunisation screening. • Clarify catch-up vaccination and multiple injections policies as well as eligibility of school-aged children. • Create the enabling legal environment for school programmes. This may include enforcing existing laws or informing new laws on mandatory/ recommended vaccination. • Set a transparent process to inform, obtain and document the parent's consent.