

Gavi-supported rotavirus vaccines profiles to support country decision making

Pneumococcal and Rotavirus Working Group
Gavi Secretariat and partners, February 2024

This resource is complementary to Gavi's **Detailed Product Profiles (DPPs) for WHO prequalified vaccines**
<https://www.gavi.org/our-alliance/market-shaping/product-information-vaccines-cold-chain-equipment>

The primary objective of the Detailed Product Profiles (DPPs) is to provide countries with easy access to up-to-date and comprehensive information on Gavi-supported vaccines. Countries are encouraged to consider factors beyond procurement cost and impact on country co-financing requirements: the DPPs include information on vaccine presentations, pricing, indicative wastage rates, manufacturers, cold chain volume and handling. This information will help countries decide which vaccine presentation is the best 'fit' for inclusion in their immunisation programme. Selecting a vaccine that is the most programmatically favorable for a specific country's context contributes to the sustainability of an immunisation programme. The DPPs are referenced in the 2019 New Vaccine Support guidelines and available on the Gavi website.

The secondary objective of the DPPs is to provide an overview of all vaccine products that are either WHO prequalified (WHO PQ) or in review for WHO prequalification. The format of the DPPs was created specifically to allow countries to compare WHO PQ vaccine products, fully informing them of their options.

Information contained in the DPPs comes from a variety of sources including the Gavi Secretariat, WHO PQ vaccine webpages, WHO position papers and UNICEF's product menu for vaccines supplied by UNICEF for Gavi-supported programmes. The Gavi Secretariat will ensure the information in the DPPs is kept up-to-date as new products become WHO pre-qualified and are available to receive Gavi-support. The DPPs will be updated on a fixed schedule (approximately every 6 months) or with more frequency if required.

THE INFORMATION CONTAINED IN THESE SLIDES AND THE DPPs IS CURRENT AS OF FEBRUARY 2024.

Please send comments or questions dpp@gavi.org

Additional resources relevant for assessing vaccines and presentations:

- **Guidelines on Reporting and Renewal of Gavi support:**
<https://www.gavi.org/support/process/apply/report-renew/>
- **WHO position paper** <https://www.who.int/immunization/documents/positionpapers/en>

Definitions

2024 price per dose (USD)	Price in USD per individual vaccine dose based on available data. This price is an indicative vaccine price prepared by the Gavi Secretariat to be used by countries for planning purposes. Price exclusively covers the vaccine dose and does not cover associated expenses including but not limited to freight, cold-chain costs, administrative costs and wastage. In cases in which there are multiple suppliers of the same presentation of the vaccine, or when there is a range of prices offered by the same supplier of the vaccine, a weighted average price (WAP) is utilised.
2024 price per fully immunised person (USD)	The price per dose (USD) is multiplied by the total number of doses required for a completed vaccine schedule, according to the WHO recommended vaccine schedules (WHO position papers)
2024 wastage adjusted price per fully immunised person (USD)	Price per fully immunized person (USD) adjusted to account for vaccine wastage. The price adjustment factors in the projected cost of wasted vaccine for each administered dose. The wastage rate utilized in the calculation is <u>indicative</u> , but it will be applied to the 1 st year of shipment for rotavirus vaccines. It can be replaced by the country specific actual wastage rate or estimate in the following year. This value should not be used for planning purposes without considering the coverage rate, as this would overestimate needs.
Cold chain volume per fully immunised person (cm³)	The cold chain volume is multiplied by the total number of doses required for a completed vaccine schedule, according to the WHO recommended vaccine schedules (WHO position papers)
Wastage adjusted cold chain volume per fully immunised person (cm³)	The cold chain volume per fully immunized person is adjusted to account for vaccine wastage.

Select criteria to assess rotavirus vaccines

(relevance of criteria may vary by country)

1. Availability

- a. WHO prequalified rotavirus vaccines supported by Gavi

2. Efficacy, safety, and interchangeability

3. Cost (direct)

- a. Waste-adjusted price per dose / per fully immunised child
- b. Sustainability (long term agreements on price and availability)
- c. Vaccine Cost Calculator
- d. Cost-effectiveness

4. Storage and transport

- a. Cold chain requirements and implications

5. Programmatic administration considerations

Rotavirus vaccines supported by Gavi, either WHO prequalified, or expected to be prequalified

Type	Rotavirus (oral, live attenuated)											
Manufacturer	GSK		Bharat Biotech				Serum Institute of India Pvt Ltd					
Trade name	Rotarix ¹		Rotavac		Rotavac 5D		Rotasiil		Rotasiil - Liquid		Rotasiil Thermo	
NRA	Belgium		India				India					
Form	Liquid		Liquid (frozen)		Liquid		Lyophilised		Liquid		Lyophilised	
Presentation	Plastic tube	Strip of 5 single tubes	Vial	Vial	Vial	Vial	Two vial set	Two vial set	Strip of 5 single tubes	Vial	Two vial set	Two vial set
VVM Type	7	7	2	2	7	7	30	30	7	7	250+	250+
Doses in each presentation unit	1	1	5	10	1	5	1	2	1	2	1	2
WHO PQ decision	2009	2019	2018		2021		2018		2021	2021	2020	

¹The presentations of Rotarix in plastic tube or in a strip of 5 single tubes are considered similar.

A switch from Rotarix in plastic tube to Rotarix in a strip of 5 single tubes and vice versa will not receive a switch grant.

Sources: <https://extranet.who.int/pqweb/vaccines/prequalified-vaccines>

Availability of rotavirus vaccines supported by Gavi












Trade name	Presentation*	Availability for Gavi countries
		2024
Rotarix ¹	RV1, 1 dose/plastic tube, liquid	Limited supply in H1 2024 Available with planning in H2 2024
	RV1, 1 dose/plastic tube, liquid (multi-monodose presentation with 5 single tubes connected by a bar)	Expected to be available with limited supply (<i>starting end of 2024</i>)
Rotavac	RV1, 5 doses/vial, frozen	Available with planning
	RV1, 10 doses/vial, frozen	
Rotavac 5D	RV1, 1 dose/vial, liquid	Not available
	RV1, 5 doses/vial, liquid	Expected to be available with planning (<i>starting end of 2024 at best</i>)
Rotasiil	RV5, 1 dose/vial, lyophilised	Available with planning
	RV5, 2 doses/vial, lyophilised	
Rotasiil-Liquid	RV5, 1 dose/plastic tube, liquid (strip of 5 tubes)	Not available
	RV5, 2 doses/vial, liquid	Available with planning
Rotasiil Thermo	RV5, 1 dose/vial, lyophilised	Available with planning
	RV5, 2 doses/vial, lyophilised	

¹The presentations of Rotarix in plastic tube or in a strip of 5 single tubes are considered similar.
A switch from Rotarix in plastic tube to Rotarix in a strip of 5 single tubes and vice versa will not receive a switch grant.

*abbreviated description. For full description, please refer to the [Detailed Product Profiles](#)

WHO Prequalified Rotavirus vaccines supported by Gavi

As of February 2024

Trade name	Rotarix		Rotavac		Rotavac 5D		Rotasiil		Rotasiil-Liquid		Rotasiil Thermo	
Presentation*	Plastic tube	Strip of 5 single tubes	Vial	Vial	Vial	Vial	Two vial set	Two vial set	Strip of 5 single tubes	Vial	Two vial set	Two vial set
Form	Liquid	Liquid	Liquid (frozen)	Liquid (frozen)	Liquid	Liquid	Lyophilised	Lyophilised	Liquid	Liquid	Lyophilised	Lyophilised
Doses in each unit	1	1	5	10	1	5	1	2	1	2	1	2
Picture										Picture not available for the time being		



- Rotarix presentation in a strip of 5 single tubes is expected to be available again with limited supply starting end of 2024. It will gradually replace the plastic tube presentation which will be phased out by 2026.
- Rotavac 5D in 5-dose vials is expected to be available starting end of 2024 at best. Rotavac 5D in 1-dose vials will not be available in 2024.
- Rotasiil presentation in a strip of 5 single tubes will not be available in 2024.

For size comparison


(the picture below shows 6 out of 12 presentations* and will be updated as more samples will be received by Gavi)



*abbreviated description. For full description, please refer to the [Detailed Product Profiles](#)

Vaccine efficacy, safety, and interchangeability

Summary of Key Characteristics of WHO Prequalified Rotavirus Vaccines*

Characteristics		<i>Rotarix™ (GSK)</i>	 <i>Rotateq™ (Merck)</i>	<i>Rotavac™ (Bharat)</i>	<i>Rotasiil™ (Serum Institute)</i>
Efficacy for severe rotavirus gastroenteritis, at 2 years follow-up, ** by child mortality rate stratum of country of study site ¹	Low Mortality	90% (95% CI, 86-93%)	94% (95% CI, 61-99%)	No data available	No data available
	Medium Mortality	78% (95% CI, 70-83%)	81% (95% CI, 66-89%)	No data available	No data available
	High Mortality	54% (95% CI, 9-77%)	44% (95% CI, 23-59%)	54% (95% CI, 40-65%)	44% (95% CI, 26-58%)
	Study sites	Multiple countries at different income and mortality levels.		3 sites in India	6 sites in India; 1 center, multiple sites in Niger
Date of WHO prequalification		March 2009	October 2008	January 2018	September 2018
Safety		<ul style="list-style-type: none"> WHO has concluded that the prequalified rotavirus vaccines (RVVs) are safe and should be among the vaccine options to prevent severe rotavirus gastroenteritis globally.^{1,2,3,4} Continued monitoring of the risk for intussusception is recommended.^{3,4} 			
Mixed schedules & interchangeability of products ⁴		<ul style="list-style-type: none"> If the product used for a prior dose is unavailable or unknown, the series should be completed with any available licensed product. Restarting the vaccine series is not recommended. For a mixed series or a series with any unknown vaccine products, a total of 3 doses of rotavirus vaccine should be administered for a complete vaccination series. The published safety and efficacy/immunogenicity data on mixed schedules or interchangeability are reassuring for all products;^{5, 6, 7} 			

** One year follow-up efficacy estimates for severe rotavirus gastroenteritis diarrhea were reported in the 2020 Cochrane review and are similar to those for 2 year follow-up.

References:

- ¹ Systematic review and meta-analysis of the safety, effectiveness and efficacy of childhood schedules using Rotavirus Vaccines – Cochrane Response. October 2020 SAGE Meeting, Rotavirus Vaccines – Session 6. Background documents (https://www.who.int/immunization/sage/meetings/2020/october/SAGE_eYB_Oct2020final.pdf?ua=1; SAGE Meeting slide deck. Rotavirus Vaccines - Session 6. October 2020 (https://www.who.int/immunization/sage/meetings/2020/october/SAGE_Slidedeck_Oct2020-Web.pdf?ua=1).
- ² Report of the WHO Global Advisory Committee on Vaccine Safety, 6-7 December 2017. (<http://apps.who.int/iris/bitstream/handle/10665/259874/WER9303.pdf?sequence=1>).
- ³ Report of the WHO Global Advisory Committee on Vaccine Safety, 4-5 December 2019. (<https://apps.who.int/iris/bitstream/handle/10665/330607/WER9504-eng-fre.pdf?ua=1>).
- ⁴ Rotavirus vaccines: WHO position paper, July 2021 (<https://www.who.int/publications/i/item/weekly-epidemiological-record-vol.-28-2021-96-301-320>).
- ⁵ Libster R, McNeal M, Walter EB, Shane AL, Winokur P, Cress G, et al. Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules. *Pediatrics*. 2016 Feb;137(2).
- ⁶ Payne DC, Sulemana I, Parashar UD, for the New Vaccine Surveillance Network. Evaluation of Effectiveness of Mixed Rotavirus Vaccine Course for Rotavirus Gastroenteritis. *JAMA Pediatrics*. 2016;170(7):708-710.
- ⁷ Kanungo S, Chatterjee P, Bavdekar A, Murhekar M, Babji S, Garg R, et al. Safety and immunogenicity of the Rotavac and Rotasiil rotavirus vaccines administered in an interchangeable dosing schedule among healthy Indian infants: a multicentre, open-label, randomised, controlled, phase 4, non-inferiority trial. *Lancet Infect Dis*. 2022 May 16:S1473-3099(22)00161-X.

* For the rotavirus vaccines discussed in this document, the following disclaimer applies: WHO does not approve or endorse the use of specific branded products over others; this publication may not be used for any commercial or promotional purposes.

June 13, 2022

 RotaTeq™ (Merck) is not available to Gavi-supported countries anymore

Update on Rotavirus vaccines by Strategic Advisory Group of Experts (SAGE) on Immunization – October 2020

- SAGE recommended **all four live oral rotavirus vaccines** (Rotarix™, RotaTeq™, Rotavac™, and Rotasiil™) for use.
- SAGE re-affirmed 2013 recommendations that rotavirus vaccines should be **included in all national immunization programs and be considered a priority**, particularly in countries with high rotavirus gastroenteritis-associated fatality rates, that use of rotavirus vaccines should be part of a comprehensive strategy to control diarrheal diseases, and that **first dose of rotavirus vaccine should be administered as soon as possible after 6 weeks of age**.
- SAGE noted that the considerable rotavirus disease burden during the second year of life **supports catch-up vaccination for children not vaccinated on time**, particularly in high-mortality and crisis contexts, including recent disruptions to immunization services related to the COVID-19 pandemic. Because of the typical age distribution of rotavirus gastroenteritis, **rotavirus vaccination of children >24 months of age is not recommended**.

➡ Based on SAGE's recommendations, WHO updated its Rotavirus Position Paper in 2021. <https://www.who.int/publications/i/item/weekly-epidemiological-record-vol.-28-2021-96-301-320>

Vaccine cost (direct)

The cost estimated below includes the cost of devices. The cost of presentations not available in 2024 is not shown in this table.

The country specific waste-adjusted cost will vary depending on the country's own wastage rate for each presentation.

To estimate your country's wastage rate please use the new [WHO Vaccines Wastage Rates Calculator](#)

Trade name	Rotarix		Rotavac		Rotavac 5D		Rotasiil		Rotasiil-Liquid		Rotasiil Thermo	
Form	Liquid		Liquid (frozen)		Liquid		Lyophilised		Liquid	Liquid	Lyophilised	
Presentation	Plastic tube	Strip of 5 single tubes	Vial		Vial		Two vial set		Strip of 5 single tubes	Vial	Two vial set	
Doses in each unit	1		5	10	1	5	1	2	1	2	1	2
2024 price per dose (USD)	\$2.36* €2.05	\$2.06* €1.79	\$0.85	\$0.60	n/a	\$1.15	\$1.55**	\$0.95	n/a	\$0.80	\$1.85**	\$1.25**
Doses per fully immunised person	2		3									
2024 price per fully immunised person (USD)	\$4.72	\$4.12	\$2.55	\$1.80	n/a	\$3.45	\$4.65	\$2.85	n/a	\$2.40	\$5.55	\$3.75
Indicative wastage rate	4%		5%	6%	4%	5%	4%	9%	4%	9%	4%	9%
2024 waste-adjusted price per fully immunized person (USD) ¹	\$4.91	\$4.29	\$2.68	\$1.91	n/a	\$3.63	\$4.84	\$3.13	n/a	\$2.64	\$5.78	\$4.12
Reference for WHO calculator WHO Vaccines Wastage Rates Calculator	Rota_liq		Rota_liq_frozen		Rota_liq		Rota_lyo		Rota_liq	Rota_lyo	Rota_lyo	Rota_lyo

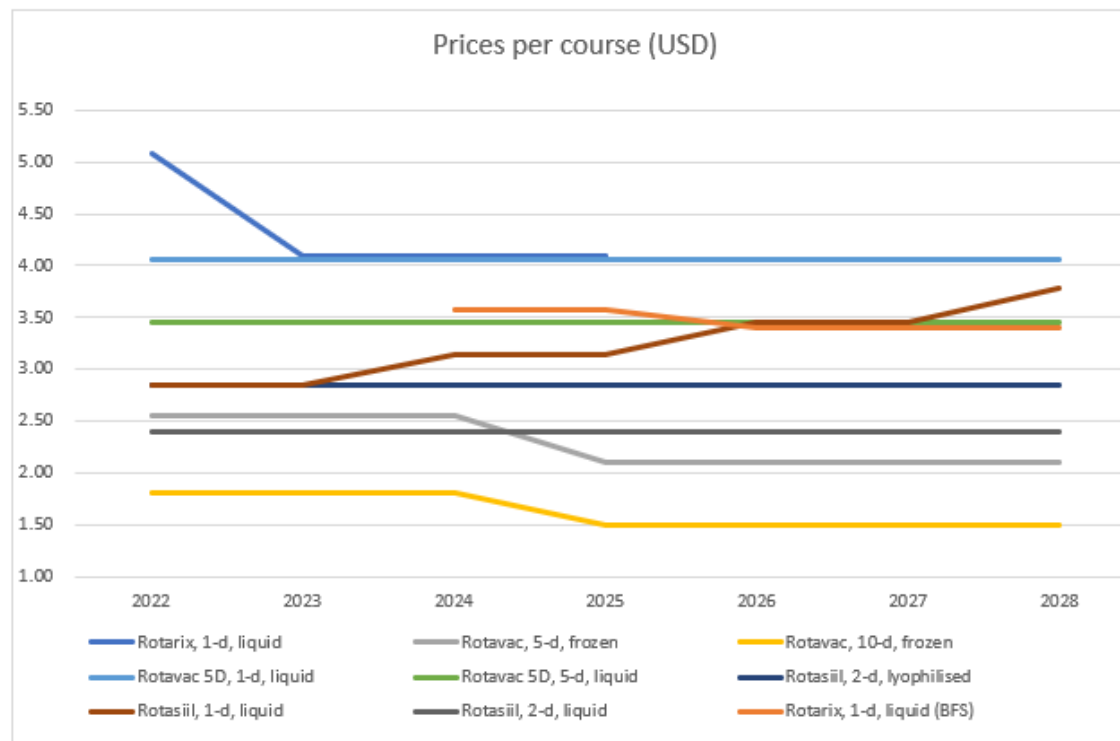
¹ Countries will pay a share of the vaccine price based on their eligibility and transition status. Initial self-financing countries only pay their share for 2 Rota doses even if they use a 3-dose product

*The price in US dollars reflects conversion at a currency exchange rate of 1.15USD/EUR, source: Bloomberg projected foreign exchange rates.

The actual exchange rate that will be utilised to calculate the USD price at the moment of the transaction may vary.

** Final price to be confirmed after signature of Long-Term Agreement between UNICEF SD and the manufacturers

Prices of awarded Rotavirus vaccines (per course)

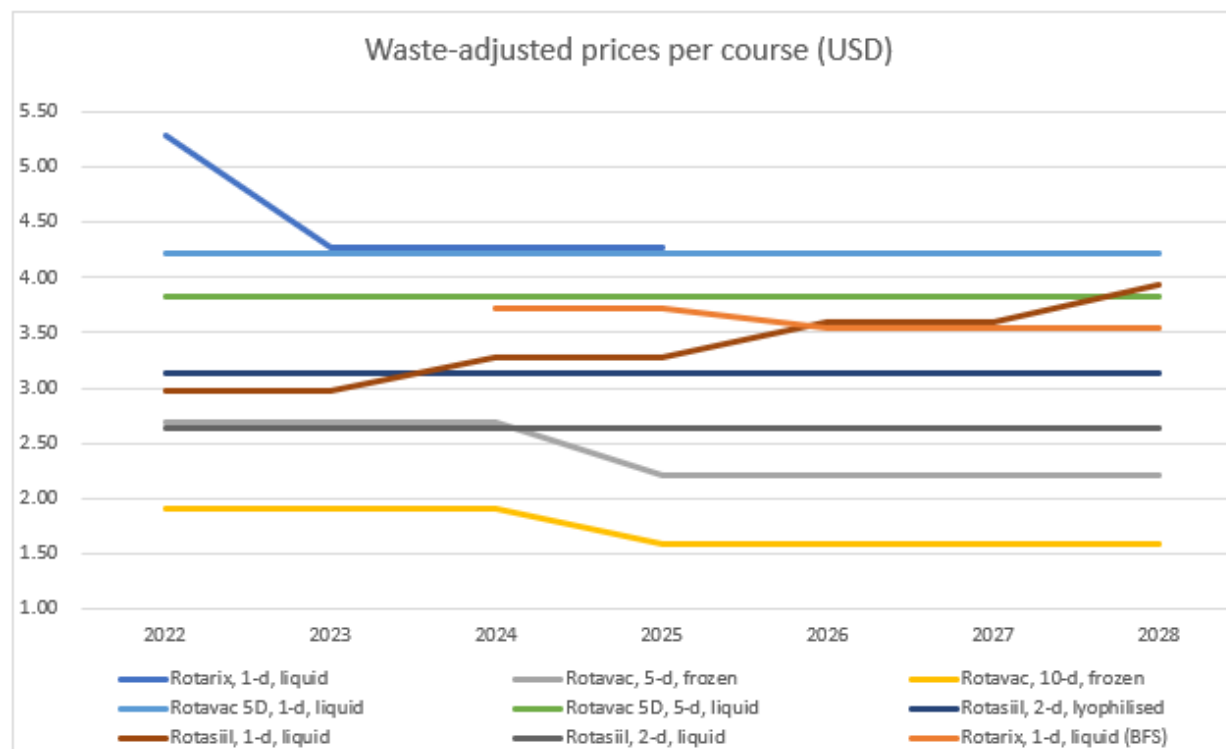


		2022	2023	2024	2025	2026	2027	2028
Rotarix, 1-d, liquid*	GSK	5.08	4.10	4.72	4.72			
Rotarix, 1-d, liquid (BFS)*	GSK			4.12	4.12	3.91	3.91	3.91
Rotavac, 5-d, frozen	Bharat	2.55	2.55	2.55	2.10	2.10	2.10	2.10
Rotavac, 10-d, frozen	Bharat	1.80	1.80	1.80	1.50	1.50	1.50	1.50
Rotavac 5D, 1-d, liquid	Bharat	4.05	4.05	4.05	4.05	4.05	4.05	4.05
Rotavac 5D, 5-d, liquid	Bharat	3.45	3.45	3.45	3.45	3.45	3.45	3.45
Rotasiil, 2-d, lyophilised	SII	2.85	2.85	2.85	2.85	2.85	2.85	2.85
Rotasiil, 1-d, liquid	SII	2.85	2.85	3.15	3.15	3.45	3.45	3.78
Rotasiil, 2-d, liquid	SII	2.40	2.40	2.40	2.40	2.40	2.40	2.40

(*): Prices of awarded Rotarix are in EUR, the price in US dollars reflects conversion at a currency exchange rate of 1.15USD/EUR starting 2024, 1.00 USD/EUR in 2023 and 1.24 USD/EUR in 2022. The actual exchange rate that will be utilised to calculate the USD price at the moment of the transaction may vary.

Source: UNICEF SD Rotavirus vaccine price data <https://www.unicef.org/supply/media/10276/file/Rota-vaccines-prices-18112021.pdf>

Waste-adjusted prices of awarded Rotavirus vaccines (per course)



		2022	2023	2024	2025	2026	2027	2028
Rotarix, 1-d, liquid*	GSK	5.30	4.27	4.91	4.91			
Rotarix, 1-d, liquid (BFS)*	GSK			4.29	4.29	4.07	4.07	4.07
Rotavac, 5-d, frozen	Bharat	2.68	2.68	2.68	2.21	2.21	2.21	2.21
Rotavac, 10-d, frozen	Bharat	1.91	1.91	1.91	1.60	1.60	1.60	1.60
Rotavac 5D, 1-d, liquid	Bharat	4.22	4.22	4.22	4.22	4.22	4.22	4.22
Rotavac 5D, 5-d, liquid	Bharat	3.63	3.63	3.63	3.63	3.63	3.63	3.63
Rotasiil, 2-d, lyophilised	SII	3.13	3.13	3.13	3.13	3.13	3.13	3.13
Rotasiil, 1-d, liquid	SII	2.97	2.97	3.28	3.28	3.59	3.59	3.94
Rotasiil, 2-d, liquid	SII	2.64	2.64	2.64	2.64	2.64	2.64	2.64

(*): Prices of awarded Rotarix are in EUR, the price in US dollars reflects conversion at a currency exchange rate of 1.15USD/EUR starting 2024, 1.00 USD/EUR in 2023 and 1.24 USD/EUR in 2022. The actual exchange rate that will be utilised to calculate the USD price at the moment of the transaction may vary.

Source: UNICEF SD Rotavirus vaccine price data <https://www.unicef.org/supply/media/10276/file/Rota-vaccines-prices-18112021.pdf>

Rota manufacturers' pricing commitments for transitioned countries


Manufacturer pricing commitments are 'public announcements' made during the 2015 Gavi replenishment, they are not legally binding.

This information is meant for the convenience and benefit of countries and should not give a false sense of assurance that Gavi is "guaranteeing" prices, and that prices are determined for every single product and country.

Vaccine	Manufacturer	Commitment Duration	Summary of commitment and conditions
Rotarix	GSK	10 years*	Country introduced with Gavi support** Country already using GSK product May procure through UNICEF/PAHO Price freeze (=price paid during last year of support)
Rotasiil	Serum Institute of India (SII)	-	No price commitment <ul style="list-style-type: none"> Price offered in current UNICEF tender applies to currently Gavi eligible, transitioning and transitioned countries that have already introduced Rotavirus vaccine, provided procurement takes place through UNICEF SD. <i>Excluded PAHO, fully self-financing countries that have not introduced RV, and three traditionally self-procuring countries - India, Vietnam & Indonesia</i>
Rotavac	Bharat Biotech	-	

* From date of transition to fully self-financing, where the country receives no Gavi support

** Gavi support = country and Gavi co-financing

 Middle-Income Countries that were never-Gavi eligible should contact UNICEF or refer to UNICEF vaccine price sheet <https://www.unicef.org/supply/media/10276/file/Rota-vaccines-prices-18112021.pdf> for more information about prices.

Vaccine Cost Calculators to inform decision-making

All immunization programs face the challenge of sustainability. Optimizing the costs of one vaccine program could potentially free up resources for another. Ensuring a careful comparison of costs before selecting the best vaccine option for introduction or switch is a critical factor in country decision-making.

PATH's Vaccine Cost Calculators are simple, Excel-based tools for assessing and comparing costs of certain vaccination programs over a period of 10 years with each vaccine product available in the global market. Users input a limited set of local data to compare products and estimate vaccination program costs, exploring up to six vaccine options at once.

Available to download:

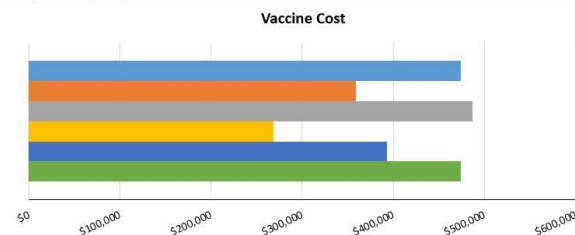
- Rotavirus Vaccine Cost Calculator in English, French, Russian, and Spanish
<https://www.path.org/resources/rotavirus-vaccine-cost-calculator/>
- Pneumococcal Conjugate Vaccine Cost Calculator in English, French, Russian, and Spanish
<https://www.path.org/resources/pneumococcal-conjugate-vaccine-cost-calculator/>
- Human Papillomavirus Vaccine Cost Calculator in English, French, and Spanish
<https://www.path.org/resources/hpv-vaccine-cost-calculator/>

For questions or support regarding the Vaccine Cost Calculators, contact PATH's Health Economics and Outcomes Research team: HEOR@path.org.

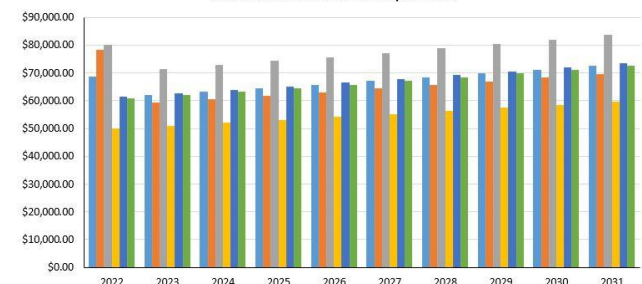
A user guide is included within each calculator with detailed instructions on how to use the tool and interpret the results, which are provided in both tables and charts (examples below).

Vaccination program cost Vaccine cost + incremental health system costs		Vaccination program cost Vaccine cost + incremental health system costs	
Total for 10 years	\$244,076	Total for 10 years	\$342,106
2022	\$29,560	2022	\$49,417
2023	\$21,991	2023	\$30,005
2024	\$22,431	2024	\$30,605
2025	\$22,880	2025	\$31,217
2026	\$23,337	2026	\$31,842
2027	\$23,804	2027	\$32,479
2028	\$24,280	2028	\$33,128
2029	\$24,766	2029	\$33,791
2030	\$25,261	2030	\$34,466
2031	\$25,766	2031	\$35,156

10-year summary results



Vaccination Program Cost
Vaccine cost + incremental health system costs



Rotavirus Vaccine Cost Calculator

A simple, Excel-based tool that generates cost information for rotavirus vaccine programs, comparing up to six different vaccine options at once. Available to download in English, French, Russian, and Spanish:


<https://www.path.org/resources/rotavirus-vaccine-cost-calculator/>

- Country-specific tool that requires minimal data entry
- Can be used by all countries—currently receiving Gavi support, in any transition phase, and non-Gavi countries
- Provides results on cost to country only and cost to country and Gavi (where applicable)
- Allows direct cost comparison of products and helps with identifying the least costly option
- Leverages up-to-date Gavi detailed product profiles data (tool last updated August 2022)

Rotavirus vaccine cost calculator

A simple tool to assess and compare costs of rotavirus vaccination programs with each rotavirus vaccine product available in the global market

Version 1.2 / 21 July 2020
For questions or support, contact PATH's Health Economics and Outcomes Research team: HEOR@path.org



The Rotavirus vaccine cost calculator is a tool that helps countries compare products and estimated vaccination program costs for different rotavirus vaccines, exploring up to six different vaccine options at a time. Costs are calculated annually and for a total period of 10 years. All boxes with a yellow background require user inputs. When available, default data are already entered, with the source of information indicated. Note that default data are for currently Gavi-eligible countries. Countries not eligible for Gavi support should confirm all data inputs individually. The tool generates projected costs based on the best currently available information for each vaccine. All cost data are in US\$, and use of local currency requires separate currency conversion before inputting values in relevant fields.

Please be sure to complete all inputs on this tab for the following three steps before going to the **Results** tab:

- Step 1: Immunization program
- Step 2: Co-financing and financial support
- Step 3: Rotavirus vaccine options

Disclaimer

*The Rotavirus vaccine cost calculator is a tool that aims to inform vaccine introduction decision-making and product selection. It is important to note that cost is only one consideration, and users involved in decision-making around new vaccine introduction or product selection should always consider other dimensions as well. This model is meant to provide insights into the **potential** costs of alternative product choices and should not replace detailed budget planning once a product has been selected.*

STEP 1: IMMUNIZATION PROGRAM

>>>>>>> START HERE >>>>>>>		
Start year	0	
Target population	0	children per year
Annual population growth rate	0%	%
Expected coverage dose 1	0%	annual coverage
Expected coverage dose 2	0%	annual coverage
Expected coverage dose 3	0%	annual coverage will only be used for

STEP 2: CO-FINANCING AND FINANCIAL SUPPORT

Gavi transition phase - please select the appropriate option in drop-down menu to the right	Initial self-financing phase	If you selected "Other transition phase", fill in the country co-financing share below
Country co-financing share		
0	0%	
1	0%	
2	0%	
3	0%	
4	0%	
5	0%	
6	0%	
7	0%	
8	0%	
9	0%	
Gavi Vaccine Introduction Grant (VIG) or Gavi Switch Grant (SG)	\$0	

Gavi support guidelines

Gavi Vaccine Introduction Grant (VIG) calculation

The VIG calculation depends on the country's Gavi transition phase:

Initial self-financing countries: \$0.80 per infant in the birth cohort* in year of introduction, or a lump sum of \$100,000, whichever is higher.

Preparatory transition phase countries: \$0.70 per infant in the birth cohort* in year of introduction, or a lump sum of \$100,000, whichever is higher.

Accelerated transition phase countries: \$0.60 per infant in the birth cohort* in year of introduction, or a lump sum of \$100,000, whichever is higher.

Gavi Switch Grant (SG) calculation

The SG calculation is the same for all countries and corresponds to up to \$0.25 per infant in the birth cohort.*

*Birth cohort = live births in the year of introduction

Vaccine cost-effectiveness (1/2)

- “Irrespective of the vaccine used, vaccination against rotavirus disease was found to be cost effective.” ([WHO position paper](#) on Rotavirus vaccines)
 - Background document on rotavirus epidemiology and rotavirus vaccines, including economic evidence for use and programmatic considerations for vaccine implementation. October 2020 SAGE Meeting, Rotavirus Vaccines – Session 6. Background documents; https://www.who.int/immunization/sage/meetings/2020/october/SAGE_eYB_Oct2020final.pdf?ua=1,
- A 2020 cost–benefit analysis done in eight sub-Saharan African countries not using Rota vaccines, found that the benefits of introducing the rotavirus vaccine outweighed the costs in all eight countries [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(21\)00220-5/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00220-5/fulltext)
- A 2019 reanalysis of the cost-effectiveness of rotavirus vaccination in 73 Gavi countries found that "rotavirus vaccination continues to represent good value for money across most Gavi countries despite lower rotavirus mortality estimates and more stringent willingness-to-pay thresholds." [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(19\)30439-5/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(19)30439-5/fulltext)
 - Over the period 2018–2027, rotavirus vaccination has the potential to prevent nearly **600,000 deaths** in Gavi countries and save approximately **\$484 million from the government perspective** and **\$878 million from the societal perspective**.
- An analysis demonstrates that the use of **ROTARIX, ROTAVAC, or ROTASIIL** would be highly cost-effective relative to no rotavirus vaccination in Bangladesh, Ghana, and Malawi. <https://www.sciencedirect.com/science/article/pii/S0264410X18314531?via%3Dihub>
 - While ROTARIX was found to be the least costly and most cost-effective product in the three countries, differences were small and subject to change with minor adjustments to uncertain input variables (esp. *incremental health system cost per dose*).
 - A further analysis examining non-Gavi countries paying higher vaccine prices would likely highlight additional economic benefits of the new vaccines: <https://www.sciencedirect.com/science/article/pii/S0264410X19316561>
 - Links to the original analyses that this reanalysis is based on:
 - Bangladesh: <https://www.ncbi.nlm.nih.gov/pubmed/28623028>
 - Ghana: <https://www.ncbi.nlm.nih.gov/pubmed/29223486>
 - Malawi: <https://www.ncbi.nlm.nih.gov/pubmed/27059360>

Vaccine cost-effectiveness (2/2)

- Country-specific analyses:

- NEW**
 - Niger (ROTARIX/ROTAVAC/ROTASIIL): <https://bmjopen.bmj.com/content/12/10/e061673.full>
- NEW**
 - Mozambique (ROTARIX/ROTAVAC/ROTASIIL): <https://www.sciencedirect.com/science/article/pii/S0264410X22009409>
 - Nigeria (using "general vaccine" averaging ROTARIX, ROTASIIL, ROTAVAC, ROTAVAC 5D, and ROTASIIL LQ): <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0232941>
 - Mongolia (ROTARIX/ROTAVAC/RotaTeq): <https://www.sciencedirect.com/science/article/pii/S0264410X19300258>
 - Palestine (switch from ROTARIX to ROTAVAC): <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0228506>
- NEW**
 - Ghana (switch from ROTARIX to ROTAVAC): <https://www.path.org/resources/switch-rotarix-rotavac-ghana-answers-four-key-questions/>
 - India (ROTAVAC): <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0187446>
 - Afghanistan (ROTARIX/RotaTeq): <https://doi.org/10.1016/j.vaccine.2017.10.058>
 - Pakistan (ROTARIX/RotaTeq): <https://www.sciencedirect.com/science/article/pii/S0264410X18301725>
 - Senegal (ROTARIX/RotaTeq): <https://www.ncbi.nlm.nih.gov/pubmed/25919151>
 - Kenya and Uganda (ROTARIX/RotaTeq): <https://www.ncbi.nlm.nih.gov/pubmed/25919149>
- Other relevant analyses
 - Multi dose vials cost-effectiveness (Thailand, measles): <https://www.ncbi.nlm.nih.gov/pubmed/21439313>
 - Multi dose vials cost-effectiveness (model across several antigens): <https://www.ncbi.nlm.nih.gov/pubmed/20566395>

Storage and transport

(shelf life, VVM, volume per fully immunised person)

Trade name	Rotarix		Rotavac		Rotavac 5D		Rotasiil		Rotasiil-Liquid		Rotasiil Thermo	
Presentation	1 dose/plastic tube, liquid	1 dose/plastic tube, liquid in strip of tubes	5 doses/vial, frozen	10 doses/vial, frozen	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, lyophilised	2 doses/vial, lyophilised	1 dose/plastic tube, liquid (strip of 5 tubes)	2 dose/vial, liquid	1 dose/vial, lyophilised	2 doses/vial, lyophilised
Shelf-life ¹	24 months at 2 - 8 °C		24 months at -20 °C, 6 months at 2-8 °C post thaw		24 months at 2-8°C		30 months at 2-8 °C		24 months at 2-8 °C		30 months <25 °C	
Cold chain volume per fully immunised person (cm ³) ¹	In cartons of 50 doses: 34.2 cm ³	In cartons of 50 doses: 23.6 cm ³	12.6 cm ³	9.6 cm ³	43.35 cm ³	12.6 cm ³	52.7 cm ³ , with diluent stored at ambient temperature 105.5 cm ³ , with diluent stored in the cold chain	31.6 cm ³ , with diluent stored at ambient temperature 63.3 cm ³ , with diluent stored in the cold chain	60.2 cm ³	42.9 cm ³	52.7 cm ³ , with diluent stored at ambient temperature 105.5 cm ³ , with diluent stored in the cold chain	31.6 cm ³ , with diluent stored at ambient temperature 63.3 cm ³ , with diluent stored in the cold chain
Wastage adjusted cold chain volume per fully immunised person (cm ³) ²	35.6 cm ³	24.6 cm ³	13.26 cm ³	10.2 cm ³	45.2 cm ³	13.26 cm ³	55.5 cm ³ , with diluent stored at ambient temperature 111.0 cm ³ , with diluent stored in the cold chain	34.7 cm ³ , with diluent stored at ambient temperature 69.9 cm ³ , with diluent stored in the cold chain	62.7 cm ³	47.14 cm ³	55.5 cm ³ , with diluent stored at ambient temperature 111.0 cm ³ , with diluent stored in the cold chain	34.7 cm ³ , with diluent stored at ambient temperature 69.9 cm ³ , with diluent stored in the cold chain
Vaccine vial monitor type ¹	Type 7	Type 7	Type 2	Type 2	Type 7	Type 7	Type 30	Type 30	Type 7	Type 7	Type 250+	Type 250+
Handling open vials ¹	n/a	n/a	Opened vials may be kept for use in subsequent immunization sessions (up to a maximum of 28 days) provided the conditions outlined in the WHO Policy Statement		n/a	Opened vials may be kept for use in subsequent immunization sessions (up to a maximum of 28 days) provided the conditions outlined in the WHO Policy Statement	n/a	Opened vials should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.	n/a	TBD	n/a	Opened vials should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.
Remarks WHO ¹	n/a	n/a	Can be stored at 2-8°C until discard point of VVM2. (at 5°C, VVM2 discard point is 225 days). For delivery to PAHO, without VVM, maximum storage of 6 months at 2-8°C		n/a	n/a	n/a	n/a	n/a	TBD	n/a	n/a
Notes	n/a	n/a	ROTAVAC® can be subjected to 6 freeze- thaw cycles		n/a	n/a	The shelf-life of diluent is 60 months at 2 to 8°C. The diluent should not be frozen.		n/a	TBD	Vaccine should be stored at temperatures lower than 25°C and countries should ensure adequate facilities (conditioned rooms) with temperatures not exceeding 25°C.	

1 Source: WHO PQ webpage: WHO updates these webpages as new information on products becomes available. Please refer to these [pages](#) for the most up-to-date information. For presentations not yet WHO prequalified, data is based on discussions with manufacturers and partners in 2022.

2 Source: Review of WHO vaccine wastage rate tool, 2021

Cold Chain implications for Rotavac Frozen (Gavi Analysis)

	Central level	Sub-national level (region/ province/store)	District/ health zone/ LGA stores	Service delivery level
Storage	Store at negative temperatures (freezer or freezer room)	Store at negative temperatures (freezer or freezer room)	If frozen: store in freezers If liquid (thawed): store in refrigerators	Store in refrigerators
	<p>If freezer capacity is insufficient:</p> <ul style="list-style-type: none"> • countries could move lyophilized vaccines from the freezer rooms to the cold rooms (refrigerators) to make space • countries may procure a couple of freezers if the quantity is not superior to 5 (for which a small freezer room may be more efficient) 	<ul style="list-style-type: none"> • All countries have freezers that are used for storing polio vaccines and/or ice packs • Countries may decide to procure a small freezer room which could be used for storing this vaccine and others 	<ul style="list-style-type: none"> • Storing in refrigerators is fine if the district collects vaccines on a monthly basis 	
Distribution to the next level	<p>Transport in negative temperatures</p> <ul style="list-style-type: none"> • Transport in cold boxes with fully frozen ice packs (same for refrigerated truck (2-8C) or normal truck) 	<p>Different options based upon country stock turnover rates:</p> <ul style="list-style-type: none"> • Transport at negative temperatures (cold boxes with fully frozen ice packs) (encouraged) • Transport refrigerated as liquid (thawed), which will kick start the 6 months potency threshold 	Transport refrigerated as liquid (thawed)	
Gavi support (as an example)*	<ul style="list-style-type: none"> • Cold boxes • Freezers 	<ul style="list-style-type: none"> • Cold boxes • Small freezer room 	<ul style="list-style-type: none"> • Freezers 	<ul style="list-style-type: none"> • Refrigerators (optional)

*countries may request support to procure the items in the budget of either VIG / switch grant / CCEOP/ HSS flexibilities

Programmatic administration considerations

	Rotarix (plastic tube)	Rotarix (in strip of 5 single tubes)	Rotavac (in 5 or 10 dose vials)	Rotavac 5D (1 dose vials)	Rotavac 5D (5 dose vials)	Rotasiil & Rotasiil Thermo (in single or 2 dose vials)	Rotasiil-Liquid (in 2 dose vials)	Rotasiil- Liquid (in strip of 5 single tubes)
Route	Oral	Oral	Oral	Oral	Oral	Oral	Oral	Oral
Form	Liquid	Liquid	Liquid (frozen)	Liquid	Liquid	Lyophilised	Liquid	Liquid
Doses per fully immunised child	2	2	3	3	3	3	3	3
Dose quantity	1.5 ml	1.5 ml	0.5 ml (5 drops)	0.5ml (5 drops)	0.5ml (5 drops)	2.5 ml	TBD	2 ml
Devices per unit	1	1 (multi- monodose presentation with 5 single tubes connected by a bar)	2 (vial and dropper)	2 (vial and dropper)	2 (vial and dropper)	4 (single dose) 5 (2 dose vial) Diluent vial, vaccine vial, adapter, syringe for reconstitution and for oral administration	4 (vaccine vial, adapter, 2 syringes for oral administration)	1 (5 single- dose tubes attached by a strip)
Preparation steps (see WHO training slides for details)	1	1	4	2	2	8	2	1
Need for dose measurement	No	No	Yes	No	Yes	Yes	TBD	No

Key references

WHO [Prequalification](#) information

WHO [Rotavirus Position Paper](#) (July 2021)

UNICEF [rotavirus market note](#) (June 2020)

Gavi [Detailed Product Profiles](#)

WHO training materials: <https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/rotavirus>

WHO Rotavirus Position Paper (2021) <https://www.who.int/publications/i/item/weekly-epidemiological-record-vol.-28-2021-96-301-320>

Key contacts for questions

Area of expertise	Agency	Person to contact
Vaccine clinical profile	WHO	<ul style="list-style-type: none"> • <u>Your Country's officer</u> • Alejandro Ramirez Gonzalez, ramirezgonzaleza@who.int
Country-led Assessment for Prioritization in Immunization (CAPACITI)	WHO	<ul style="list-style-type: none"> • <u>Your Country's officer</u> • Raymond Hutubessy, hutubessyr@who.int
Vaccine wastage rates	WHO	<ul style="list-style-type: none"> • Souleymane Kone, kones@who.int
Availability, Shipment, Prices	UNICEF SD	<ul style="list-style-type: none"> • <u>Your Country's officer</u> • Edouard Kamangaza, ekamangaza@unicef.org • David Kiambi Mutuerandu, dkmutuerandu@unicef.org
Eligibility, Price commitments	Gavi Secretariat	<ul style="list-style-type: none"> • <u>Your Country's Senior Country Manager</u> • Veronica Denti, Sr Programme Manager, PCV and Rotavirus vaccines, vdenti@gavi.org • Elie Akiki, Sr Manager Market Shaping eakiki@gavi.org