Gavi-supported rotavirus vaccines profiles to support country decision making

Pneumococcal and Rotavirus Working Group *Gavi Secretariat and partners, February 2025*















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 2025. 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

2025 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.

2025 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)

2025 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 indicative, but it will be applied to the 1st 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

Туре		Rotavirus (oral, live attenuated)										
Manufacturer	C	SSK		Bharat Biotech				Se	rum Institute	of India Pvt	Ltd	
Trade name	Rot	tarix ¹	Rota	Rotavac Rotavac 5D			Rot	asiil	Rotasiil -	- Liquid	Rotasiil ⁻	Thermo
NRA	Bel	gium		Inc	dia				Inc	dia		
Form	Lio	quid	Liquid (frozen)	Liq	uid	Lyoph	nilised	Liqu	uid	Lyoph	ilised
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	20	18	2021		20	2018		2021	202	20

To be stopped for Gavi countries in 2026

To be discontinued in April 2025

To be discontinued in April 2025

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/pgweb/vaccines/pregualified-vaccines

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

Availability of rotavirus vaccines supported by Gavi

Trade name	Presentation*	Availability for Gavi countries
Trade name	Presentation	2025
	RV1, 1 dose/plastic tube, liquid	Available with planning
Rotarix ¹	RV1, 1 dose/plastic tube, liquid (multi-monodose presentation with 5 single tubes connected by a bar)	Available with planning
Potavas	RV1, 5 doses/vial, frozen	Available with planning
Rotavac	RV1, 10 doses/vial, frozen	Available with planning
	RV1, 1 dose/vial, liquid	Not available
Rotavac 5D	RV1, 5 doses/vial, liquid	Expected to be available with planning (shipments possible starting Q1 of 2026)
Deteciil	RV5, 1 dose/vial, lyophilised	Discontinued starting April 2025
Rotasiil	RV5, 2 doses/vial, lyophilised	Discontinued starting April 2025
Rotasiil-Liquid	RV5, 1 dose/plastic tube, liquid (strip of 5 tubes)	Availability to be confirmed
	RV5, 2 doses/vial, liquid	Available with planning
Rotasiil Thermo	RV5, 1 dose/vial, lyophilised	Discontinued starting April 2025
Notasiii IIIEIIIIO	RV5, 2 doses/vial, lyophilised	Discontinued starting April 2025

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.

WHO Prequalified Rotavirus vaccines supported by Gavi

As of February 2025

Trade name	Rot	arix	Rota	Rotavac		Rotavac 5D		Rotasiil		l-Liquid	Rotasiil Thermo	
Present- ation*	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
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- 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 for Gavi countries by 2026.
- Rotavac 5D in 5-dose vials is expected to be available starting Q1 of 2026 at earliest.

 Rotavac 5D in 1-dose vials will not be available in 2025 and availability date thereafter to be confirmed by manufacturer.
- Rotasiil presentation in a strip of 5 single tubes: availibility in 2025 needs to be confirmed.
- Rotasiil (lyophilized) and Rotasiil Thermo (lyophilized) will be discontinued by the manufacturer starting April 2025.

For size comparison

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



Vaccine efficacy, safety, and interchangeability

Summary of Key Characteristics of WHO Prequalified Rotavirus Vaccines*

Characteristics		Rotarix [™] (GSK)	A Rotateq™ (Merck)	Rotavac™ (Bharat)	Rotasiiſ™ (Serum Institute)
Efficacy for	Low Mortality	90% (95% CI, 86-93%)	94% (95% CI, 61-99%)	No data available	No data available
gastroenteritis, at 2	Medium Mortality	78% (95% CI, 70-83%)	81% (95% CI, 66-89%)	No data available	No data available
years follow-up, ** by child mortality rate	High Mortality	54% (95% CI, 9-77%)			44% (95% CI, 26-58%)
stratum of country of study site ¹ Study site		Multiple countries at different inc	come and mortality levels.	3 sites in India	6 sites in India; 1 center, multiple sites in Niger
Date of WHO prequalific	ation	March 2009	October 2008	January 2018	September 2018
Safety		WHO has concluded that the pre prevent severe rotavirus gastroe			
Mixed schedules & inter of products ⁴	changeability	 If the product used for a prior do product. Restarting the vaccine s For a mixed series or a series wit for a complete vaccination series The published safety and efficacy products; 5, 6, 7 	eries is not recommended. h any unknown vaccine products	s, a total of 3 doses of rotavirus v	raccine should be administered

^{**} 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:**

^{*} 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.





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. (https://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).

Anotavirus 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.

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

- SAGE recommended <u>all four live oral rotavirus vaccines</u> (Rotarix[™], RotaTeq[™], Rotavac[™], and Rotasiil[™]) for use.
- SAGE re-affirmed 2013 recommendations that rotavirus vaccines should be <u>included in all</u> <u>national immunization programs and be considered a priority</u>, 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 <u>first</u> <u>dose of rotavirus vaccine should be administered as soon as possible after 6 weeks of age</u>.
- 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 highmortality 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 2025 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

	_											1	
Trade name	R	otarix	Rota	avac	Rotav	ac 5D	Rot	asiil	Rotasii	l-Liquid	Rotasiil	Thermo	
Form	L	iquid	Liquid (frozen)	Liq	uid	Lyoph	nilised	Liquid	Liquid Liquid		Lyophilised	
Presentation	Plastic tube	Strip of 5 single tubes	Vi	ial	Vi	al	Two v	ial set	Strip of 5 single tubes	Vial	Two v	ial set	
Doses in each unit		1	5	10	1	5	1	2	1	2	1	2	
2025 price per dose (USD)	\$2.13* €2.05	\$1.86* €1.79	\$0.70	\$0.50	n/a	\$1.15	n/a	\$0.95	n/a	\$0.80	n/a	n/a	
Doses per fully immunised person		2					3	3					
2025 price per fully immunised person (USD)	\$4.59	\$4.01	\$2.10	\$1.50	n/a	\$3.45	n/a	\$2.85	n/a	\$2.40	n/a	n/a	
Indicative wastage rate		4%	5%	6%	4%	5%	4%	9%	4%	9%	4%	9%	
2025 waste-adjusted price per fully immunized person (USD) ¹	\$4.78	\$4.18	\$2.21	\$1.60	n/a	\$3.63	n/a	\$3.13	n/a	\$2.64	n/a	n/a	
Reference for WHO calculator WHO Vaccines Wastage Rates Calculator	Ro	ta_liq	Rota_liq	_frozen	Rota	ı_liq	Rota		Rota_liq	Rota_lyo	Rota_lyo	Rota_lyo	

To be stopped for Gavi

To be discontinued in April 2025

To be discontinued in April 2025

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 1

^{*}The price in US dollars reflects conversion at a currency exchange rate of 1.04USD/EUR, source: Bloomberg projected foreign exchange rates.

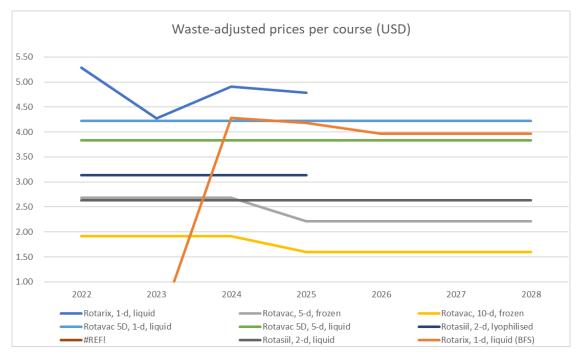
The actual exchange rate that will be utilised to calculate the USD price at the moment of the transaction may vary.

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	4.26			
Rotarix, 1-d, liquid (BFS)*	GSK			4.12	3.72	3.54	3.54	3.54
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	n/a	n/a	n/a
Rotasiil, 2-d, liquid	SII	2.40	2.40	2.40	2.40	2.40	2.40	2.40

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	4.44			
Rotarix, 1-d, liquid (BFS)*	GSK			4.29	3.88	3.68	3.68	3.68
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	n/a	n/a	n/a
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 1.04USD/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 Gavi support)
Rotasiil	Serum Institute of India (SII)	-	No price commitment made in 2015,

^{*} 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/21756/file/Rota-vaccines-prices-14052024.pdf.pdf for more information about prices.

Rotavirus vaccine prices for MICs in UNICEF tender

Former Gavi-eligible countries that have not introduced Rotavirus vaccine and Middle-Income Countries that were never-Gavi eligible should contact UNICEF or refer to UNICEF vaccine price sheet https://www.unicef.org/supply/media/21756/file/Rota-vaccines-prices-14052024.pdf, pdf for more information about prices.

Trade name (manufacturer)	Vaccine	2025	2026	2027	2028
Rotarix (GSK)	RV1, 1 dose/plastic tube, liquid	\$9.00-18.00 ^(a) € 5.16 ^(b)	€ 5.16 ^(b)	€ 5.16 ^(b)	€ 5.16 ^(b)
	RV1, 1 dose/plastic tube, liquid (multi- monodose presentation with 5 single tubes connected by a bar)	€ 5.16 ^(b)	€ 5.16 ^(b)	€ 5.16 ^(b)	€ 5.16 ^(b)
Rotavac (Bharat)	RV1, 5 doses/vial, frozen	\$ 2.00 ^(c)	\$ 2.00 ^(c)	\$ 2.00 ^(c)	\$ 2.00 ^(c)
Rotavac 5D (Bharat)	RV1, 1 dose/vial, liquid	\$ 4.50 ^(a)			
	RV1, 5 dose/vial, liquid	\$ 3.75 ^(a)			
Rotasiil-Liquid (SII)	RV5, 2 doses/vial, liquid	\$ 1.49 ^(a) \$ 0.80 ^(d)	\$ 0.80 ^(d)	\$ 0.80 ^(d)	\$ 0.80 ^(d)
	RV5, 1 dose/plastic tube, liquid (strip of 5 tubes)	\$ 2.50 ^(a)			

⁽a): Upper Middle-Income countries (UMIC)

Prices in grey indicate unavailable supply

⁽b): Lower Middle-Income countries (LMIC) with GNI per capita above Gavi eligibility threshold

⁽c): Price applies to non-Gavi eligible Middle-Income countries (MICs)

⁽d): SII applies price parity to both Gavi-eligible countries and non-Gavi eligible LMICs

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, Excelbased tools for assessing and comparing costs of certain vaccination programs over a period of five years with each vaccine product available in the Gavi market. Users input a limited set of local data to compare products and estimate vaccination program costs, exploring up to four vaccine options at once.

- Rotavirus Vaccine Cost Calculator in English, French, and Spanish https://www.path.org/resources/rotavirus-vaccine-cost-calculator/
- Pneumococcal Conjugate Vaccine Cost Calculator in English, French, 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/

A user guide is included within each calculator with detailed instructions on how to use the tool and interpret the results.

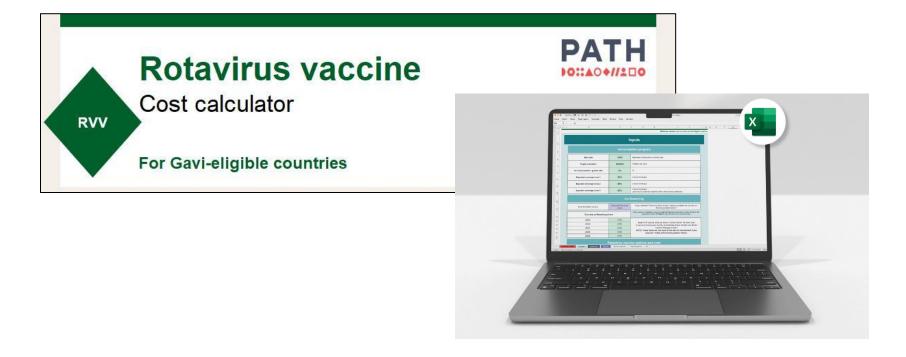
For questions or support regarding the Vaccine Cost Calculators, contact PATH's Health Economics and Outcomes Research team: HEOR@path.org.



Rotavirus Vaccine Cost Calculator

A simple, Excel-based tool that generates cost information for rotavirus vaccine programs, comparing up to four different vaccine options at once. Available to download in English, French, and Spanish: https://www.path.org/resources/rotavirus-vaccine-cost-calculator/

- Country-specific tool that requires <u>minimal data entry</u>
- Can be used by any country currently receiving Gavi support, in any transition phase
- Provides results on cost to country only <u>and</u> cost to country and Gavi
- 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 September 2024)



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
- 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
 - 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
 - o 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
- o 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
- o Mongolia (ROTARIX/ROTAVAC/RotaTeq): https://www.sciencedirect.com/science/article/pii/S0264410X19300258
- o Palestine (switch from ROTARIX to ROTAVAC): https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0228506

NEW

- o Ghana (switch from ROTARIX to ROTAVAC): https://www.path.org/resources/switch-rotarix-rotavac-ghana-answers-four-key-questions/
- o India (ROTAVAC): https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0187446
- o 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
- o Kenya and Uganda (ROTARIX/RotaTeq): https://www.ncbi.nlm.nih.gov/pubmed/25919149
- Other relevant analyses
 - o Multi dose vials cost-effectiveness (Thailand, measles): https://www.ncbi.nlm.nih.gov/pubmed/21439313
 - o 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)

To be stopped for Gavi countries in 2026

To be discontinued in April 2025

To be discontinued in April 2025

	$\overline{}$											
Trade name	Ro	tarix	Rota	avac	Rot	tavac 5D	Ro	otasiil	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 month	at 2 - 8 °C	24 months at -20 2-8 °C po		24 mor	nths at 2-8°C	30 month	ns at 2-8 °C	24 months at 2-8 °C	24 months at 2-8 °C	30 mont	hs <25 °C
Cold chain volume per fully immunised person (cm³)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 cm³	43.35 cm³	12.6 cm³	52.7 cm ³ , with diluent stored at ambient temperature 105.5 cm ³ , with diluent stored in the cold chain	31.6 cm³, with diluent stored at ambient temperature 63.3 cm³, with diluent stored in the cold chain	60.2 cm³	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 cm³, with diluent stored at ambient temperature 63.3 cm³, with diluent stored in the cold chain
Wastage adjusted cold chain volume per fully immunised person (cm³)¹ ²	35.6 cm³	24.6 cm³	13.26 cm ³	10.2 cm ³	45.2 cm³	13.26 cm ³	55.5 cm³, with diluent stored at ambient temperature 111.0 cm³, with diluent stored in the cold chain	34.7 cm³, with diluent stored at ambient temperature 69.9 cm³, with diluent stored in the cold chain	62.7 cm³	47.14 cm ³	55.5 cm³, with diluent stored at ambient temperature 111.0 cm³, with diluent stored in the cold chain	34.7 cm³, with diluent stored at ambient temperature 69.9 cm³, 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	use in subseque sessions (up to a days) provided outlined in th	nay be kept for nt immunization I maximum of 28 the conditions e WHO Policy ment	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		Opened vials should be discarded 6 hour- after opening or at the end of the immunization session, whichever comes first.		TBD	n/a	Opened vials should be discarded 6 hours after opening or at the end of the immunization session, whicheve comes first.
Remarks WHO ¹	n/a	n/a	discard point of VVM2 discard po For delivery to	I at 2-8°C until f VVM2. (at 5°C, pint is 225 days). PAHO, without m storage of 6 at 2-8°C	n/a	n/a	n/a	n/a	n/a	TBD	n/a	n/a
Notes	n/a	n/a		oe subjected to 6 naw cycles	n/a	n/a		uent is 60 months at should not be frozen	n/a	TBD	temperatures lov countries should facilities (condition	d be stored at ver than 25°C and ensure adequate oned rooms) with t exceeding 25°C.

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

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
	If freezer capacity is insufficient: •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)	 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 	Storing in refrigerators is fine if the district collects vaccines on a monthly basis	
Distribution to the next level	Transport in negative temperatures • Transport in cold boxes with fully frozen ice packs (same for refrigerated truck (2-8C) or normal truck)	Different options based upon country stock turnover rates: • 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)*	Cold boxesFreezers	Cold boxesSmall freezer room	• Freezers	Refrigerators (optional)

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

Programmatic administration considerations

To be stopped for Gavi countries in 2026

To be discontinued in April 2025

	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 <u>WHO</u> <u>training</u> slides for details)	1	1	4	2	2	8	2	1
Need for dose measurement	No	No	Yes	No	Yes	Yes	TBD	No 22

Key references

WHO **<u>Prequalification</u>** 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	 Your Country's officer Alejandro Ramirez Gonzalez, <u>ramirezgonzaleza@who.int</u>
Country-led Assessment for Prioritization in Immunization (CAPACITI)	WHO	 Your Country's officer Raymond Hutubessy, hutubessyr@who.int
Vaccine wastage rates	WHO	Souleymane Kone, <u>kones@who.int</u>
Availability, Shipment, Prices	UNICEF SD	 Your Country's officer Edouard Kamangaza, ekamangaza@unicef.org Oluwaseun Ayanniyi oayanniyi@unicef.org
Eligibility, Price commitments	Gavi Secretariat	 Your Country's Senior Country Manager Veronica Denti, Sr Programme Manager, PCV and Rotavirus vaccines, vdenti@gavi.org Elie Akiki, Sr Manager Market Shaping eakiki@gavi.org