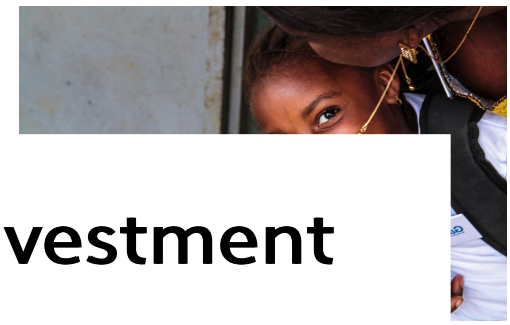

Vaccine investment strategy

Gavi's vaccine investment strategy determines which vaccines are made available to countries through our vaccine support programmes

This page will be updated in the first quarter of 2023 to reflect the Vaccine Investment Strategy (VIS) 2024. For more information in the meantime, please scroll down to "Related downloads" or contact the VIS team: VIS@gavi.org.

Every five years, Gavi takes stock of available and expected vaccines to develop a new vaccine investment strategy (VIS). The VIS sets new priorities for our vaccine support programmes in a transparent manner through in-depth, evidence-based analysis and extensive consultations. The rationale for using five-year cycles is to provide predictability to our decision-making process.

The Alliance recently developed a new VIS for the 2021–2025 strategic period ("VIS 2018"). The assessment and evaluation of vaccine candidates were completed in three distinct phases.

Phase one prepared the ground for the VIS by developing a decision-making process and analytical plan, identifying and categorising vaccine candidates, and setting out a first set of evaluation criteria.

Phase two shortlisted vaccine candidates for use in routine immunisation programmes, set criteria for evaluating vaccine investments in epidemic preparedness and response, and identified an approach for inactivated polio vaccine (IPV) support beyond 2020.

Phase three: in the final phase, recommendations for new vaccine investments were developed and presented at the Gavi Board meeting in November 2018.

VACCINE CANDIDATES

In April 2017, WHO conducted a landscape analysis, which identified candidate vaccines for consideration in VIS 2018. The inclusion criteria included public health relevance to low- and middle-income countries and expected licensure by 2023. The latter was used to ensure that the vaccines would likely be available during the next strategic period.

The vaccines considered in VIS 2018 fit into one of the following three categories:

vaccine investments for endemic disease prevention through planned, preventive immunisation;

vaccine investments for epidemic preparedness and response; and

IPV support post-2020, as a global public good.

	Vaccines/products linked to current investment	New vaccine/product
Endemic disease prevention	Diptheria, tetanus & pertussis containing boosters Hepatitis B (birth dose) Cholera (preventive immunisation) Meningococcal (multivalent conjugate) Rabies Malaria*	Hepatitis A Dengue Influenza (maternal) Respiratory syncytial virus maternal vaccine and monoclonal antibody
Epidemic disease preparedness and response		Pandemic influenza (initial in-depth briefing)
Polio eradication	IPV (post-2020)	

**Malaria was not subject to investment decisions in VIS 2018 as the malaria vaccine implementation programme is still ongoing, but was treated as a comparator.*

EVALUATION OF VACCINES FOR ENDEMIC DISEASE PREVENTION

Phase one

In November 2017, the Gavi Board approved a set of criteria to be used for evaluating vaccines for endemic disease prevention.

EVALUATION CRITERIA FOR VACCINES FOR ENDEMIC DISEASE PREVENTION THROUGH PLANNED, PREVENTIVE IMMUNISATION

	Criteria	Indicators
Ranking criteria:	**Health impact**	Total future deaths averted in the 2020-2035 period, and per 100,000 vaccinated Total future cases averted in the 2020-2035 period, and per 100,000 vaccinated
	Value for money	Vaccine procurement cost per death averted Vaccine procurement cost per case averted
	Equity and social protection impact	Disproportionate impact of disease on vulnerable groups Special benefits of vaccination for women and girls
	Economic impact	Direct medical costs averted Indirect costs averted

	Global health security impact	Epidemic potential of disease Impact of vaccination on antimicrobial resistance (AMR)
Secondary criteria:	**Other impact**	Total under-five deaths averted in the 2020-2035 period, and per 100,000 vaccinated Total DALYs averted in the 2020-2035 period, and per 100,000 vaccinated Vaccine procurement cost per disability-adjusted life year (DALY) averted
	Gavi comparative advantage	Degree of vaccine market challenges Potential for Gavi support to catalyse additional investment
	Implementation feasibility	Ease of supply chain integration Need for healthcare worker behaviour change Feasibility of vaccination time point Acceptability in target population Long-term financial implications
	Alternative interventions	Optimal use of current and future alternative interventions (prevention and treatment)
	Broader health system benefits	*No specific indicator – evaluated on a case-by-case basis*
Financial implications:	**Vaccine cost**	Total procurement cost to Gavi and countries, 2020-2035
	Operational cost	Incremental in-country operational costs per vaccinated person
	Additional implementation costs	Additional costs for introduction

Data sources used in the evaluation included consultations with in-country stakeholders, peer-reviewed literature, expert and partner input, health impact modelling and analytics developed for the VIS process.

Phase two

Based on the analysis of each vaccine against the criteria included in the Board-approved evaluation framework, in June 2018, the Gavi Board shortlisted six vaccine candidates for endemic disease prevention for further consideration and investment case development:

- multivalent meningococcal conjugate vaccine;
- hepatitis B birth dose;
- oral cholera vaccine for planned, preventive immunisation;
- diphtheria-, tetanus- and pertussis- (D,T&P)-containing boosters;
- respiratory syncytial virus (RSV) immunisation products; and

rabies post-exposure prophylaxis.

At this time the Board also deprioritised dengue, hepatitis A and maternal influenza vaccines. More information on the rationale for shortlisting and deprioritisation can be found in the June 2018 report to the Gavi Board.

For the six shortlisted candidates, Gavi undertook further in-depth analyses including extensive consultations with country stakeholders and vaccine and disease experts, as well as financial analyses to inform investment recommendations. Detailed investment cases for each of the six vaccines can be downloaded below.

Phase three

In November 2018, the Gavi Board reviewed the final investment cases and decided to extend support for oral cholera vaccine to 2020, as well as to support a learning agenda for cholera in the 2019–2020 period.

In addition, the Board decided that, subject to availability of funding for the 2021–2025 strategic period and alignment with the final parameters of Gavi's next strategy, from 2021 Gavi would:

make available support for D, T & P-containing booster vaccines, hepatitis B birth dose and human rabies vaccines for post-exposure prophylaxis;

expand the existing meningococcal programme support to include multivalent (ACW-containing) conjugate vaccines, subject to availability of a licensed product, WHO prequalification and SAGE recommendation;

expand support for the oral cholera vaccine programme to include planned, preventive immunisation;

support a learning agenda for D, T & P-containing booster vaccines, hepatitis B birth dose, human rabies vaccines for post-exposure prophylaxis and multivalent meningococcal conjugate vaccines, to commence in 2019; and

support RSV immunisation products contingent on availability of a licensed product, WHO prequalification and SAGE recommendation, and support pre-introduction activities (including demand generation).

Further details on the specific support that was conditionally approved are available in the November 2018 report to the Board.

EVALUATION OF VACCINES FOR EPIDEMIC PREPAREDNESS AND RESPONSE

In June 2018, the Gavi Board approved an approach and set of evaluation criteria for vaccines for epidemic preparedness and response. This builds on the approach for evaluating vaccines for endemic disease prevention but also includes criteria that are unique to epidemic risk reduction.

Recognising that many diseases may be categorised as having both epidemic and endemic characteristics, assessment against one or the other framework will be determined by the public health goal and the type of investment (ie planned preventive immunisation, such as routine immunisation, versus a stockpile or similar intervention). More information can be found in the June 2018 report to the Gavi Board.

The framework for epidemic preparedness and response is intended to structure the assessment and decision-making process around four critical questions.

Disease risk and burden: is the epidemic potential of the disease sufficient to prioritise a stockpile or similar investment?

Vaccine impact and feasibility: would the vaccine be feasible to use and impactful as part of epidemic preparedness and response?

Fit for Gavi and partners: what is Gavi's comparative advantage and how can Gavi's expertise contribute to the funding and delivery of this vaccine?

Financial implications: what is the appropriate scale of the stockpile (or related intervention)

and what would be the financial implications of an investment?

EVALUATION CRITERIA FOR VACCINES FOR EPIDEMIC PREPAREDNESS AND RESPONSE

	Criteria	Indicators
Disease risk & burden	**Epidemic potential of disease**	Transmission route
		Reproductive rate (R0) and generation time
		Timing of symptoms and infectivity
		Disease transmissibility and human transmission
		Human/animal interface
		Global risk
		Frequency of outbreaks
	Endemic potential	Risk of the disease becoming endemic
	Disease burden	Total cases/year
		Total deaths/year
		Case-fatality rate or severity of disease
		Cases of long-term disability
	Disease impact on equity, society and economy	Disproportionate burden of disease in vulnerable groups
		Special benefits of vaccination for women and girls
		Health system impact – healthcare workers and services
		Social disruption – impact on vital services Economic impact – cost of epidemics (direct & indirect)
	Additional factors to be considered in disease risk and burden scenarios include: evolutionary potential of the pathogen, vector burden, impact of climate change and demographic changes.	
Vaccine impact and feasibility	**Epidemic risk reduction/ mitigation**	Efficacy of vaccine
		Time to immunity
		Indirect effects (herd protection/transmission blocking)

	Implementation feasibility	Ease of storage
		Dosing schedule
		Acceptability in the target population
		Considerations relating to timely delivery and use (composition of stockpile and factors influencing timely case detection and verification, including surveillance and the availability of rapid, effective diagnostics)
	Long-term benefit	Cross-strain protection
		Duration of protection
	Stockpile attributes	Availability of medical countermeasures/alternative interventions
		Stockpile turnover and value
Fit for Gavi & partners	**Gavi comparative advantage**	Burden in Gavi-supported countries as a proportion of global burden
		Need for Gavi financing and market shaping
		Complementarity with other initiatives
Financial implications	**Vaccine stockpile cost**	Annual cost of global stockpile
	Operational cost	Incremental in-country operational costs per outbreak response

Gavi works with WHO to identify candidate vaccines to be considered for Gavi support on an ongoing basis. Once preliminary safety and immunogenicity data is available for a candidate vaccine (usually in phase 2a/b), a "living assessment" is developed. This includes preliminary information on disease risk and burden, vaccine impact and feasibility, and determines whether Gavi's engagement has a comparative advantage.

A full investment case for decision by the Gavi Board is triggered by one of the following: a defined pathway to licensure, an updated WHO recommendation or an urgent public health need (eg disease epidemic). Recommendations on investment could be taken to the Board for decision as part of the VIS or as standalone investment cases.

Pandemic influenza preparedness

Based on the approach approved in June 2018, pandemic influenza met the trigger criteria for an investment case. In response to a Board request, Gavi worked with WHO to develop a gap analysis and detailed briefing on pandemic influenza preparedness, including an assessment of potential vaccine supply and demand interventions.

In November 2018, the Board approved the development of a "learning agenda" for pandemic influenza. The aim is to assess the feasibility and impact of immunising healthcare workers with

seasonal influenza vaccine to support epidemic and pandemic influenza preparedness.

Further details on the assessment and approved learning agenda are available in the November 2018 report to the Board.

EVALUATION OF IPV SUPPORT POST–2020

Gavi's investment in IPV beyond 2020 was also considered as part of VIS 2018. However, VIS evaluation criteria, such as lives saved and value for money, do not adequately capture the unique role of IPV in preventing the re-emergence of poliovirus. As a result, Gavi has conducted a tailored assessment and consultation process for IPV support beyond 2020.

Our engagement in IPV post-2020 is guided by three main principles.

> Polio eradication constitutes a global public good. IPV is the global "insurance policy" to mitigate the risk of poliovirus re-emergence after global certification.
>
> Gavi support should be aligned with SAGE recommendations.
>
> The level and duration of Gavi support should balance the risk of IPV programme discontinuation with the principles of country ownership.

An investment case was brought to the Gavi Board in November 2018. Due to the importance of supporting the polio eradication initiative, the Board signalled its approval of support for IPV post-2020, subject to alignment with the final parameter setting for Gavi's 2021-2025 strategy and sufficient funds being available following Gavi's next replenishment. The Board emphasised that this investment must be additional to other Gavi investments, while recognising the full programmatic integration of IPV into Gavi's immunisation approach. The Board also stressed the importance of close collaboration between Gavi, the Global Polio Eradication Initiative (GPEI) and polio partners and requested GPEI to include IPV costs within its 2019-2023 programmatic strategy.

In addition, the Board approved in-principle support for IPV-containing whole-cell pertussis hexavalent vaccine (containing antigens against diphtheria, tetanus, pertussis, hepatitis B, *Haemophilus influenza*e type b and IPV). This will be contingent on the availability of a licensed product, WHO prequalification, SAGE recommendation and positive market attributes (including maintaining healthy vaccine markets).

Further details on the specific support approved can be found in the November 2018 report to the Board.

The next VIS will be developed in 2023, while consideration of vaccines for epidemic preparedness and response will be ongoing. VIS 2018 has identified some questions and gaps in the process of assessing the value of the candidate vaccines. The Gavi Secretariat will work to convey these to the research community ahead of the next VIS process.

For further information about the VIS process, please contact VIS@gavi.org.

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Vaccine investment strategy 2013

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