Respiratory Syncytial Virus (RSV) Investment Case – Annex B

BOARD MEETING
24-25 July 2025, Geneva, Switzerland

gavi.org

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Executive summary

Respiratory Syncytial Virus: Summary of findings

Gavi key findings

RSV immunisation products to protect infants, a maternal vaccine and a long-acting monoclonal antibody, were approved in-principle through Gavi's 2018 Vaccine Investment Strategy (VIS) due to their significant potential to avert disease burden, particularly in Gavi-supported countries. Gavi's role in shaping the market and ensuring equitable access to the vaccine aided in this decision. However, this initial decision was accompanied by many uncertainties due to the lack of licensed products at the time.

Since the 2018 decision, key pipeline developments have included the licensing and WHO/SAGE recommendation of a maternal vaccine and a mAb for protecting infants, and the WHO prequalification of the maternal RSV vaccine meeting the criteria to potentially open a funding window for it.

RSV continues to be the leading cause of pneumonia in children and the second leading cause of infant deaths. Each year, RSV causes approximately 33 million cases of LRTIs and 3.6 million hospitalisations among children under five, with the highest burden in the first year of life, and an estimated 101,400 annual deaths, over 97% occurring in LMICs, with the highest impact in Africa. Alarmingly, 50-80% of RSV-related deaths occur outside hospital settings in LMICs, underscoring inequities in healthcare access.

A maternal vaccine for protecting infants against RSV, has high projected impact on children mortality and value for money compared to other current investments and VIS 2024 candidates, representing a relatively low-cost investment in Gavi 6.0, as shown by the updated analysis.

Maternal vaccination has long been an established delivery point in Gavi-supported countries, with extensive experience in administering tetanus vaccines. While delivery challenges need to be addressed and continuous investment in ANC is needed, introduction of a maternal RSV vaccine could be done by leveraging existing health systems. However, additional HSS support will be essential to achieve higher coverage, particularly beyond the ANC setting. Disease awareness and demand generation at the community level, and Gavi's support through sustainable funding have been highlighted as critical enablers.

LRTI = Lower Respiratory Tract Infection. LMICs = Low and middle-income countries. ANC = antenatal care. HSS = Health system strengthening.

Key vaccine benefits

	Key benefits	Comments
Strategic fit	**Aligned with SDG3 and IA2030's life-course approach**	• An RSV maternal vaccine would protect vulnerable infants, particularly in Gavi-eligible countries, enhancing Gavi's efforts to safeguard infants. It would also support stronger immunisation policies and IA 2030's life-course service delivery, aligned with the VIS 2024 Board's in-principle support for the Group B Strep maternal vaccine.
Outcome and impact	**High direct impact on mortality and morbidity**	• An RSV maternal vaccine for protecting infants could avert 3.4 million severe cases, 209,000 deaths, and 18.6 million DALYs between 2026-2040 in Gavi-eligible countries. • With no specific treatment available, RSV prevention remains the best strategy to mitigate RSV impact, lower pneumonia cases, prevent infant deaths, and decrease hospitalisations, leading to broader health system benefits.
Value for money	**High value for money when compared to other VIS candidates and existing portfolio**	• An RSV maternal vaccine for protecting infants would have high value for money, with $3.8K per death averted and US$ 43 per DALY averted when compared to the VIS 2024 endemic vaccines candidate and the existing portfolio as well.
Cost		
Feasibility	**Existing vaccination timepoint in countries**	• Existing maternal immunisation programmes can be leveraged. Only one dose needed which simplifies delivery. Offering RSV vaccine during ANC to protect infants may also benefit ANC coverage, uptake, and perceived quality of care
Market implications	**Moderate-country interest and Market Shaping opportunities**	• Consultations indicate that the introduction of a new RSV maternal vaccine is a moderate priority in the short term. To support preparedness and readiness efforts, a Maternal Immunisation Readiness Consortium in Africa and Asia, comprising eight Gavi-eligible countries, is actively working on facilitating its introduction. • Gavi is well-positioned to proactively shape market outcomes and address any market shaping risks that may arise. The leading manufacturer has an access commitment to Gavi-eligible countries.

51 Utilizing total costs (delivery + procurement) for Gavi-eligible countries and Gavi.

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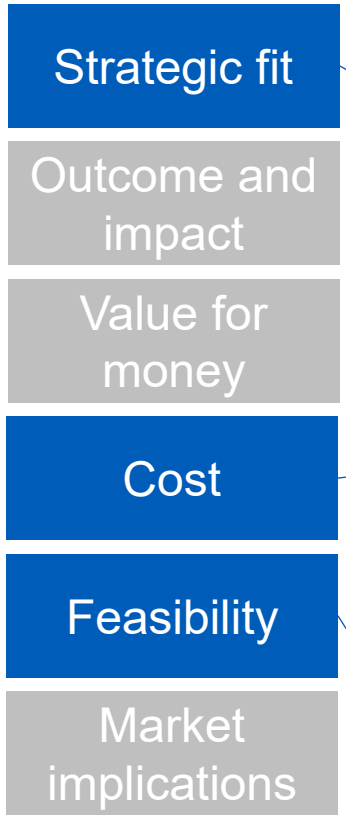
Key vaccine challenges and risks



Key challenges

Antenatal care as a priority for investment and competing priorities

Continuous investment in HSS is needed with still unknown impact of recent US funding cuts

Programmatic challenges need to be addressed

Comments

- In 2024, Gavi's Board did not prioritise cash investments in ANC platform strengthening during the Gavi 6.0 design phase, and potential reductions in HSS funding may further constrain progress. However, averting infant deaths continues to be a key priority.
- Multiple competing priorities for immunisation and maternal, child health programmes.

- ANC investing remains a continuous need, as it is essential for reaching women at the right time during pregnancy.
- With varying levels of ANC service coverage across Gavi-supported countries, additional outreach and alternative delivery models may be required to achieve high coverage beyond what is expected from ANC settings.
- Recent cuts in donor funding for maternal health and ANC services may worsen these challenges, potentially weakening service delivery and limiting vaccine access.

- Awareness gaps or perceptions about new RSV products may affect acceptability. Tailored demand strategies are needed.
- Reaching pregnant women in specific gestational age windows & expanding pregnancy registry surveillance/linking mother-infant records may be challenging in certain settings.

RSV: Summary of health impact, cost, and value for money Gavi-eligible, baseline scenario

Vaccination strategy: Maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy. Baseline scenario.

		Strategic period	*6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons	9.5M	67.7M	236M
		Total future deaths averted	6.9K	60.8K	209K
		Total future DALYs averted	0.6M	5.4M	18.6M
Procurement and Delivery Cost	**Gavi**	Gavi procurement costs	$10.3M	$69M	$231M
		Gavi share of delivery costs[1]	$4.5M	$18.3M	$31M
		Total Gavi cost	$14.8M	$87.4M	$262M
	Country	Country procurement costs	$6.2M	$44.5M	$153M
		Country share of delivery costs	$12.2M	$101M	$386M
		Total Country cost	$18.5M	$145M	$539M
	Total	Total procurement costs	$16.6M	$113M	$384M
		Total delivery costs	$16.7M	$119M	$417M
		Total cost	$33.2M	$ 233M	$802M
Value for money		Gavi cost per death averted	$2.2K	$1.4K	$1.3K
		Gavi cost per DALY averted	$24.2	$16.2	$14.1
		Total cost (Procurement & Delivery) per death averted	$4.8K	$3.8K	$3.8K
		Total cost (Procurement & Delivery) per DALY averted	$54.3	$43.1	$43.1

[1] Gavi's share of delivery cost was estimated using Vaccine Introduction Grant (VIG) costs as per Gavi's current Vaccine Funding Guidelines – VIGs will be consolidated into one cash support envelope in 6.0.

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Previous decisions and key updates

RSV products – Previous decisions

Board Meeting

Nov 2018

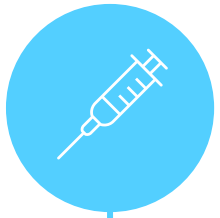
Vaccine Investment Strategy 2018:
RSV immunisation products for protecting infants (maternal vaccine & mAbs) were approved in-principle

Some VIS 2018 investments were paused due to COVID-19 **RSV-eligible** products not yet available

Sep 2020

Recalibrating 5.0 strategy

Pipeline updates



2022 - 2023

New products licensed for protecting infants:

- Maternal vaccine, RSV PreF (Pfizer)
- Long-acting mAb, Nirsevimab (Sanofi/Astrazeneca)

The PPC provided guidance to resume previously paused VIS 2018 vaccines and begin programme design.

May 2023

Unpausing of VIS 2018

Improved burden data and enhanced surveillance enable more informed analysis & decision-making

RSV identified as the leading pneumonia cause in children: The Pneumonia Etiology Research for Child Health (PERCH) Study: A multi-site, international case-control study to estimate causes of pneumonia in children in Bangladesh, The Gambia, Kenya, Mali, South Africa, Thailand, and Zambia.

50-80% of RSV-related deaths occur outside hospital settings: The Child Health and Mortality Prevention Surveillance (CHAMPS) and other studies: conducted mortality surveillance in sub-Saharan Africa and South Asia, and other countries, underscoring inequities in healthcare access.

Afro Region accounts for 40% of all RSV acute LRTI cases: A global, regional, and national disease burden analysis provided clearer insights into age-specific burden in young children and regional differences. Over 95% of RSV-associated acute lower respiratory infections and more than 97% of RSV-related deaths occurred in LMICs.

Stronger surveillance systems are now in place for RSV, with WHO and countries integrating RSV into the Global Influenza Surveillance and Response System (GISRS) platform since 2015, to provide epidemiologic and virologic evidence that informs the introduction of new products

This information, along with increased country-representative data, **supported recent recommendations by key decision-making bodies**—such as HICs & MICs NITAGs, Euro RITAG, PAHO, SAGE and WHO—and may soon inform a potential decision by Afro RITAG (expected June 2025).

The maternal vaccine to protect infants has now met original VIS 2018 investment conditions

Maternal vaccine

- **Single dose** given during the third trimester
- Active immunity to the mother and **passive immunity and protection to the newborn (6mo)**
- **SAGE-WHO recommendation:** ✓
- **WHO Prequalification:** Single-dose vial. ✓ Multi-dose vial expected in 2026.
- **Meeting 2018 financial assumptions:** ✓
- **Licensed and introduced in many HICs & MICs**

Infant mAb

- **Single dose** given at birth or first weeks of life
- **Passive immunity** during the first 6 months of life
- **SAGE-WHO recommendation:** ✓
- **WHO Prequalification:** ✗ Earliest exp. 2029
- **Meeting 2018 financial assumptions:** ✗ (~US$ 200 – US$ 520 per dose). Potentially more affordable mAbs are in the pipeline
- **Licensed and introduced in many HICs & MICs with high coverage**

- **This investment case focuses on the maternal vaccine to protect infants**, because it has met the original investment conditions and the high cost of the currently licensed monoclonal antibody.
- **Specifically, on its multi-dose vial presentation**, due to its expected implementation efficiencies and the manufacturer's commitment to offering terms for Gavi access.

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Key studies have assessed the strength and readiness of the maternal immunisation in Gavi-supported countries, with some focusing on RSV maternal vaccine implementation

- **The country preparedness, key system enablers, and HSS needs** for maternal immunisation in LIMCs were identified.[1]
- **A consortium of 9 countries (8 Gavi-eligible) in Africa and Asia** has been actively working on creating evidence and harmonising MI readiness activities across countries serving as **potential early implementing countries** [2]
- **New maternal immunisation checklists**, tailored to and based on Gavi-supported country needs, are available to help identify potential bottlenecks and key areas for improvement in vaccine introduction. [3]
- **A strong demand generation and disease & product awareness strategy** has been underway, including communication materials, webinars, RITAG presentations, and regional/country workshops.[4]
- **Pilot introduction, Implementation Studies in LICs and a Vaccine Accelerator in Gavi-eligible countries** are being developed to capture the vaccine's full potential public health impact, and expedite and sustain evidence-informed decisions regarding its use. [5]

1 MIACSA, a multi-method study aiming to improve understanding of the challenges and successes of ANC and EPI services in delivering maternal immunisation. 2 Maternal Immunisation Readiness in Africa and Asia : Bangladesh, Burkina Faso, Ethiopia, Ghana, Kenya, Nigeria, Pakistan, Uganda & South Africa. 3 https://www.tandfonline.com/doi/full/10.1080/21645515.2020.1750248 4 WHO & PATH RSV roadshows. 5 Funded by the Gates Foundation

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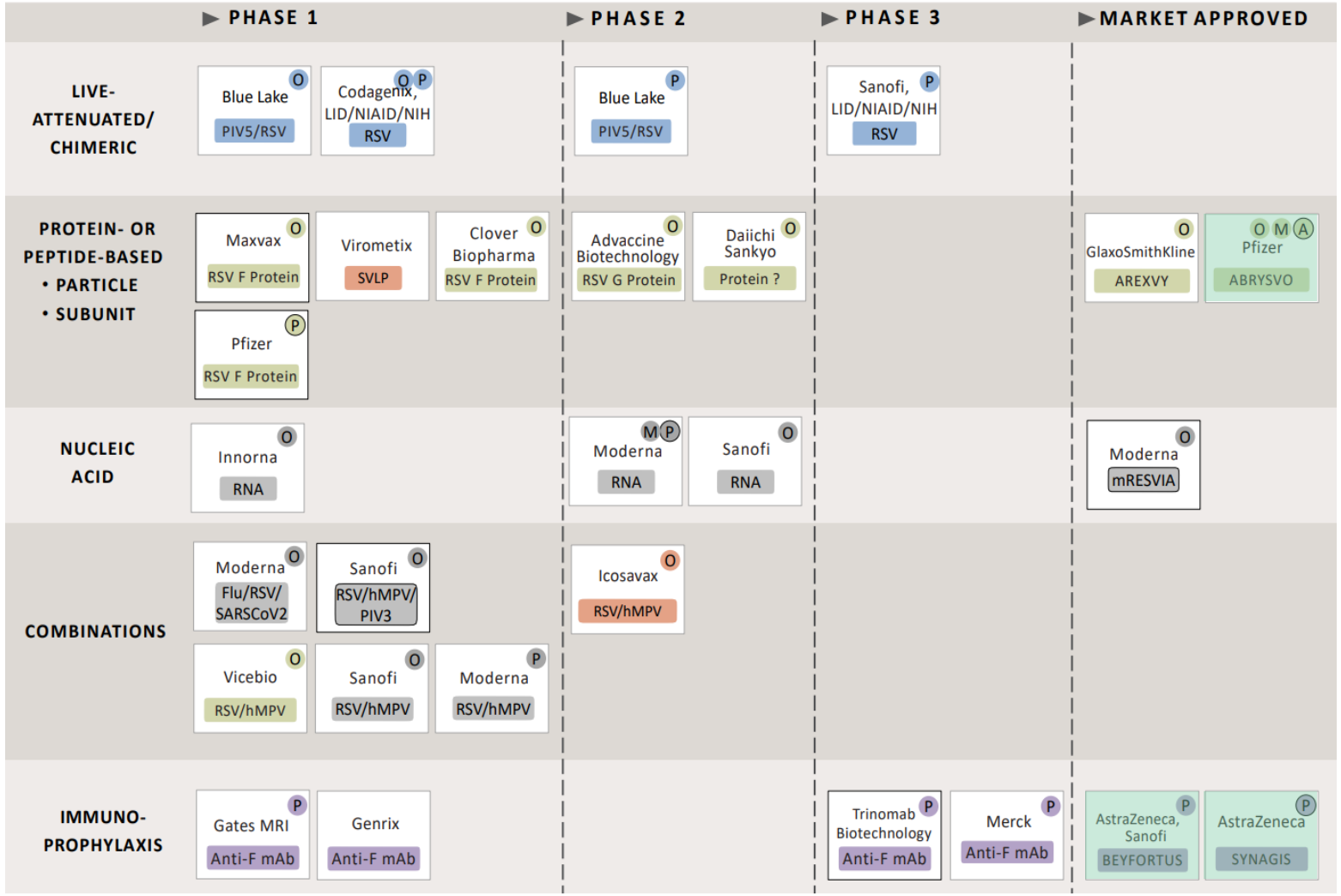
3

Vaccine pipeline & programmatic timeline

Five RSV preventive products now licensed — Three designed to protect infants



Key:
O = Older adults
M = Maternal
P = Pediatric
A = Adult increased risk
■ = To protect infants

- In line with the VIS 2018 in-principle decision, only RSV products aimed at protecting infants were considered
- Promising pediatric candidates aiming to protect older children (second RSV season) were not prioritised.
- Palivizumab (Synagis) was excluded due to its high cost, requirement for multiple doses, and recommendation limited to high-risk children, contrasting with the VIS 2018 focus on long-acting monoclonal antibodies

Source: https://www.path.org/resources/rsv-vaccine-and-mab-snapshot/. Last Updated February 2025.

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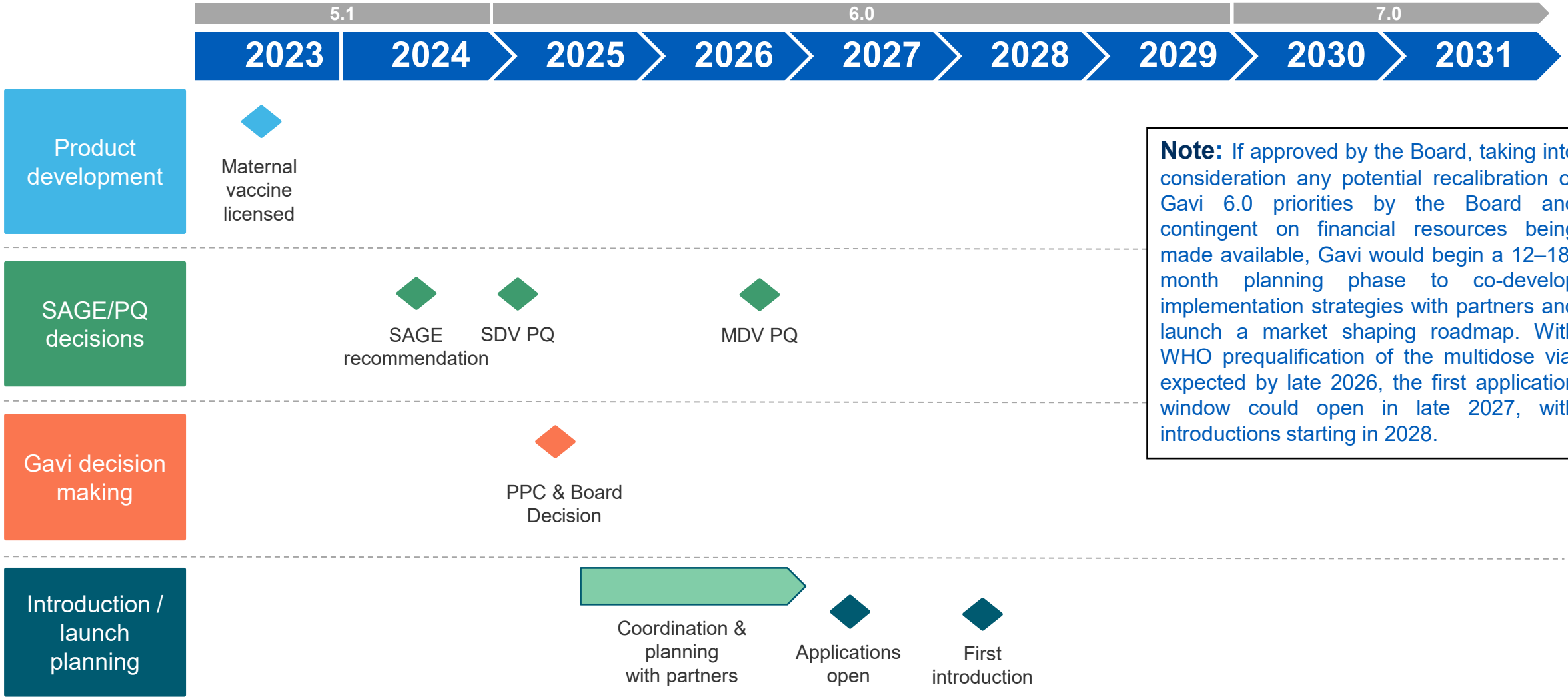
RSV Maternal Vaccine Draft timeline – *estimated June 2025*



Note: If approved by the Board, taking into consideration any potential recalibration of Gavi 6.0 priorities by the Board and contingent on financial resources being made available, Gavi would begin a 12–18-month planning phase to co-develop implementation strategies with partners and launch a market shaping roadmap. With WHO prequalification of the multidose vial expected by late 2026, the first application window could open in late 2027, with introductions starting in 2028.

15 SDV = single-dose vial. MDV = multi-dose vial.

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Updated Demand Forecast

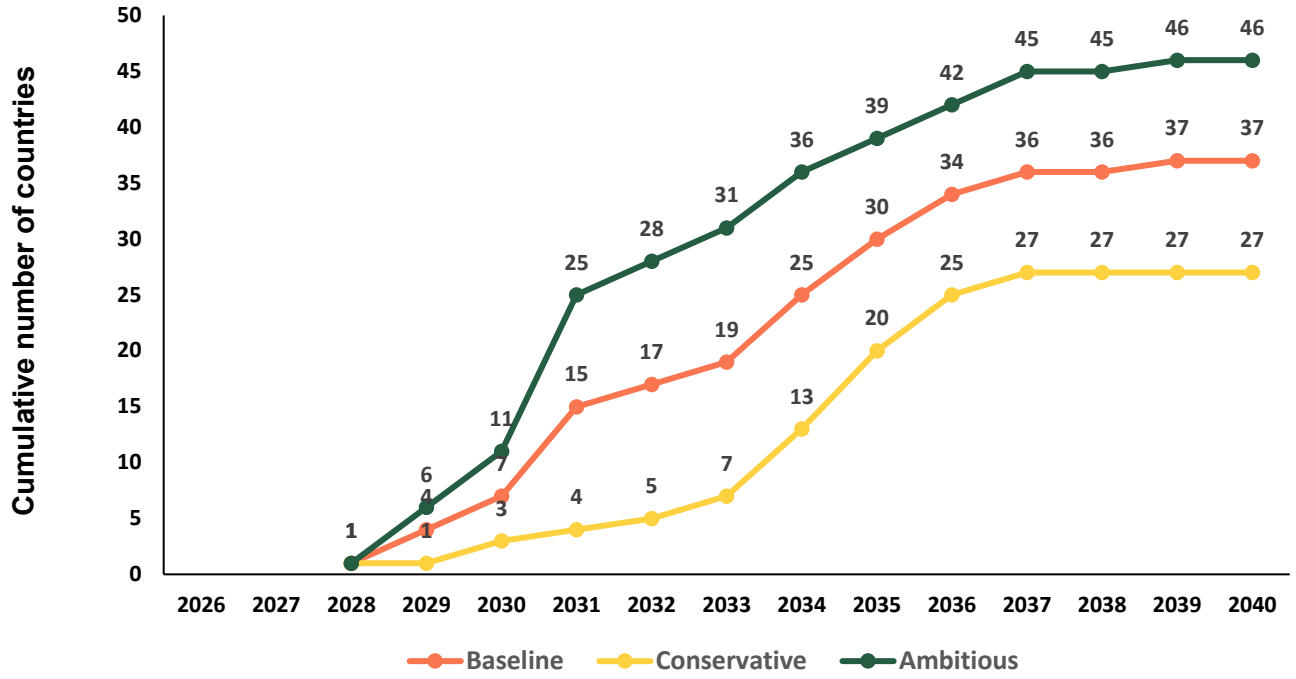
Demand forecasting assumptions

Element	Assumptions	Rationale/source
Country scope	Gavi-54	VIS 2024 country scope and 2025 Gavi-eligibility.
Country introduction scoring	Country specific assumptions influencing adoption: Financial capability / Prioritisation of other vaccines / PW Influenza vaccination policy / MI platform capacity / RSV burden / Participation in RSV studies	Per WHO 2024 RSV Global Market Study
Target population	Pregnant women (3rd trimester)	SAGE recommendation 2024. 2024 World Population Prospect Medium variant projections by single age band, which were adjusted for still birth using still birth rate projections from Lawn et al.
Delivery Strategy	ANC platform – 1 dose. Year round.	SAGE recommendation 2024. Seasonality in Gavi-supported countries.
Introduction dates	Main scenario: 2028. Alternative: 2027.	SAGE recommendation 2024. PQ SDV early 2025. PQ MDV end 2026.
Vaccine uptake	2 Years (80% Y1, 100% Y2) High-Impact countries except. Nigeria (Pakistan, India, Ethiopia, DRC) 3 Years (33,3% Y1, 66.6% Y2, 100% Y3)	Gavi VIS 2024 methodology
Coverage	Modeled ANC coverage during gestation period 28-40 weeks Annual coverage increases were based on the initial coverage level: • Coverage <70%: 3% annual coverage increase • Coverage between 70%-90: 1% annual coverage increase with a cap at 90% • Coverage >90%: no coverage increase over the years.	Expert consultation RSV VIS 2018 Investment Case GBS VIS 2024 Investment case Baral R, et al. 2020.
Products	Anticipated MDV PQ Date: End 2026 Schedule: 1 dose Presentation: Multi-dose packaging, 3 doses	Expert consultation and market intelligence
Logistics	Wastage Factor: 1.13 Buffer stocks = 25% of the difference in demand from the previous year	Standard assumption for routine vaccination

Countries adoption rate per Gavi's VIS 2024 methodology

RSV – maternal vaccine to protect infants

Programme start in 2028



Ambitious scenario: based on rotavirus vaccine introduction rate as an example of high introduction rate with introductions in all Gavi countries.

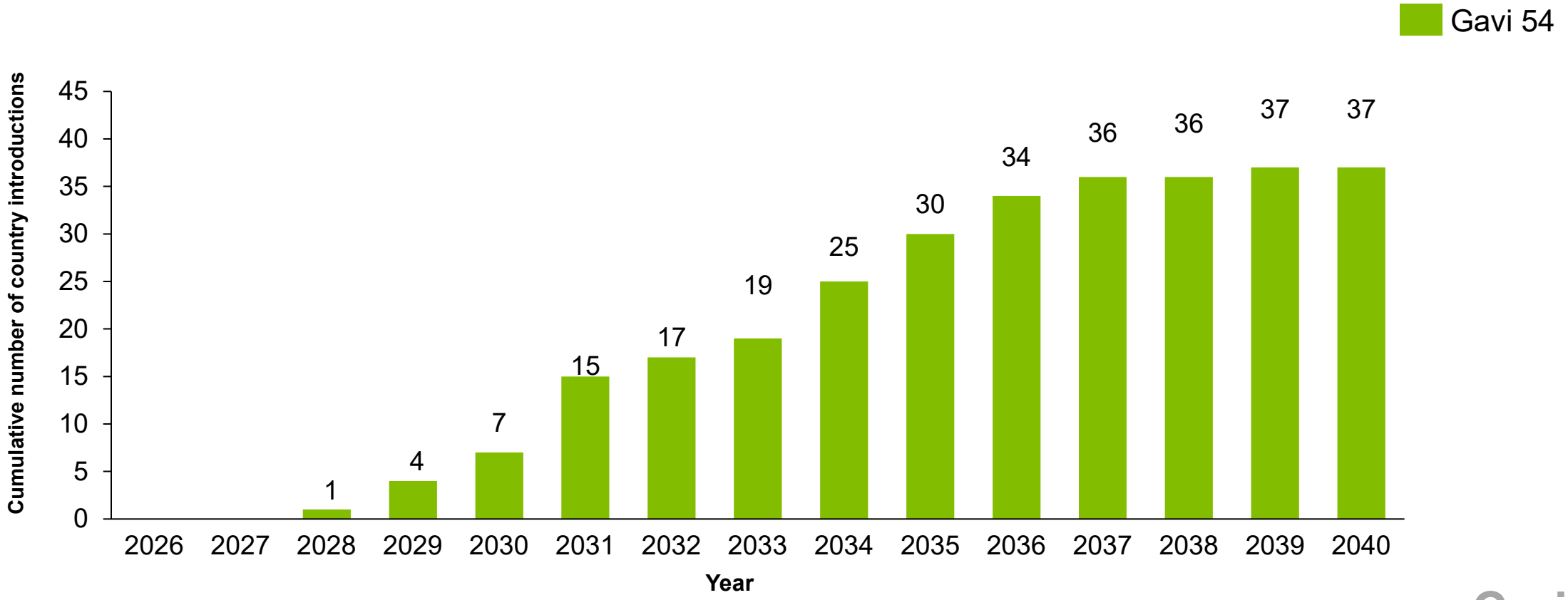
Baseline scenario: set as an average of conservative and ambitious scenarios.

Conservative scenario: based on TCV rate of introduction to reflect lower introduction rate due to 'crowded' vaccine space

The baseline scenario, in which seven countries introduce the vaccine between 2028 and 2030 (Gavi 6.0), is further reinforced by expert consultations and the ongoing participation of countries in key maternal immunisation and RSV studies. Notably, eight Gavi-eligible countries in Africa and Asia are part of the Maternal Immunization Readiness Network in Africa and Asia.

Forecast assumes 37 out of Gavi-54 countries would introduce an RSV maternal vaccine by 2040

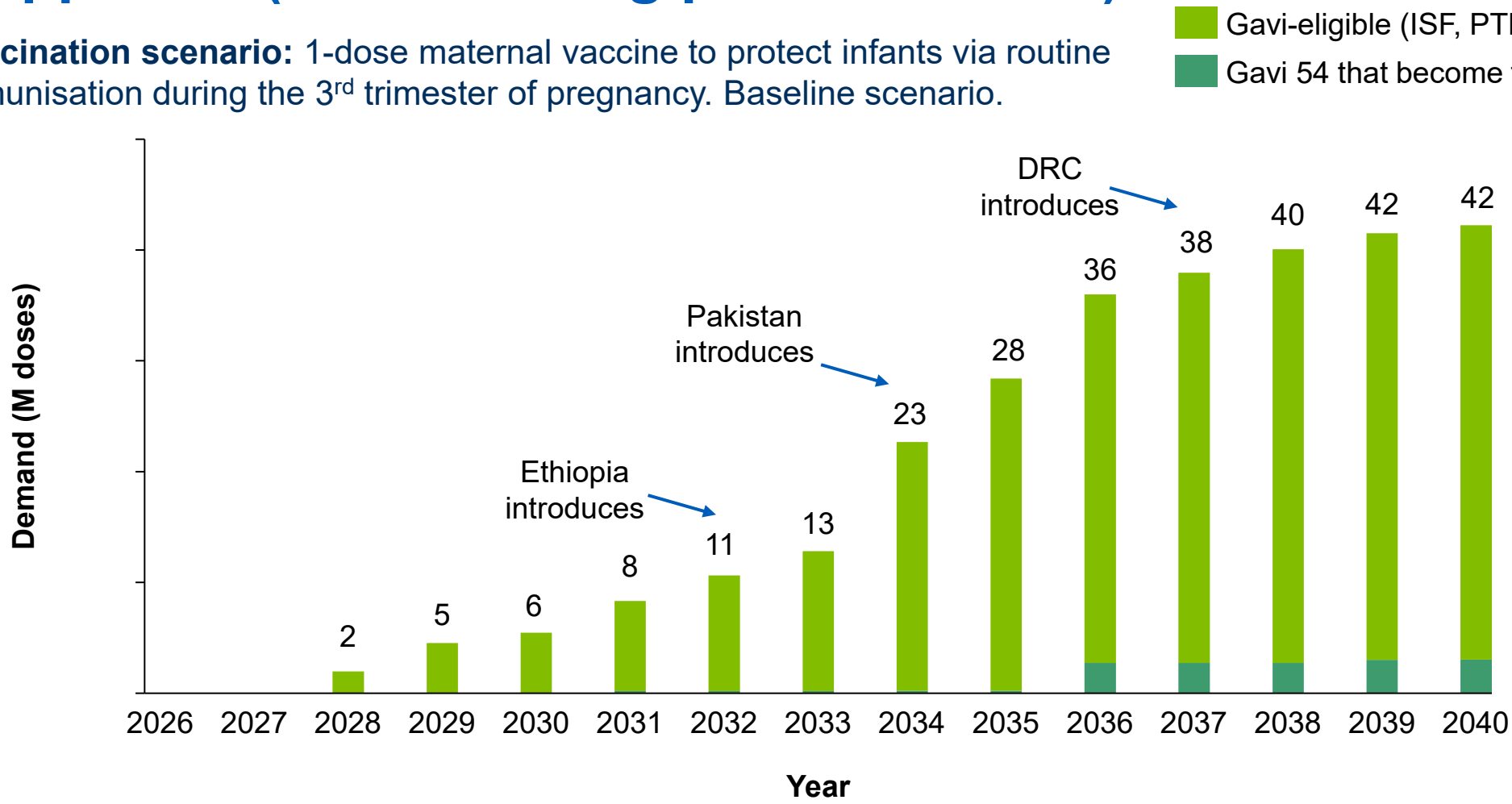
Baseline scenario:
Cumulative country introductions - assumed to start in 2028, based on expected pre-qualification of RSV maternal vaccine multi-dose vial presentation by the end of 2026.



[19] Gavi-eligible countries are based on Gavi's eligibility and transition policy, including ISF, PTP, and ATP. Approach including those Gavi54 that transition to FSF. *NB: Initial Self-Financing phase (ISF), Preparatory Transition phase (PTP), and Accelerated Transition phase (ATP).

Demand in Gavi-eligible countries – routine immunisation ~293 million doses through 2040, of which ~277 million when Gavi supported (i.e. excluding post-transition)[1]

Vaccination scenario: 1-dose maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy. Baseline scenario.



1. Gavi-eligible countries are based on Gavi's eligibility and transition policy, including ISF, PTP, and ATP. *NB: Initial Self-Financing phase (ISF), Preparatory Transition phase (PTP), and Accelerated Transition phase (ATP).

5

Updated Health Impact

Impact modelling assumptions

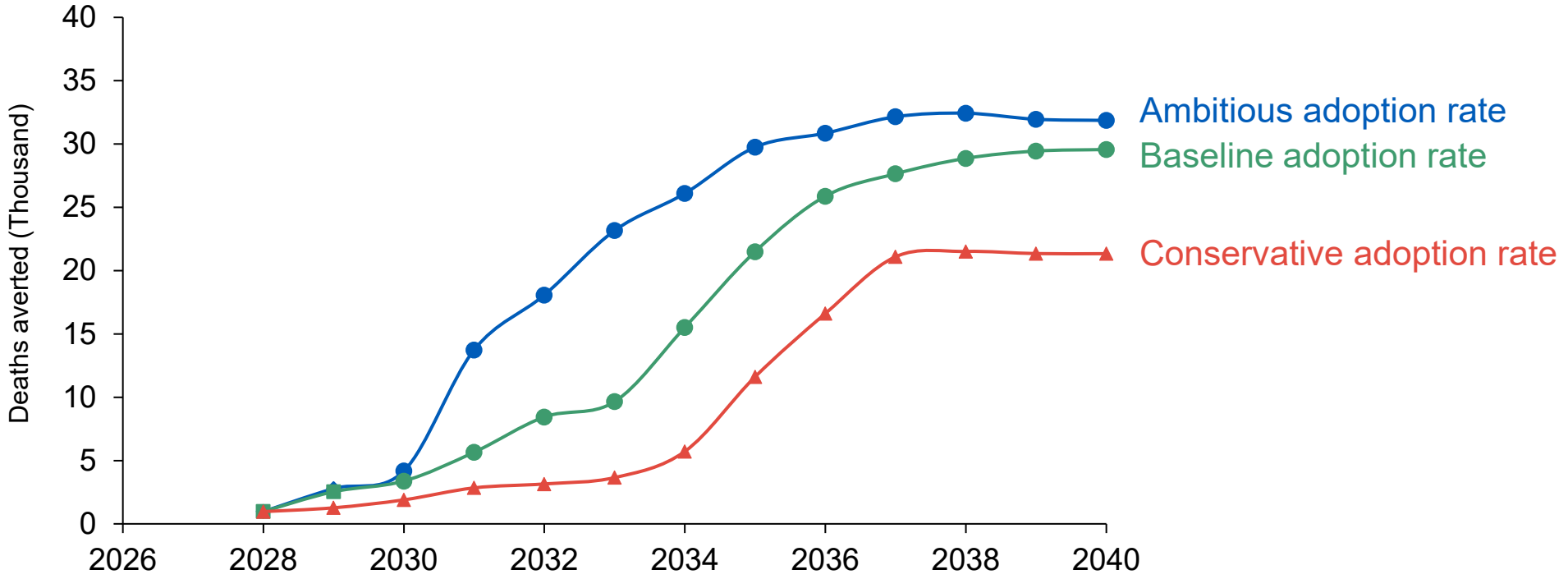
	Assumptions	Rationale / Source
Model	• Name: Gates Foundation Integrated Portfolio Management • Model structure: static model.	• Utilised in VIS 2018 and VIS 2024
Burden of disease	Global, regional and national disease burden in children <5 years. Incidence, hospitalisation, and mortality estimates across WB income regions and development status. Country level estimates for incidence rate for 0-<60 months. Burden scenarios: • **Constant mortality rate:** RSV mortality based on Li Y. 2022 and IHME's FHS for all cause mortality in 2026. Trends in mortality change due to population growth only. RSV incidence rate, mortality rate, and CFR are constant over time. • **IHME forecasted reduction in all-cause mortality:** RSV mortality based on Li Y. 2022 and IHME's FHS for all-cause mortality. Trends in mortality change due to population growth and decline due to the assumed trend in IHME's mortality forecast, due to multiple factors such as improving social demographics, declining risk, etc. RSV incidence is stable over time, and mortality changes; thus, RSV CFR changes over time.	• Li Y, et. al. Lancet 2022.

Efficacy	• **Baseline:** Maternal vaccine (Abrysvo) phase 3 RCT values.
	  • RSV incidence: Severe RSV Cases: 76%. Non-Severe RSV Cases: 52%
	  • Hospitalisations: RSV Hospitalisations = 64%. All cause LRTI Hospitalisation: 31%
	  • Deaths: RSV Attributed/Associated Deaths = 76%. All Cause LRTI Deaths: 23%
	• **Sensitivity:** Based on additional effectiveness data from mAb implementation studies.
		• Phase 3 clinical trial
		• Early implementing countries' mAb effectiveness data

Duration of protection	• 6 months. Exponential waning following vaccination	• Phase 3 clinical trial

RSV maternal vaccine could avert 209,000 total deaths through 2040 in Gavi-eligible countries, 88 deaths per 100,000 fully vaccinated

Vaccination strategy: 1-dose maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy.



Total deaths averted (2026-2040)

Max	278K
Min	133K

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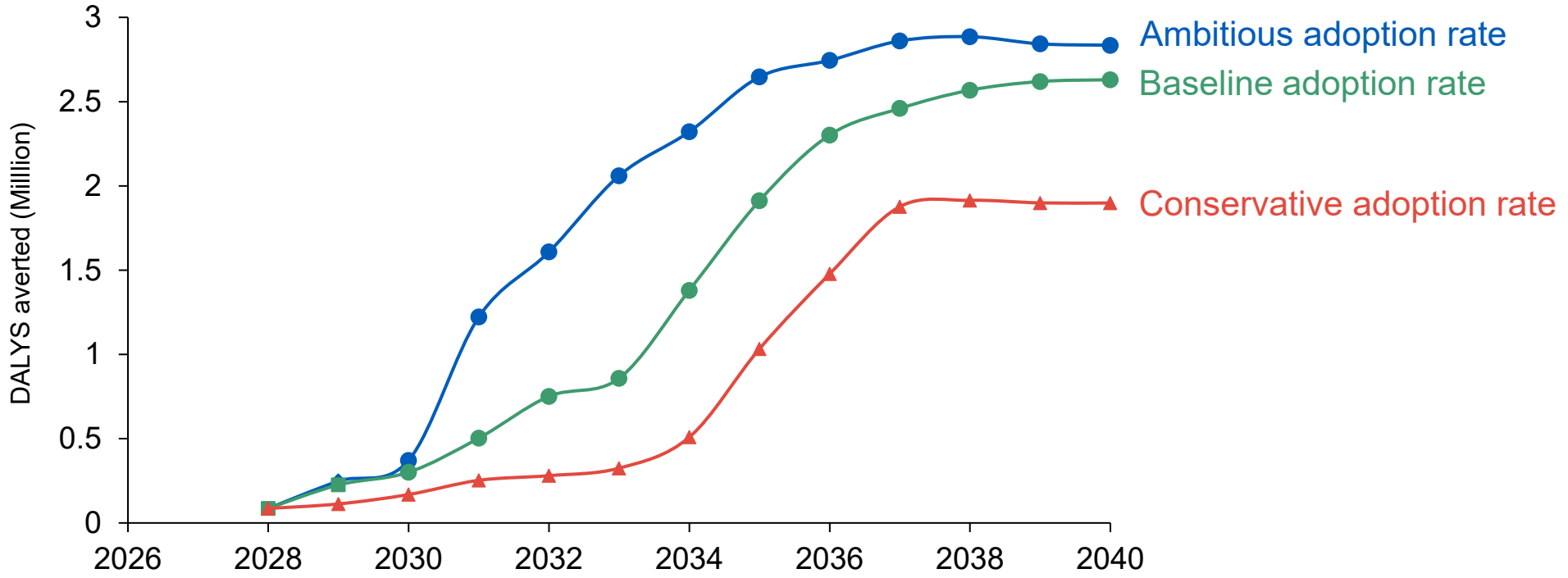
RSV maternal vaccine through routine immunisation could avert 18.6M total DALYs through 2040 in Gavi-eligible countries, 7.8K DALYs per 100K fully vaccinated

Vaccination strategy: 1-dose maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy.



Total DALYs averted (2026-2040)

Max	24.7M
Min	11.8M

1. Gavi-eligible countries are based on Gavi's eligibility and transition policy including ISF, PTP and ATP. MICs countries are based on Gavi's Middle-Income Countries Approach including those Gavi54 that transition to FSF.
2. *NB: Initial Self-Financing phase (ISF), Preparatory Transition phase (PTP), and Accelerated Transition phase (ATP).

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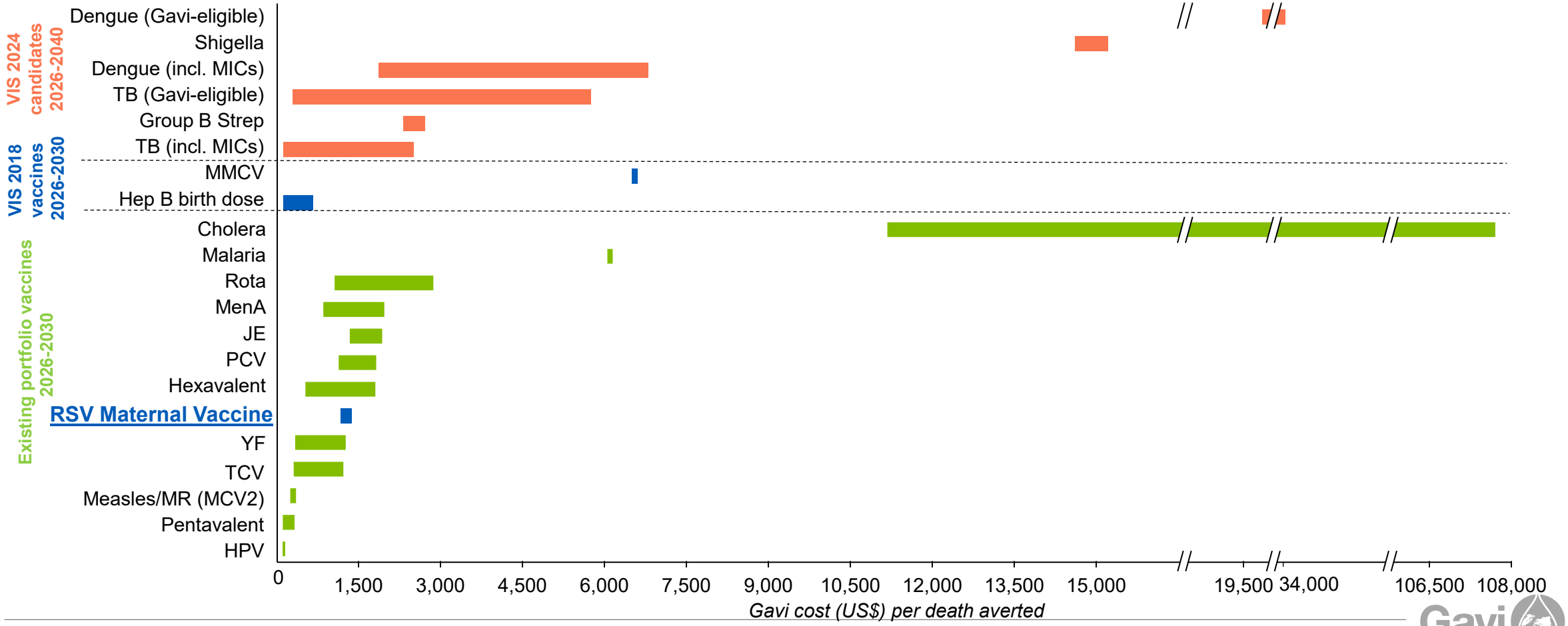
VIS candidate vaccines vs. Current portfolio of Gavi-supported vaccines: Gavi cost (Procurement + Delivery US$) per death averted

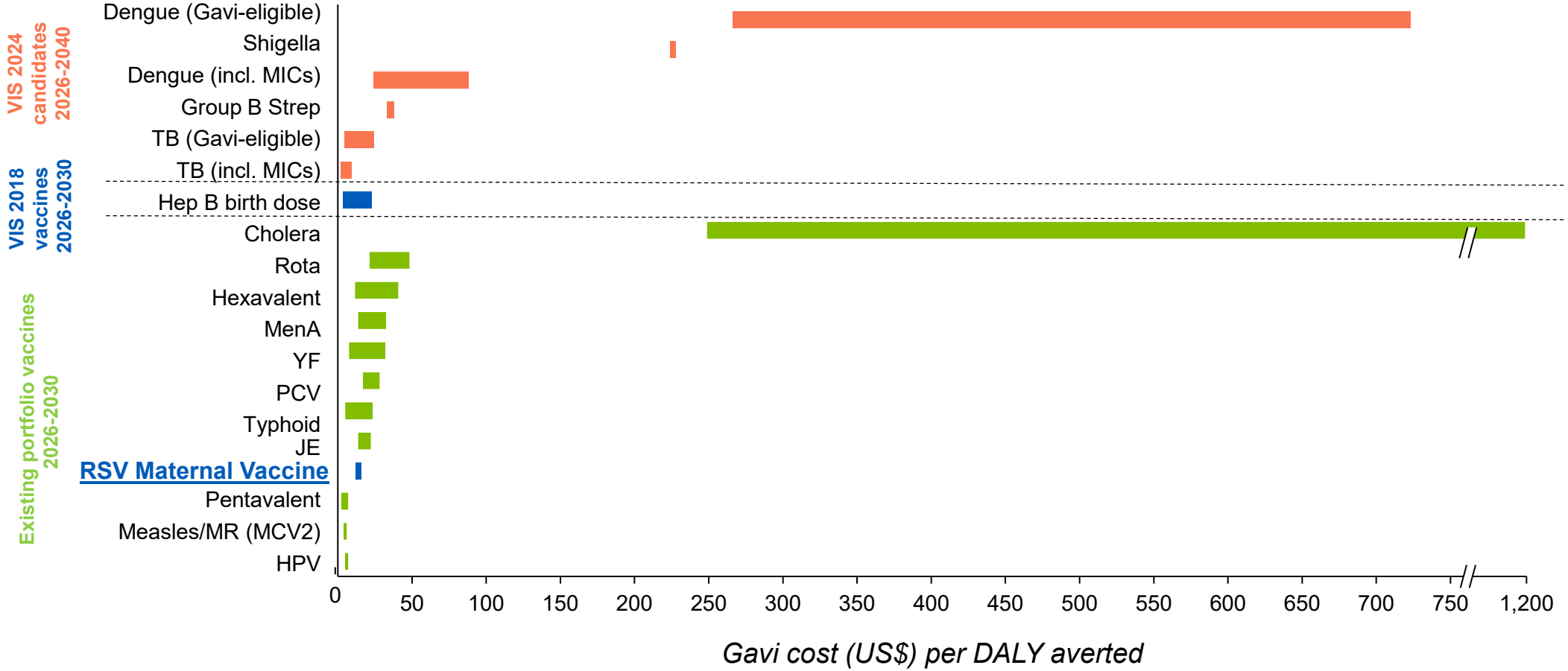
Note: Many of Gavi's current portfolio vaccines have been widely introduced and scaled in Gavi-supported countries. Many VIS candidates will still be in a period of introduction and ramp-up between 2026-2040.



25 Vaccine impact for current GAVI portfolio vaccines is based on Gavi operational forecasting version 21.1 (2026-2030). Vaccine impact for VIS candidate vaccines are based on the investment case (2026-2040). Future deaths averted are not available for vaccines against rabies, or rubella. Estimates of impact were unavailable through VIMC for malaria and MMCV. Indicative point estimates were derived based on investment cases. Gavi does not pay procurement costs for MICs, which drives MICS cost per death averted lower compared to Gavi-eligible.

VIS candidate vaccines vs. Current portfolio of Gavi-supported vaccines: Gavi cost (Procurement + Delivery US$) per DALY averted

Note: Many of Gavi's current portfolio vaccines have been widely introduced and scaled in Gavi-supported countries. Many VIS candidates will still be in a period of introduction and ramp-up between 2026-2040.



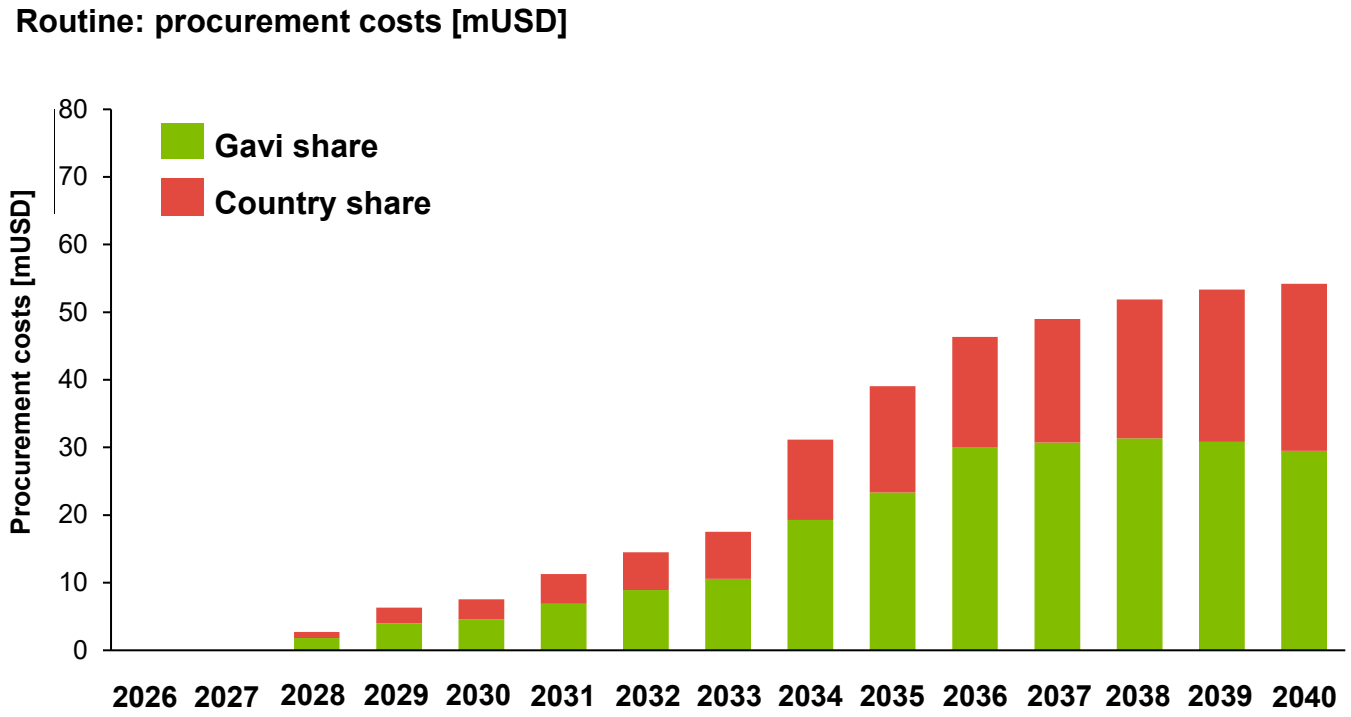
Vaccine impact for current GAVI portfolio vaccines is based on Gavi operational forecasting version 21.1 (2026-2030). Vaccine impact for VIS candidate vaccines are based on the investment case (2026-2040). The future DALYs averted are not available for vaccines against 1st DTP booster, malaria, MMCV, rabies, RSV, or rubella. Gavi does not pay procurement costs for MICs, which drives MICS cost per death averted lower compared to Gavi-eligible.

6

Updated Costs

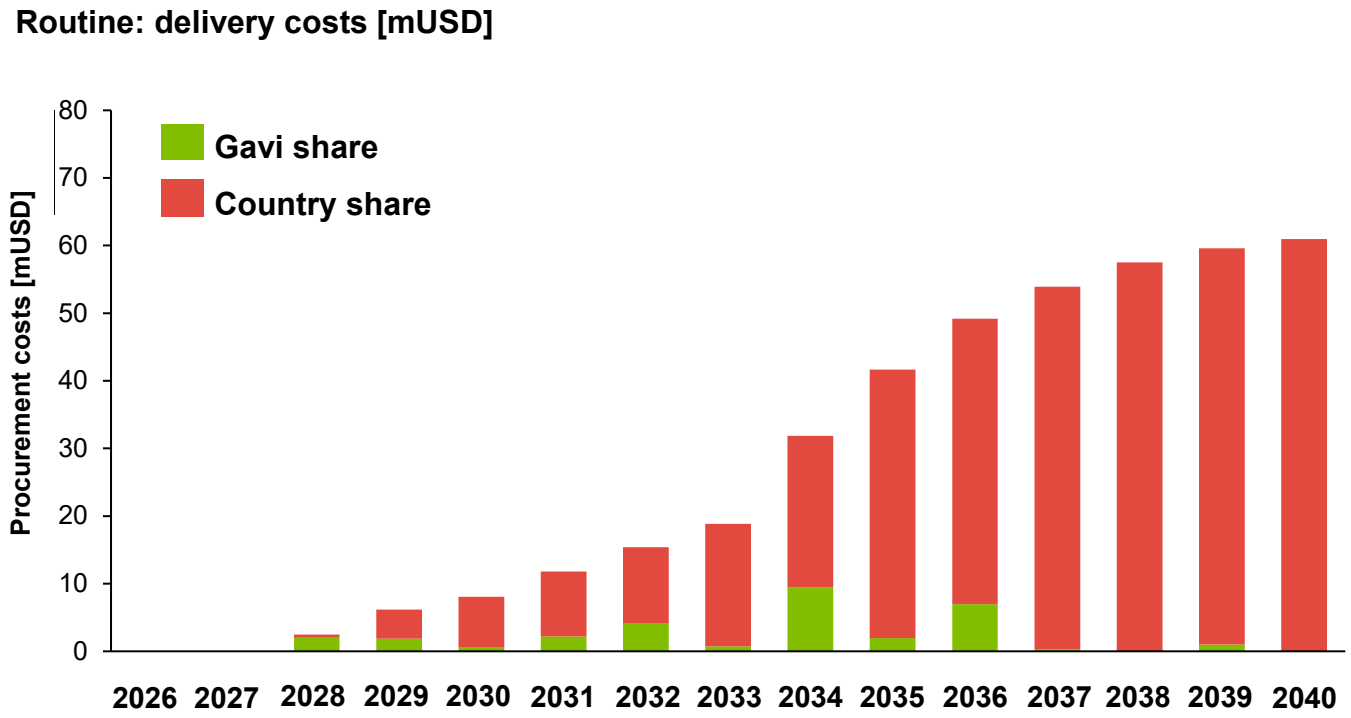
Total procurement costs are estimated at US$ 384 million for Gavi-eligible countries in 2026-2040, with US$ 231 million to be funded by Gavi

Vaccination strategy: 1-dose maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy. Baseline scenario.



Total delivery costs are estimated at US$ 41 million for Gavi-eligible countries in 2026-2040, with US$ 31 million to be funded by Gavi

Vaccination strategy: 1-dose maternal vaccine to protect infants via routine immunisation during the 3rd trimester of pregnancy. Baseline scenario.



Delivery costs provide a view of the full cost to implement these vaccines. They are estimated based on best available costing evidence.

- **Gavi's share of delivery cost** was estimated using Vaccine Introduction Grant (VIG) costs as per Gavi's current Vaccine Funding Guidelines – VIGs will be consolidated into one cash support envelope in 6.0. **During 6.0**, countries will be required to prioritise their consolidated cash envelope towards vaccine introduction support, delivery support through health system strengthening, and technical assistance.

7

Evaluation framework

RSV Vaccine Scorecard: Key criteria

Vaccination strategy presented: vaccination of pregnant women during 3rd trimester

VIS criteria	Indicator	Results	Evaluation[1]
Health impact	Total deaths averted	209,000 future deaths averted, 2026-2040	
	Deaths averted per 100,000 vaccinated	88 future deaths averted, 2026-2040, per 100,000 vaccinated population	
	DALYs averted per 100,000 vaccinated	7.8K future DALYs averted, 2026-2040, per 100,000 vaccinated population	
Value for money	Total procurement cost per death averted	~US$ 1.8K procurement cost per death averted	
	Total procurement cost per DALY averted	~US$ 20.7 procurement cost per DALY averted	
Equity & social protection impact	Impact on vulnerable groups	The disease burden (deaths and DALYs) is higher in low-income and rural poor, with a significant impact on individuals with high-risk conditions. Premature infants and elderly individuals are also at higher risk but may receive limited or indirect protection under proposed strategy.	
	Addresses gender-related barriers	Vaccination of pregnant women, could provide opportunity to reduce gender-related barriers around access to vaccination and improve maternal health care.	
Gavi comparative advantage	Vaccine market challenges	No market shaping challenge identified, although there is a strong and urgent need to clarify the magnitude of the potential Gavi demand as soon as possible to ensure supply is aligned with expected materialization of demand	
	Gavi role in addressing market challenges	Gavi is well placed to engage manufacturers to ensure supply of MDV presentation to LMICs at programme launch	
Economic impact	Direct medical cost averted per 100,000 vaccinated	Not applicable	N/A
	Indirect cost averted per 100,000 vaccinated	Not applicable	N/A

31 Evaluation based on the single value of the vaccine for each criterion. For Health impact and Value for money, evaluation based on comparison against recent VIS 2024 vaccines (TB, GBS, Dengue, Shigella)

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RSV Vaccine Scorecard: Modulating criteria

Vaccination strategy presented: vaccination of pregnant women during 3rd trimester

VIS criteria	Indicator	Results	Evaluation[1]
Global health security impact	Epidemic potential of disease	Not listed in the IHR or WHO R&D Blueprint, RSV is endemic worldwide, which results in a lower outbreak potential	
	Impact on AMR	The vaccine could moderately impact AMR by reducing antibiotic use through vaccine-averted infections	
	Climate change risks and mitigation	No specific risks identified related to climate change	
Other impact	Stillbirths averted	Not applicable	
	U5 deaths, per 100,000	88 future deaths averted, 2026-2040, per 100,000 vaccinated population	
	U5 DALYs, per 100,000	7.8K future DALYs averted, 2026-2040, per 100,000 vaccinated population	
Implementation feasibility	Ease of supply chain integration	Standard storage requirements and MDV presentation is expected. Final MDV presentation characteristics are unknown.	
	Need for HCW behaviour change	No significant healthcare worker behavior change required	
	Requirements of vaccination time point	As part of routine ANC for pregnant women or EPI. All Gavi-supported countries administer tetanus or tetanus/diphtheria vaccine during pregnancy. HSS is required for obtaining high coverage beyond ANC settings.	
	Need for demand promotion	Low vaccine uptake and potential hesitancy must be effectively addressed through demand-generation activities	
	Availability of epidemiological data to inform programmes	There is strong data availability for country and global surveillance of respiratory viruses	
	Diagnostics availability/ needs	Diagnostics are not required for vaccine delivery but are essential for surveillance.	
Alternative interventions	Alternative interventions	No treatment available. RSV infant prevention strategies are key for disease control.	
Contribution to global agenda	Fit with SDGs, IA2030, other agendas, Regional manufacturing	Supporting the maternal RSV vaccine aligns with Gavi's mission, complements existing pneumonia prevention efforts, and strengthens maternal immunisation platforms to enable future vaccine introductions.	
Broader health system impact	Broader health system impact	Preventing RSV through maternal vaccination reduces hospitalisations, antibiotic use, and pneumonia cases, easing pressure on health systems and delivering immediate broad benefits.	

[1] Evaluation based on the single value of the vaccine for each criterion. For Health impact and Value for money, evaluation based on comparison against recent VIS 2024 vaccines

IHR: International Health Regulations
HSS: Health System Strengthening

Gavi The Vaccine Alliance

RSV market assessment and Gavi role

Healthy market framework attribute		RSV market description	Assessment[1]
Supply dynamics	Market sustainability & attractiveness	• **Dual market including HIC and MICs**	
	Geopolitical & regulatory risk	• **No risk identified. One vaccine (SDV) already prequalified, and MDV prequalification expected end of 2026 or early 2027** at the latest	
	Supplier base risk	• One **established US-based supplier** with public commitment to access in LMIC	
	Meeting country product preference	• **MDV presentation, 1 dose schedule**	
	Supply meets demand	• **No supply risk identified**	
Demand health		• **Maternal immunisation is a new timepoint for Gavi,** although there are non Gavi-supported maternal vaccines such as tetanus toxoid as part of ANC visits • **Some countries already working on readiness for RSV,** such as the 8 Gavi-eligible countries part of the Maternal Immunization Readiness Network in Africa and Asia (MIRNA) • **Evidence needed for prioritisation of RSV across an increasing portfolio of vaccines still TBD**	

- **Market shaping challenges:** No market shaping challenge identified, although there is a strong and urgent need to clarify the magnitude of the potential Gavi demand as soon as possible to ensure supply is aligned with expected materialisation of demand
- **Gavi market shaping role in addressing challenges:** Gavi is well placed to engage manufacturers to ensure supply of MDV presentation to LMICs at programme launch

1. Green = health market attribute; Orange = somewhat healthy; red = unhealthy. 2. Bangladesh, Burkina Faso, Ethiopia, Ghana, Kenya, Nigeria, Pakistan, Uganda.
MS: Market Shaping, PQ: Prequalification, SDV: Single-dose vial, MDV: Multi-dose vial

8

Country perspective

Interviews with country stakeholders highlight the existing country readiness for the introduction of the RSV maternal vaccine[1]

What is the country experience in vaccinating PW?

- **All countries currently vaccinate pregnant women** with tetanus toxoid (TT) or tetanus-diphtheria (Td), and plan to deliver RSV vaccination through existing ANC and EPI platforms. This existing integration was echoed widely - there's "no need to reinvent the wheel."
- **Countries emphasized building on established structures**, such as leveraging antenatal care (ANC) visits and coordination across maternal, newborn, and child health (MNCH) programs.

What is the readiness level for its introduction?

- **Maternal immunisation is not viewed as a major challenge**, due to prior experience with TT/Td delivery.
- Many countries are actively engaging their National Immunisation Technical Advisory Groups (NITAGs) early – 6-9 months ahead of potential vaccine introduction - to begin decision-making.

What key factors will enable effective country-level decision-making?

- **WHO/SAGE** recommendations and **Afro RITAG** potential one are supporting and promoting this process.
- **Early NITAG engagement:** Essential for national decision-making, with early involvement encouraged (all MIRNA countries (8 Gavi-eligible) currently engaging with their NITAG).
- **Varying introduction pathways:** Countries have clear but different pathways, with federal nations like Pakistan needing national and provincial approval.
- **Stakeholder and political buy-in**: Political support, including from parliament and regulators (e.g, Nigeria's National Agency for Food and Drug Control), shapes decisions.
- **Data use & needs:** While national representative data are helpful, countries recognize that RSV is widespread, and high-level data is often sufficient. Countries recognise they could rely on regional data for introduction.
- **Respiratory disease priority:** RSV and other respiratory illnesses are a key focus for stakeholders.
- **Professional networks and champions:** Engaging health professional organisations and identifying vaccine champions (e.g. Nigeria) is critical for progress.

1. Stakeholders' consultation and country interviews were conducted through Gavi's RSV Working Group and during the 2nd Annual Meeting of the Maternal Immunisation Readiness Network in Africa and Asia (MIRNA).

Gavi Funding and Demand Generation identified as the key enablers for introduction in country consultations[1]

What are the key enablers for the successful introduction of the vaccine?

- **Leverage existing platforms:** Use of TT/Td platforms and ANC services is widespread and seen as a ready foundation for RSV vaccine rollout.
- **Private sector engagement:** Early involvement of the private sector is crucial.
- **Demand generation & advocacy:** Raising awareness about RSV disease (before vaccine awareness) was emphasized. Professional associations and community leaders are seen as critical partners for advocacy and misinformation management. In countries like Nigeria, decisions are often swayed by influential regional leaders.
- **Early communication & education:** Countries like Kenya are already working to build awareness among mothers and health workers on RSV, vaccine safety, and importance of ANC attendance.
- **Advocacy & policy integration:** Inclusion of maternal immunisation in national ANC guidelines (e.g., Nigeria), involvement of professional associations, and strong vaccine champions will be vital.
- **Coordination across sectors:** Successful rollout will require strong collaboration between EPI & MNCH. Strengthening and continuous investments ANC platforms was noted as a priority (e.g., Burkina Faso). Countries like Kenya and Ghana stressed the need to align across departments (EPI, MNCH, Child Health) early in the process.

What are the expected challenges for its sustainable rollout?

- **Sustainable financing:** The most frequently cited barrier. Involvement of Ministries of Finance is crucial to ensure long-term sustainability. Countries like Burkina Faso and Ghana have fully funded Td vaccines, offering lessons in domestic sustainability. However, **RSV introduction will need Gavi support -** especially for countries in Accelerated Transition (AT) phase graduating Gavi.
- **Worries about the impact of US Funding cuts:** Countries raised concerns on the impact on health systems and ANC of the recent US funding cuts.
- **Stakeholder awareness:** Many decision-makers and communities are still unaware of the full burden of RSV. Countries stressed the importance of initiating disease awareness now, while vaccine-specific messaging can follow once Gavi decisions are made.
- **Competing priorities:** Polio eradication (e.g. in Pakistan) and other pressing health issues may limit attention or resources for RSV introduction.
- **Misinformation & trust**: Ghana raised concerns about misinformation, especially at the district level, requiring proactive communication and trusted messengers.

1. Stakeholders' consultation and country interviews were conducted through Gavi's RSV Working Group and during the 2025 2nd Annual Meeting of the Maternal Immunisation Readiness Network in Africa and Asia.