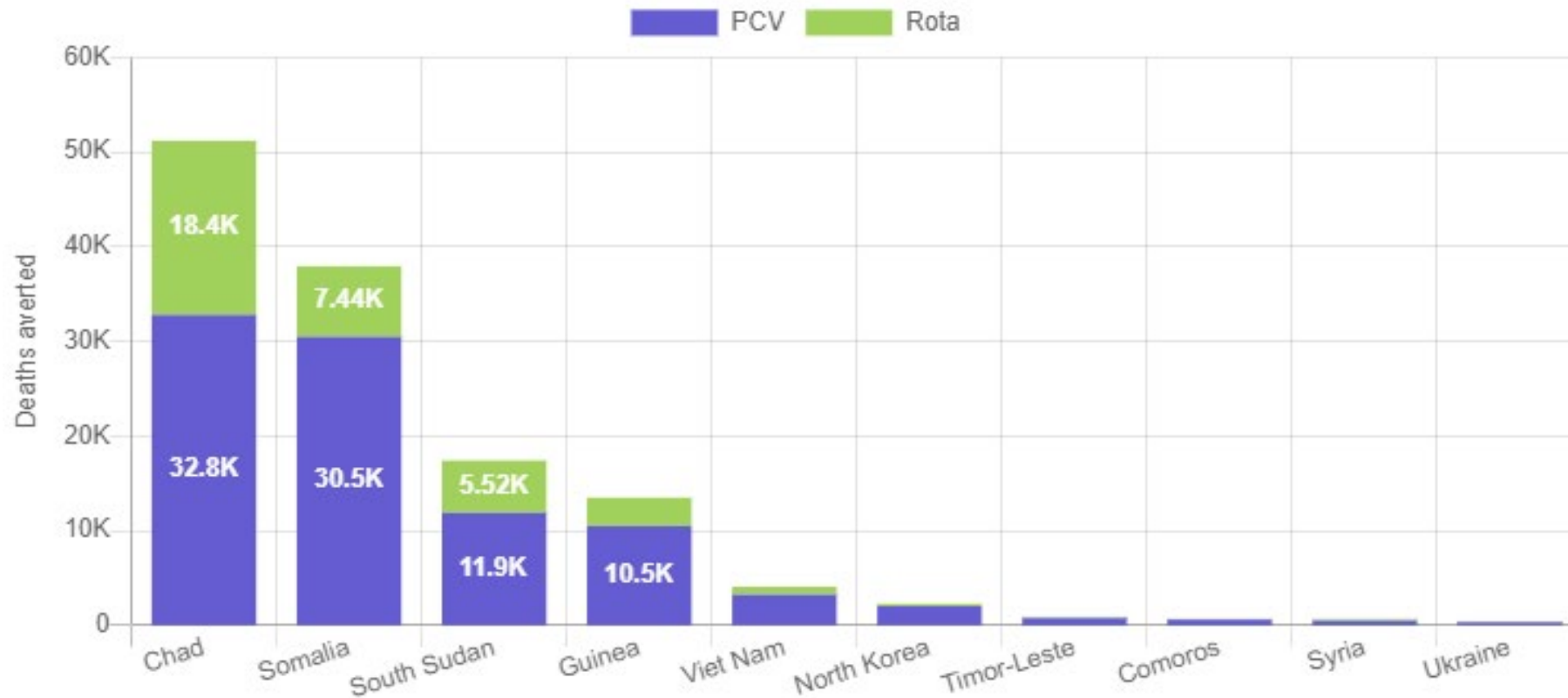


# PCV / Rota introduction: Gavi support and options

# Impact expected from introducing PCV and Rota in remaining Gavi-supported countries

In the next 7 years in the remaining Gavi-eligible / PCV AMC-eligible countries, nearly **90.000** deaths are expected due to pneumonia - most of these vaccine-preventable, and nearly 75.000 to diarrhoea, of which **~36.000** vaccine-preventable.

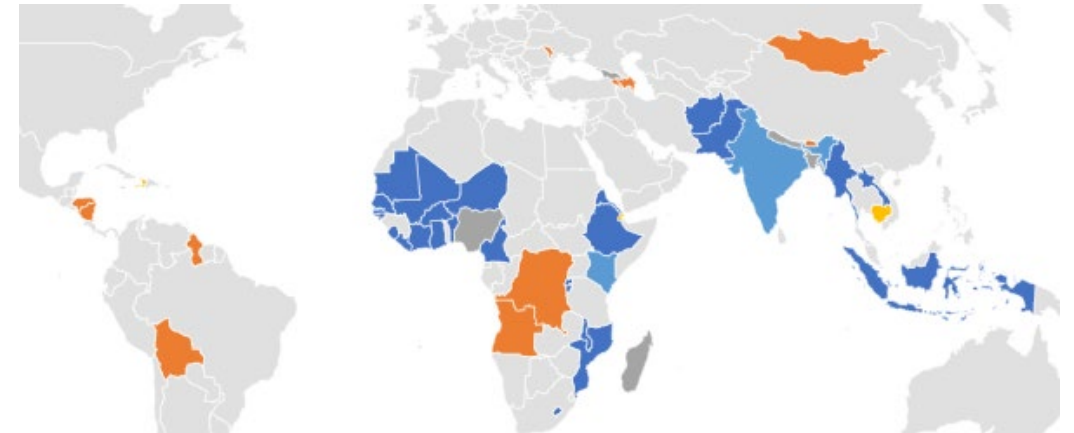
Potential deaths averted between 2023 and 2030



# Gavi supported more than 372M children vaccinated with PCV between 2009-2022

- 63 introductions supported, of which 3 through access to the PCV AMC price\*.
- Routine support ongoing in 40+ countries in 2023
- ~140-180.000 deaths averted per year moving forward.
- Three manufacturers offering 3 multi-dose vials and two single-dose options in a price range of 3.30-2.00\$/dose

63 Gavi countries vaccinating against PCV with 4\*\* different presentations in 2023



■ PCV13 in 4dv ■ PCV13 ■ PCV10 in 4dv ■ PCV13 in 1 dv ■ PCV10 in 5dv

Source: Gavi VLD, CHOICES Country matrix, May 2023

3

Source: Gavi v20.1 financial forecast 2023 \*Mongolia, Bhutan, Indonesia. Timor Leste was originally granted access and subsequently introduced with Gavi support. Ukraine, has been approved but has not introduced yet

\*\*no country known to use PCV10 in 1dv yet

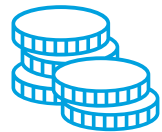
# Gavi support for pneumococcal vaccine (PCV)

## PCV routine

(since 2009)



Vaccines for children <1 yr of age, annually (3 doses), with country co-financing.  
Countries can choose among 3 products in 5 presentations, and two different schedules (3+0 or 2+1)



Vaccines Introduction Grant



Technical assistance (through TCA or CHOICES)

## PCV catchup

(since 2018)



Vaccines for children from 12 to 59 months of age, to be immunized on a one-off basis within 12 months from introduction (1 dose), all doses paid by Gavi. Countries are encouraged to pick within the 3 MDV presentations.

Operational support grant

Technical assistance (through TCA or CHOICES)

When submitting an application for support to introduce PCV in routine, the country can opt for an **additional** support to implement a catch-up campaign at launch.

If the country only requests support to launch PCV in routine, **without** catchup, a rationale for why the country will not do a catch-up must be provided.

Countries are encouraged to utilise the fill VIG and Ops funds and invest synergies to fund integration for pneumonia control.

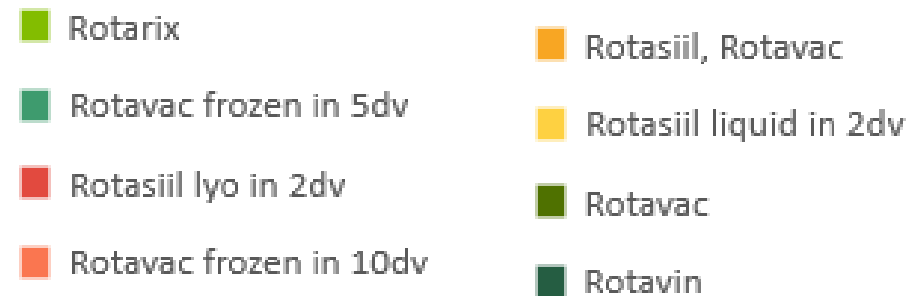
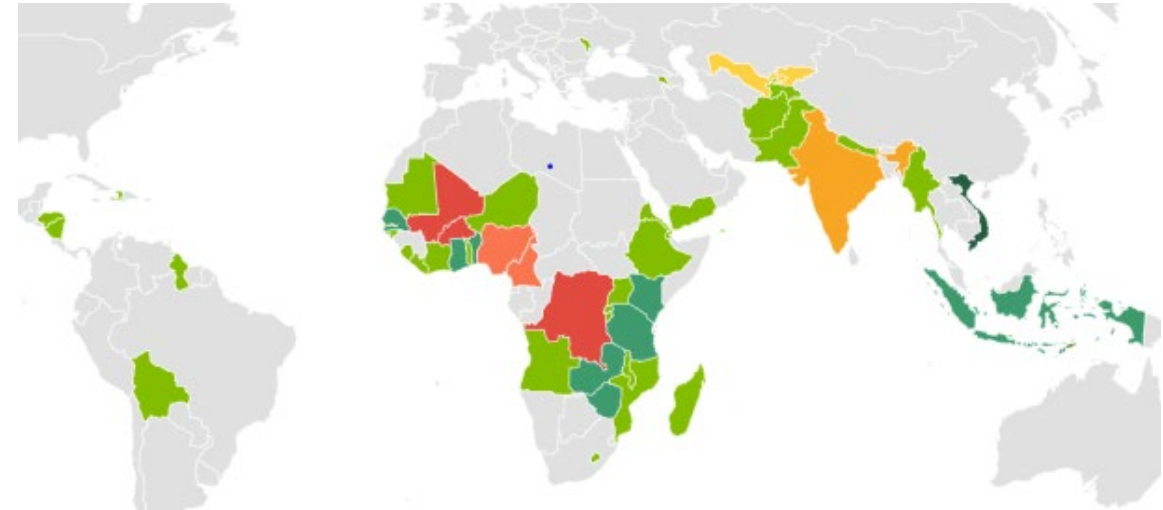
# Gavi supported PCV vaccine presentation options

Vaccine type <sup>1</sup>	Pneumococcal conjugate vaccine, 10 valent		Pneumococcal conjugate vaccine, 13 valent
Serotypes <sup>1</sup>	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F	1, 5, 6A, 6B, 7F, 9V, 14, 19A, 19F, 23F	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
Manufacturer <sup>1</sup>	GlaxoSmithKline	Serum Institute of India Pvt. Ltd.	Pfizer
Vaccine trade name <sup>1</sup>	Synflorix	Pneumosil	Prevenar 13
Country of manufacture <sup>1</sup>	Belgium	India	UK
National regulatory agency <sup>1</sup>	European Medicines Agency (EMA)	Central Drugs Standard Control Organization (India)	European Medicines Agency (EMA)
Presentation (doses per container, primary container type, pharmaceutical form) <sup>1</sup>	PCV10, 4 doses/vial, liquid	PCV10, 5 doses/vial, liquid	PCV13, 4 doses/vial, liquid
Product availability 2023 <sup>2</sup>	supply exceeds demand	supply exceeds demand	supply exceeds demand
Routine and/or campaign	routine	routine	routine
WHO recommended vaccine schedule <sup>3</sup>	3 doses	3 doses	3 doses
2023 price per dose (USD) <sup>4</sup>	\$2.90	\$2.00***	\$2.75
Doses per fully immunised person	3	3	3
2023 price per fully immunised person (USD) <sup>4</sup>	\$8.70	\$6.00	\$8.25
Indicative wastage rate <sup>5</sup>	8%	8%	8%
2023 wastage adjusted price per fully immunised person (USD) <sup>4</sup>	\$9.46	\$6.52	\$8.97
WHO PQ-date <sup>1</sup>	16/10/2017	18/12/2019	14/07/2016
Administration <sup>1</sup>	intramuscular	intramuscular	intramuscular
Secondary packaging <sup>1</sup>	carton of 100 vials	Carton of 50 vials (250 doses)	carton of 25 vials carton of 50 vials *
Shelf-life <sup>1</sup>	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C
Cold chain volume per dose (cm <sup>3</sup> ) <sup>1</sup>	2.4 cm <sup>3</sup>	3.515 cm <sup>3</sup>	3.5 cm <sup>3</sup> *
Cold chain volume per fully immunised person (cm <sup>3</sup> ) <sup>1</sup>	7.2 cm <sup>3</sup>	10.55 cm <sup>3</sup>	10.5 cm <sup>3</sup>
Wastage adjusted cold chain volume per fully immunised person (cm <sup>3</sup> ) <sup>1 5</sup>	8.0 cm <sup>3</sup>	11.46 cm <sup>3</sup>	11.67 cm <sup>3</sup>
Vaccine vial monitor type <sup>1</sup>	Type 30	Type 30	Type 30

# Gavi supported more than 291M children vaccinated with Rota between 2008-2022

- 53 introductions, and 46 countries supported in 2022
- Est. ~45.000 deaths averted yearly across 53 countries

53 Gavi countries vaccinating against Rota with 7\* different presentations (2023)



# Gavi support for rotavirus vaccination (RVV)

## Rota routine

**Target population:**

Children up to 12 months of age

**Dose schedule**

Full dose schedule (2 or 3 doses depending on vaccine product)

**Vaccines support**

Standard country co-financing applies

*Exceptional waiver can be requested in specific country situations*

**Cash grant**

A one-time Vaccine Introduction Grant at \$0.80/\$0.70/\$0.60 (as per country co-financing phase) per target child in the birth cohort of the year of introduction

# Gavi supported Rotavirus vaccine presentation options

Vaccine trade name <sup>1</sup>	Rotarix <sup>6</sup>	Rotavac		Rotavac 5D		Rotasiil		Rotasiil-Liquid	
Country of manufacture <sup>1</sup>	Belgium	India		India		India		India	
Presentation (doses per container, primary container type, pharmaceutical form) <sup>1</sup>	RV1, 1 dose/plastic tube, liquid	RV1, 5 doses/vial, frozen	RV1, 10 doses/vial, frozen	RV1, 1 dose/vial, liquid	RV1, 5 doses/vial, liquid	RV5, 1 dose/vial, lyophilised <sup>10</sup>	RV5, 2 doses/vial, lyophilised	RV5, 1 dose/plastic tube, liquid (strip of 5 tubes)	RV5, 2 doses/vial, liquid
Product availability 2023 <sup>2</sup>	needs planning	needs planning	needs planning	not available <sup>8</sup>	not available <sup>9</sup>	needs planning	needs planning	not available <sup>11</sup>	needs planning
2023 price per dose (USD/EUR) <sup>4,6</sup>	\$2.05	\$0.85	\$0.60	n/a	n/a	\$1.55	\$0.95	n/a	\$0.80
Doses per fully immunised person	2	3	3	3	3	3	3	3	3
2023 price per fully immunised person (USD) <sup>4</sup>	\$4.10	\$2.55	\$1.80	n/a	n/a	\$4.65	\$2.85	n/a	\$2.40
Indicative wastage rate <sup>5</sup>	4%	5%	6%	4%	5%	4%	9%	4%	9%
2023 wastage adjusted price per fully immunised person (USD) <sup>4, 5</sup>	\$4.27	\$2.68	\$1.91	n/a	n/a	\$4.84	\$3.13	n/a	\$2.64
WHO PQ-date <sup>1</sup>	12/03/2009	05/01/2018	05/01/2018	18/06/2021	18/06/2021	21/09/2018	21/09/2018	18/02/2021	08/10/2021
Shelf-life <sup>1</sup>	24 months at 2 - 8 °C	60 months at -20 °C, 6 months at 2-8 °C post thaw	60 months at -20 °C, 6 months at 2-8 °C post thaw	24 months at 2-8 °C	24 months at 2-8 °C	30 months at 2-8 °C	30 months at 2-8 °C	24 months at 2-8 °C	24 months at 2-8 °C (proposed)
Wastage adjusted cold chain volume per fully immunised person (cm <sup>3</sup> ) <sup>1 5</sup>	35.6 cm <sup>3</sup>	13.26 cm <sup>3</sup>	10.2 cm <sup>3</sup>	45.15 cm <sup>3</sup>	13.26 cm <sup>3</sup>	55 cm <sup>3</sup> [the diluent can be stored at ambient temperature; if the diluent is also stored in the cold chain volume per dose is 111.0 cm <sup>3</sup> ]	34.7 cm <sup>3</sup> [the diluent can be stored at ambient temperature; if the diluent is also stored in the cold chain volume per dose is 69.9 cm <sup>3</sup> ]	62.68 cm <sup>3</sup>	47.14 cm <sup>3</sup>
Vaccine vial monitor type <sup>1</sup>	Type 7	Type 2	Type 2	Type 7	Type 7	Type 30	Type 30	Type 7	Type 7



# Selecting the vaccine, presentation and formulation

<b>Ease of use</b> <i>(e.g. single dose, liquid form, oral, shorter dose schedule)</i>	<b>Cold chain, transport, storage requirements</b>	<b>Effectiveness or safety</b>	<b>Coverage</b> <i>(acceptability, missed opportunities)</i>	<b>Financial sustainability</b> <i>(cost, price, wastage)</i>	<b>Supply</b> <i>(availability / security / locally-made)</i>
<ul style="list-style-type: none"> <li>• Number of doses in the schedule</li> <li>• Number of steps to prepare the dose to administer (eg does or not require dose measurement, does or not require reconstitution)</li> </ul>	<ul style="list-style-type: none"> <li>• Cold chain capacity needs</li> <li>• Type of cold chain needed</li> <li>• Freeze-thaw flexibility</li> <li>• Auxiliary equipment needed</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical profile</li> <li>• Real-world data</li> <li>• Country-specific evidence</li> <li>• Efficacy against additional serotypes</li> </ul>	<ul style="list-style-type: none"> <li>• Impact on HCW hesitancy to open a vial</li> <li>• Means of administration (eg oral)</li> <li>• Existing EPI touchpoint (target population age already reached)</li> </ul>	<ul style="list-style-type: none"> <li>• Wastage-adjusted cost to fully immunize a child</li> <li>• Price per dose</li> <li>• Wastage rates</li> <li>• Future price outlook based on tender outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• Current availability and predictability of future availability</li> <li>• Made locally</li> <li>• Size of supplier's capacity</li> <li>• Lead time for supplier to manufacture</li> </ul>

# Complementarities in PCV and Rota implementation

Gavi supports combined applications for PCV and Rota support

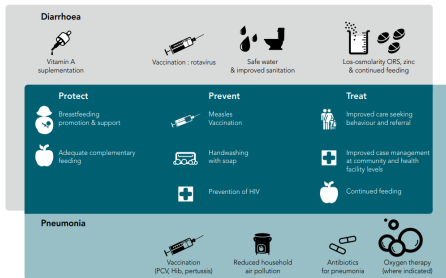


Same **target population**:  
children <1 year of age

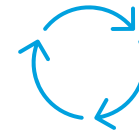


Overlapping **dose schedule** at 6,10,14 weeks

FIGURE 4. Complementarity of pneumonia and diarrhoea interventions



Amplification of impact through **integration** with other interventions recommended by WHO's GAPPD plan



**Implementation activity synergies** (e.g. planning, training, printing & updating data collection materials, social mobilization)

**Similarity of Gavi application requirements**  
(e.g. NITAG assessment, budget, implementation planning)

# Similar routine schedule and presentations exist for PCV and Rota

Adopting similar schedule and presentations with similar vial sizes and similar storage could simplify training and reduce risk of implementation confusion

	Rota routine	PCV Routine	<i>Similar options across both PCV and Rota vaccination programmes</i>
<b>Target population:</b>	Children up to 12 months of age		
<b>Number of doses</b>	2 or 3 doses	3 doses	3 doses
<b>Dose schedule</b>	6 – 10 – 14 weeks	6 – 10 – 14 weeks or 6 – 14 wks – 9 mths or more	6 – 10 -14 weeks
<b>Vaccine presentations</b>	1 dose vial liquid 1 dose plastic tube liquid 2 dose vial liquid or lyophilised <b>5 dose vial liquid</b> or frozen 10 dose vial liquid or frozen	1 dose vial liquid 4 dose vial liquid <b>5 dose vial liquid</b>	<b>5 dose vial liquid</b>

**NITAG to assess and recommend**

# Combining PCV and Rota application to maximise impact

Rota and PCV support can be requested independently from each other.

**A combined launch of PCV and Rota in routine + PCV Catchup can offer synergies.**

It is now possible to submit **one application package combining three types of support**

- PCV introduction in routine

- PCV catch-up at launch

- Rotavirus vaccination introduction in routine

Submitting an application to Gavi is a heavy lift with a considerable transaction cost. If it is feasible to combine multiple introductions together, especially in fragile settings, Gavi encourages it.

Several Gavi countries introduced both PCV and Rota together: Burkina Faso, Ghana, Guinea Bissau, India, Nicaragua, Niger, Tanzania, Togo and Zambia.

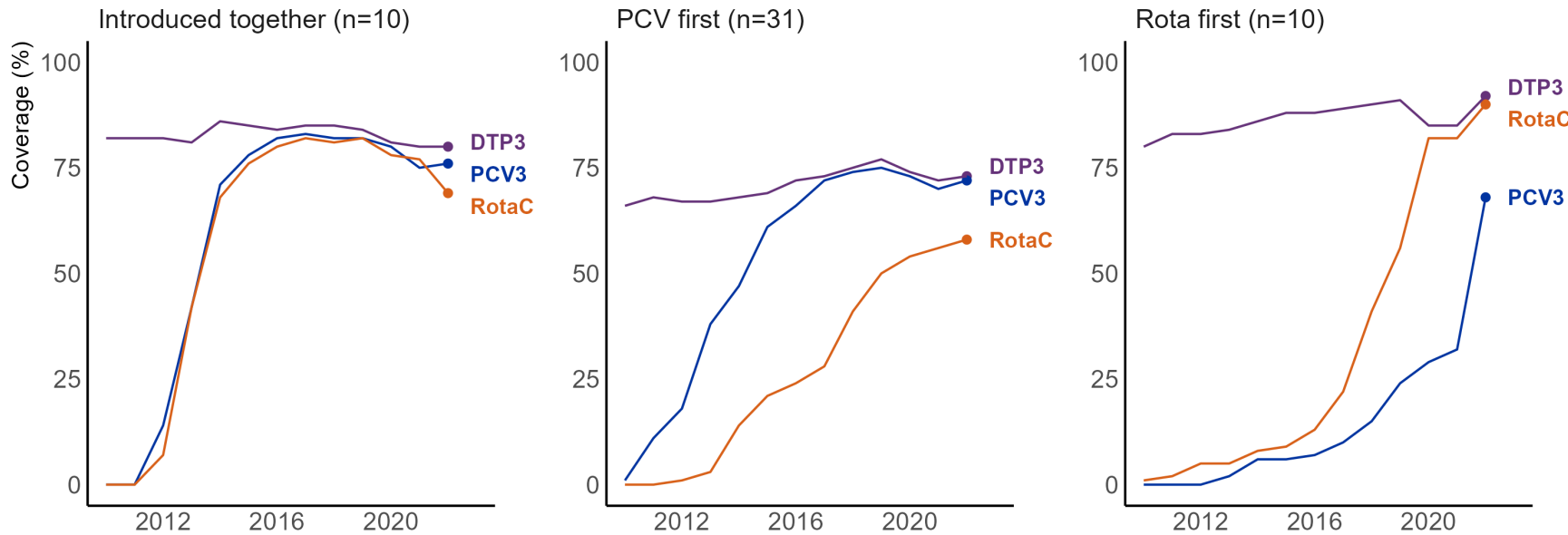
On average, the 30+ Gavi countries that introduced PCV before Rota took another a 3.5 years to introduce Rota.

In the 11 Gavi countries that did introduce PCV but not RVV, **the average time lag is now 8 years.**

# How do coverage of PCV and Rota compare when introduced together vs. introduced separately?

## Coverage by introduction order

Among Gavi countries that have introduced both vaccines



Source: WUENIC, July 2023 release

- Overall we see that among those Gavi68 countries that introduced both PCV and RV **together**, the aggregate coverage is quite close
- Among countries that introduced PCV and RV **separately**, we see higher aggregate coverage of the vaccine that was introduced first

# Impact of PCV and Rota in Gavi countries

## Deaths averted 2000-2022 by vaccine in Gavi68 countries according to PCV/Rota intro status

	PCV	Rota	Total
PCV and Rota introduced at the same time (n=10)	179,043	60,390	239,433
PCV before Rota (n=31)	748,131	108,821	856,952
Rota before PCV (n=10)	113,416	65,595	179,011
PCV only (n=7)	64,856	-	64,856
Rota only (n=2)*	-	1,313	1,313
<b>Total</b>	<b>1,105,447</b>	<b>236,118</b>	<b>1,341,565</b>

- Introducing and scaling PCV and rotavirus vaccines have averted **over 1.3m deaths**
- Impact driven by PCV vaccinations, accounting for over 80% of the deaths averted
- Rotavirus vaccinations confer the opportunity of averting additional deaths
- Co-introducing PCV and Rota provides the opportunity to scale coverage together

\*The two countries, TLS and TJK, introduced PCV in 2022 but we do not yet have WUENIC coverage estimate for 2022

# Gavi support for PCV and Rota

PCV Catchup can only be requested together with PCV routine introduction at launch. Rota and PCV support can be requested independently from each other. A combined launch of PCV and Rota in routine + PCV Catchup can offer significant synergies.

	Rota routine	PCV Routine	PCV Catch-up
Target population:	Children up to 12 months of age	Children up to 12 months of age	Children from 12 months to 59 months of age, to be immunized on a one-off basis within 12 months from introduction
Dose schedule	Full dose schedule (2 or 3 doses depending on vaccine product)	Three dose schedule (either 3+0 or 2+1)	A single dose only
Vaccines support	Standard country co-financing applies <i>Exceptional waiver can be requested in specific country situations</i>	Standard country co-financing applies <i>Exceptional waiver can be requested in specific country situations</i>	<b>All doses financed by Gavi</b>
Cash grant	A one-time Vaccine Introduction Grant at \$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 Vaccine Introduction Grant at \$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 Operations grant (in addition to the VIG) at \$0.65/\$0.55/\$0.45 (as per country co-financing phase) per target child in the catch-up cohort

# Recommended steps to apply for support



**An evidence-based NITAG recommendation** is critical to define the appropriate introduction modality, vaccine and schedule choices for a successful application to PCV and/or Rota support.

## Key questions for PCV introduction

1. Which vaccine product and presentation to use?
2. Which PCV routine schedule to use (3+0 or 2+1)?
3. Will a PCV catch-up campaign be done at the time of launch (if yes: when)?
4. Are there opportunities for integration with other antigens, both for a catch-up campaign and for introduction in routine immunization?
  - *In routine, whether to launch PCV in routine together with vaccination against rotavirus (dose schedule identical in most cases, high potential for impact)*
  - *If introducing PCV and rotavirus vaccine together, which rotavirus vaccine presentations are preferred*



# Gavi Application requirements

## Key requirements for PCV (or Rota) routine support

1. **NITAG / ICC recommendation** supporting the introduction and the choice of product, the presentation, and the dose schedule.
2. **New Vaccine Introduction Plan** including chronogram of activities, confirmation of cold chain readiness and efforts to integrated / link to existing health interventions (including Catch-up plans if requesting catch-up support)
3. **Gavi Budget** template to request VIG support

## Key requirements for PCV Catch-up:

5. Plan use of the **WHO SIA Readiness Assessment** tool
6. Plan to submit a **post-campaign survey** within 3 months of implementation
7. Add a tab for **Operational Support** in the same Gavi budget file

### How to submit:

As a standalone application (no plan to run FPP in next 1-2 years): Use a standard application form and email the application or use the Country Portal

As an FPP application: Use Gavi New Support Detail file (Do not use Country Portal)