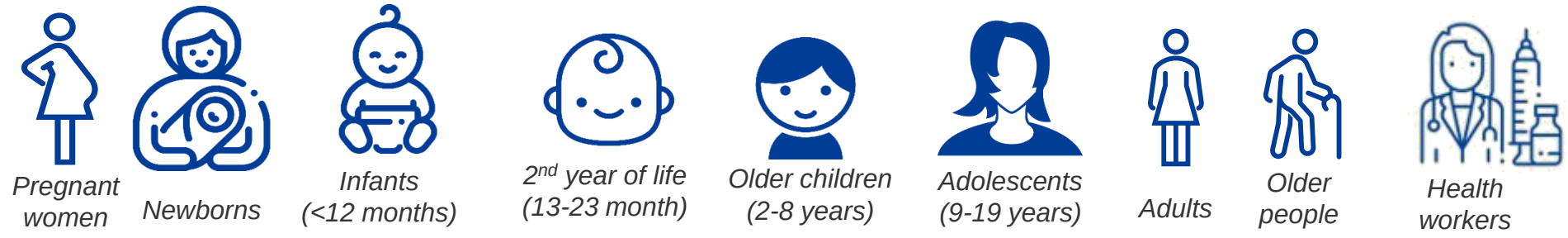
Vaccine Investment Strategy 2024

Annex B: Summary of recommendations and costs

Contents

VIS vaccines represent an expansion to the current portfolio



Existing portfolio

Emergency Stockpiles

C-19 *(until 2025)*

VIS 2018 vaccines

VIS 2024

GBS

Shigella *(not recommended at this time)*

Dengue

TB Dengue

Emergency Stockpiles

Hepatitis E, Mpox*

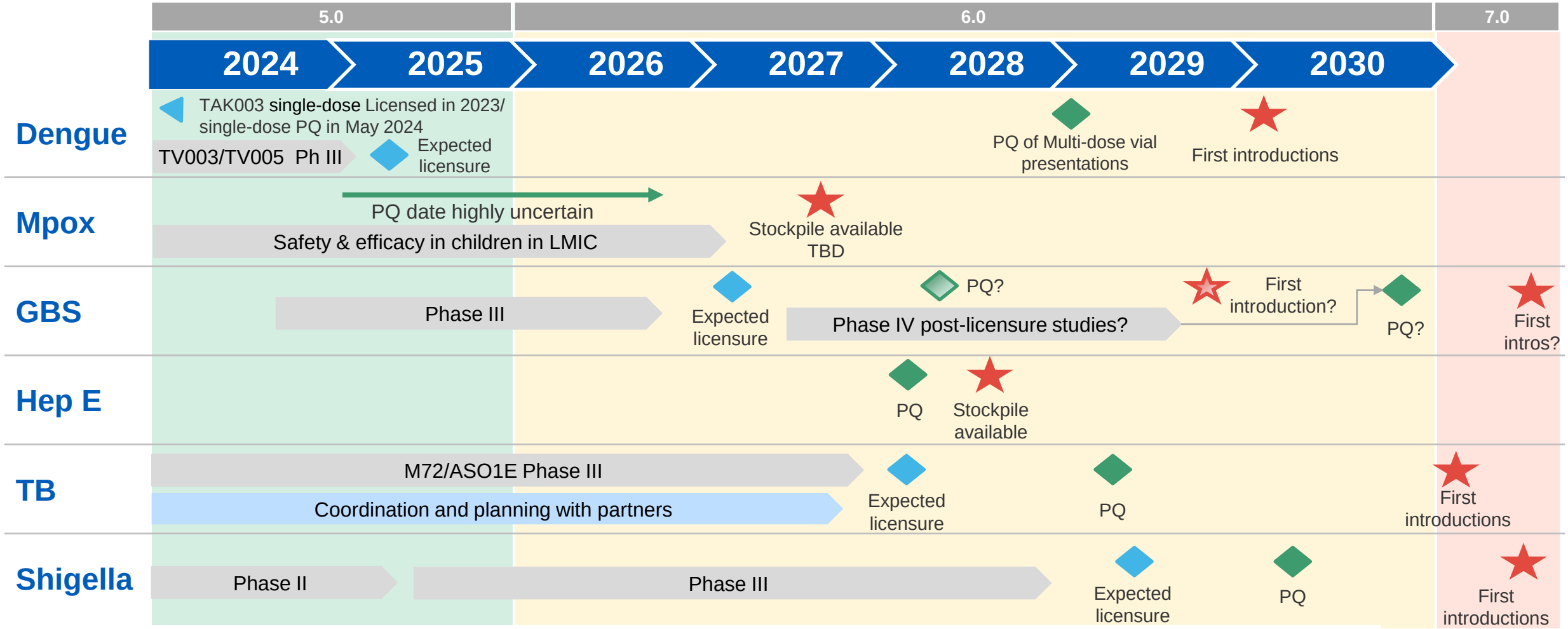
*+additional investment options considering ongoing outbreak in DRC

Gavi The Vaccine Alliance

VIS 2024: recommendations & conditions from the PPC

Vaccine	Support for investment	Learning Agenda	Conditions/Comments
GBS	✓	✓	• Timeline shifted to 7.0, dependent on SAGE recommendation based on correlates of protection • Must be accompanied by support to strengthen maternal immunisation and integration of vaccine delivery in antenatal care and primary care settings, in partnership with other stakeholders
Dengue	Conditional	✓	• Dependent on availability of data on burden of disease in Africa
Tuberculosis	✓	✓	• Vaccine programme not costed in 6.0, possible anticipatory market shaping intervention and programme preparedness activities may require a specific funding solution • Consider routine immunisation at 15y plus campaigns for a narrow age range (~16-18y), SAGE recommendation dependent
Hepatitis E	✓	✓	• Stockpile investment pending regulatory and technical approvals
Mpox	✓	✓	• Stockpile investment pending regulatory and technical approvals
Shigella	✗	✓	• Vaccine not expected until 7.0, too early to recommend • Important to signal to manufacturers to maintain vaccine pipeline
COVID-19 (from 2026)	✗	✗	• Country demand expected to continue to decrease
Chikungunya	**Not shortlisted in Dec 2023**	✗	• Gavi Secretariat to continue to monitor through the living assessment process

VIS 2024 vaccines may only available later in 6.0 – market signaling and preparedness activities required earlier



PQ dates based on earliest expected dates based on expert input

1

Summary of recommendation

Shigella

Shigella: Summary of findings and guidance

Gavi VIS 2024 key findings

Second leading cause of diarrheal deaths

- Affects children <5y of low socio-economic status
- ~90% of disease burden in Gavi-eligible countries

Moderate projected impact on mortality and morbidity and value for money compared to other VIS candidates

- Important additional impact on stunting and development capacity of individuals and countries
- Insufficient data on disease burden and systematic surveillance not in place. Gavi impact would depend on development and scaling of new diagnostic testing.

High risk that without a signal from VIS, a Shigella vaccine may not enter late-stage development, which would be required for the development of a combination vaccine in the future

Guidance from Steering Committee

Support for an investment in Shigella vaccines, given the importance of Gavi's signal to maintain the vaccine pipeline

- Many uncertainties in terms of country demand and disease burden – these should be reevaluated once the vaccine pipeline is further advanced

Guidance from PPC

Requested the Secretariat provide an updated investment case when further information on country product preference, guidance and policy and regulatory pathways is available and endorsed the learning agenda

- Acknowledged the public health importance of a future vaccine programme and the importance of a market signal from Gavi at this time to maintain the vaccine pipeline
- Noted the uncertainty about country demand in the context of other vaccine introductions and a crowded vaccination schedule as well as potential preference for combination products

Shigella: Summary of health impact, cost, and value for money for Gavi-eligible countries only

Vaccination scenario: 2-doses at 9 and 12 months (MCV1/2 coverage), Gavi-eligible only

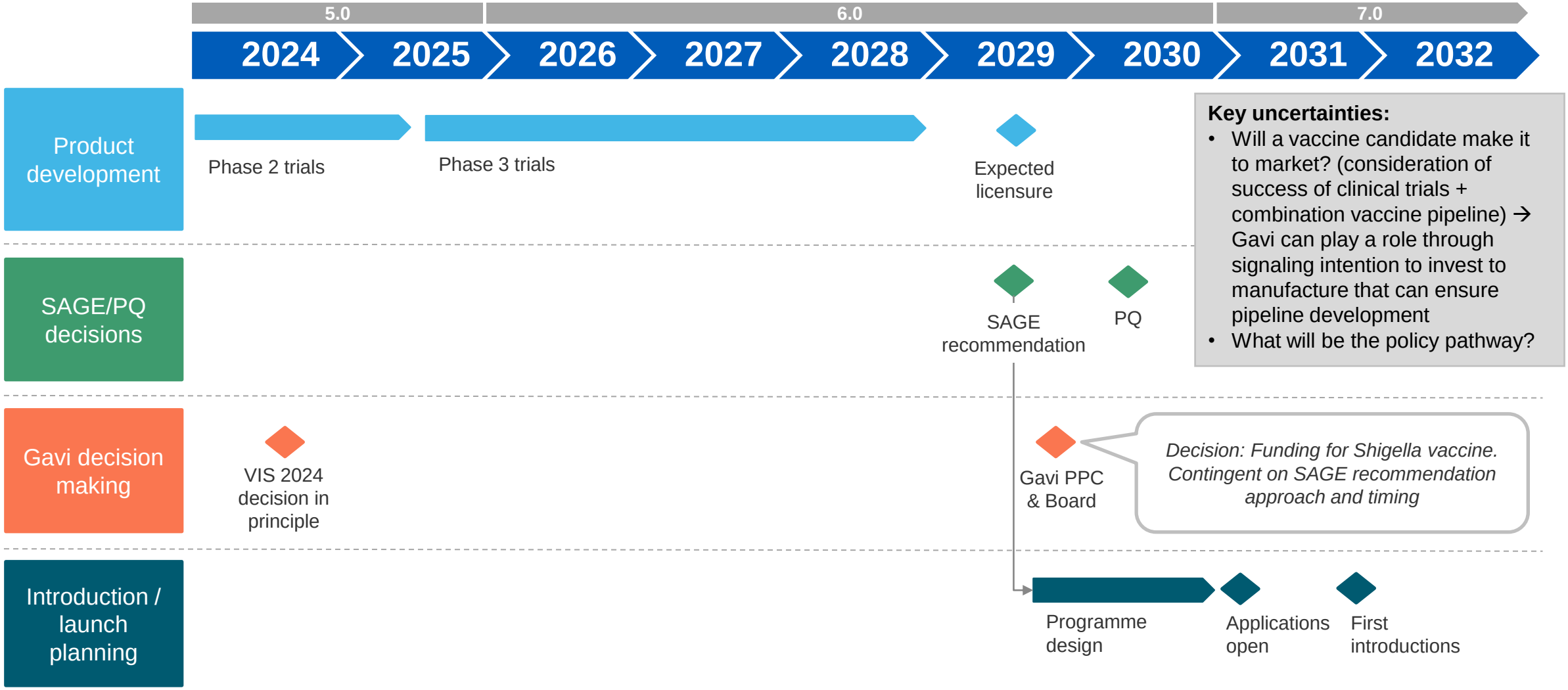
			Strategic period	*6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons		No introductions expected in 6.0 as PQ expected in 2030.	26M	126M
		Total future deaths averted			3K – 5K	17K – 44K
		Total future DALYs averted			0.2M – 0.4M	1M – 3M
Cost	***Gavi***	Gavi procurement costs			US$ 58M – 143M	US$ 252M – 662M
		Gavi share of delivery costs[1]			US$ 1M	US$ 2M
		Total Gavi cost			US$ 59M – 144M	US$ 255M – 664M
	Country	Country procurement costs			US$ 80M – 191M	US$ 386M – 958M
		Country share of delivery costs			US$ 79M	US$ 349M
		Total Country cost			US$ 158M – 270M	US$ 735M – 1.3B
	Total	Total procurement costs			US$ 137M – 334M	US$ 638M – 1.6B
		Total delivery costs			US$ 80M	US$ 351M
		Total cost			US$ 217M – 414M	US$ 989M – 2B
Value for money		Gavi cost per death averted			US$ 22K – 28K	US$ 14.6K - 15.2K
		Gavi cost per DALY averted			US$ 331 – 389	US$ 224 – 228
		Total cost (Procurement & Delivery) per deaths			US$ 79K – 81K	US$ 45K – 57K
		Total cost (Procurement & Delivery) per DALY			US$ 1.1K – 1.2K	US$ 676 – 869

[1]Includes Vaccine Introduction Grant (VIGs) and Operational (Ops) costs

Potential learning agenda questions for Shigella

Objective	Key questions
Burden of disease and climate change / social determinants	• Impact of different environmental threats (climate change, access to clean water sources) on burden of disease • Impact of social determinants (breastfeeding, handwashing practices, living settings) on burden of disease
Feasibility - programmatic	• What programmatic and surveillance requirements are needed for effective delivery of a Shigella vaccine programme? e.g., Timepoint feasibility (crowded schedules), diagnostics support, outreach + awareness around Shigella vs. other enteric diseases
Demand	• What would be the demand for a Shigella or Shigella + X vaccine in Gavi countries?
Total 6.0 cost: ~US$ 2M	

Shigella Vaccine Development timeline – *estimated March 2024*



2

Summary of recommendation

Group B Streptococcus (GBS)

Group B streptococcus: Summary of findings and guidance

Gavi VIS 2024 key findings

Leading cause of neonatal and infant sepsis and meningitis globally

- ~91K deaths and ~57K stillbirths per year

Vaccine ranked 2nd with high projected impact on mortality and value for money compared to other VIS candidates

- Will require strengthening of the maternal immunisation touchpoint

Gavi can help ensure vaccine uptake and demand generation

- Earliest vaccine licensure expected by 2026 based on immune correlates of protection
- Introduction of vaccine in countries might be dependent on evidence from post-licensure studies and thus potentially delayed to Gavi 7.0 strategy
- No significant market challenges are expected

Guidance from Steering Committee

Support for an investment in Group B Streptococcus vaccines, alongside strengthening maternal immunisation and integration of vaccine delivery in ANC and primary care settings

- Vaccine contributes to reducing neonatal mortality which is key to Gavi's mission
- In partnership/with support from other stakeholders due to complexity and level of investment, and linked to the introduction of RSV maternal vaccine
- Include demand generation activities to ensure country demand when vaccine available

Guidance from PPC

PPC recognised the high public health impact of the vaccine and recommends an in-principle investment alongside a learning agenda

GBS: Summary of health impact, cost, and value for money for Gavi-eligible countries only

Vaccination scenario: 1 dose to pregnant people in 2nd/3rd trimester, Gavi-eligible only

		Strategic period	*6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons	-	65M	207M
		Total future deaths averted	-	60K – 115K	193K – 376K
		Total future DALYs averted	-	4M – 8M	14M – 26M
Procurement and Delivery Cost	**Gavi**	Gavi procurement costs	-	US$ 187M – 300M	US$ 520M – 878M
		Gavi share of delivery costs[1]	-	US$ 2M	US$ 3M
		Total Gavi cost	-	US$ 189M – 302M	US$ 523M – 881M
	Country	Country procurement costs	-	US$ 179M – 295M	US$ 535M – 914M
		Country share of delivery costs	-	US$ 102M	US$ 344M
		Total Country cost	-	US$ 280M – 396M	US$ 879M – 1.3B
	Total	Total procurement costs	-	US$ 366M – 595M	US$ 1.1B – 1.8B
		Total delivery costs	-	US$ 104M	US$ 347M
		Total cost	-	US$ 470M – 699M	US$ 1.4B – 2.1B
Value for money		Gavi cost per death averted	-	US$ 2.6K – 3.2K	US$ 2.3K – 2.7K
		Gavi cost per DALY averted	-	US$ 37 – 45	US$ 33 – 38
		Total cost (Procurement & Delivery) per death averted	-	US$ 6K – 8K	US$ 6K – 7K
		Total cost (Procurement & Delivery) per DALY averted	-	US$ 86 – 111	US$ 81 – 103

[1]Includes Vaccine Introduction Grant (VIGs) and Operational (Ops) costs

Potential learning agenda questions for GBS

Objective	Key questions
Burden of disease/ surveillance	• What are the capacity building requirements for programme implementation at national and community level, including vaccine integration into antenatal care (ANC)? E.g., workforce, training requirements and guidelines on roles & responsibilities between ANC/EPI staff, etc.
Demand	• What are the required demand generation activities required for programme implementation at national and community level? E.g. demand creation, acceptability assessment, community engagement – assessment of financial incentives and exemption of user fees for attending ANC
Observational study	• Potential limited-scale observational study in selected Gavi countries with demonstrated burden, to support post-licensure evidence generation
Total 6.0 cost: ~US$ 5.6M	

The level of impact of the GBS vaccine in Gavi countries would be dependent on health system strengthening pursued by partners collectively, demand from countries and guidance on policy pathways and timelines

HSS requirements for strengthening maternal immunisation, examples:

- Strengthening NITAGs
- Surveillance
- Capacity building and coordination of staff between EPI and ANC
- Demand generation and addressing vaccine hesitancy
- Role of partners

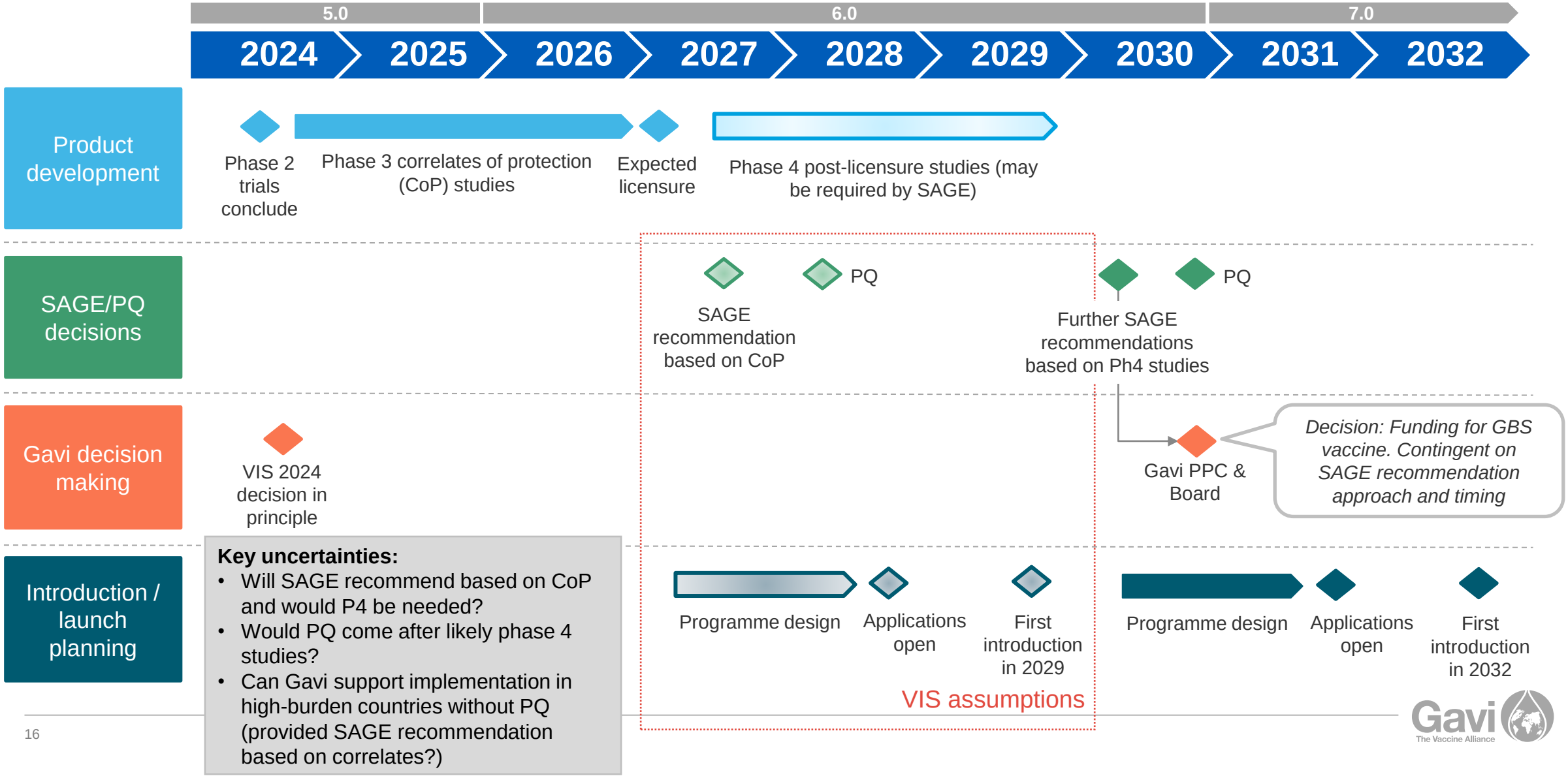
Demand generation:

- Burden of disease and surveillance of disease outcomes poorly surveilled – data gaps in Asia
- Demand generation seen as critical for uptake in Gavi countries

Potential regulatory approval through Correlate of Protection studies:

- Important to understand need of post-licensure studies
- SAGE recommendations

GBS Development timeline – *estimated March 2024*



3

Summary of recommendation

Dengue

Dengue: Summary of findings and guidance

Gavi VIS 2024 key findings

Important disease with ~100M cases/year

- Potential for explosive outbreaks, increased geographic spread and epidemiological changes with climate change

Low projected impact on mortality and value for money compared to other VIS candidates

- A Dengue vaccine in Gavi countries could avert ~390-450 deaths and ~29K-33K DALYs between 2026-2040.* This estimate does not include countries in Africa due to the lack of data.
- Were Dengue to be supported in Gavi-eligible MICs, an additional ~8.6K-9.5K deaths and ~670K-740K DALYS would be averted between 2026-2040*

High impact on health systems due to outbreaks

- Although relatively low mortality, there is high morbidity associated with the disease

Uncertain demand in Gavi-supported countries

- However, one vaccine already licensed, and another expected in next 2-3 years

Guidance from Steering Committee

Support for an investment with the condition that data on burden of disease in Africa is developed

- Insight into disease burden and epidemiology is necessary to inform a programme launch
- Important to signal: a) growing burden of dengue in LMICs, b) importance of vaccines in addressing this, and c) need for more data to better understand disease epidemiology and optimal vaccination strategies

Guidance from PPC

PPC recognised the importance of the changing epidemiology and increased number of outbreaks as highlighted by implementing countries but agreed that availability of burden data from Gavi countries should be a condition for the in-principle decision, and recommends a learning agenda.

*For a routine + campaign vaccination scenario

Dengue: Summary of health impact, cost, and value for money Gavi-eligible, routine + campaign

Vaccination strategy: Routine, 1 dose, 2 yo + Campaign, 3-5 yo, Gavi-eligible seroprevalence > 50%

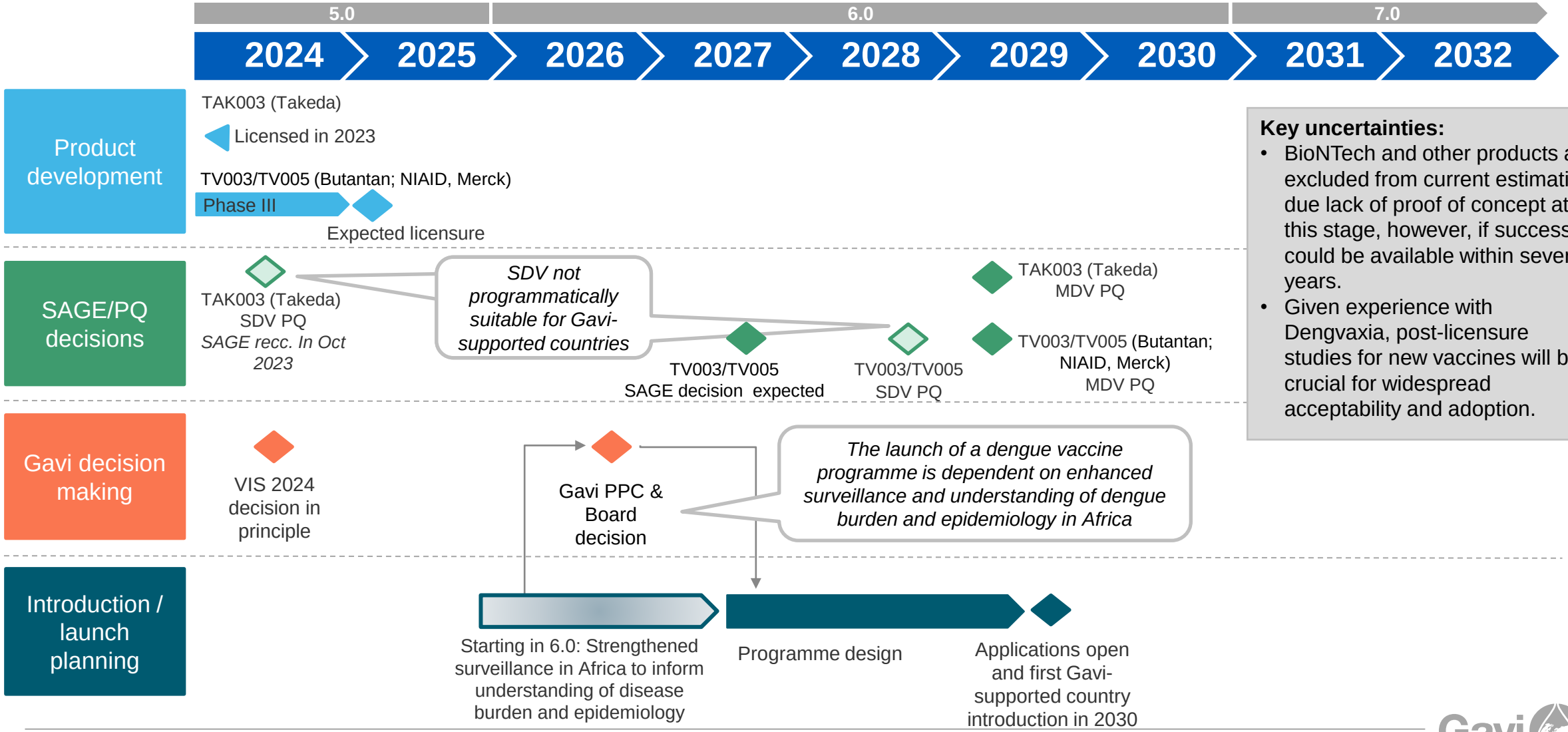
			Strategic period *6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons	1M	2M	4M
		Total future deaths averted	95 - 113	198 - 232	388 - 447
		Total future DALYs averted	7K – 8.5K	15K – 17K	29K - 33K
Procurement and Delivery Cost	**Gavi**	Gavi procurement costs	$3-10M	$3M – 11M	$7M – 23M
		Gavi share of delivery costs[1]	$500K	$500K	$1M
		Total Gavi cost	$3.5M-10.5M	$3.5M – 11.5M	$8M – 24M
	Country	Country procurement costs	$0.4M – 1.3M	$4M – 13.5M	$7M – 25M
		Country share of delivery costs	$4M	$5.6M	$11.2M
		Total Country cost	$4.4M – 5.4M	$9.6M – 19M	$18.3M – 36M
	Total	Total procurement costs	$3.4M – 11.6M	$7M – 24.3M	$14M – 48M
		Total delivery costs	$4.6M	$6M	$12M
		Total cost	$8M – 16M	$13M – 30M	$26M – 60M
Value for money		Gavi cost per death averted	$37.5K - 96K	$18K - 48K	$20K-54K
		Gavi cost per DALY averted	$500 – 1.3K	$240-648	$266-723
		Total cost (Procurement & Delivery) per death averted	$85K - 144K	$66.5K-131K	$67K-134K
		Total cost (Procurement & Delivery) per DALY averted	$1K-2K	$891-1.7K	$896-1.8K

[1]Includes Vaccine Introduction Grant (VIGs) and Operational (Ops) costs

Potential learning agenda questions for dengue

Objective	Key questions
Burden of disease/ surveillance	• Understand the burden of disease of dengue in Gavi-supported countries in Africa to inform the development of a vaccination programme and characterise the disease epidemiology in the region.
Clinical charaterisation	• Need for in-depth clinical characterisation of both symptomatic (including severity of symptoms, course of disease) and asymptomatic cases to identify similarities/ differences
Diagnostics	• What test deployment and testing strategies should be used to determine and monitor dengue incidence/seroprevalence at a site? What are the potential risks and trade-offs, including timeliness and accuracy of results, volume of tests required, confirmatory testing strategies and overall costs? • What kind of capacity assessments and capacity building, including data management and reporting, trainings, should be undertaken prior to deployment of dengue tests, and to integrate such dengue test use into existing disease surveillance systems? • Post Campaign Coverage Surveys to monitor the effectiveness and gaps in vaccination campaigns, including identification of unimmunised and underimmunised children and communities
Vaccine acceptance, safety	• What is the safety and acceptability of dengue vaccine in Africa
Total 6.0 cost: ~US$ 3.5M	

Dengue Development timeline – *estimated March 2024*



Key uncertainties:

- BioNTech and other products are excluded from current estimation due lack of proof of concept at this stage, however, if successful could be available within several years.
- Given experience with Dengvaxia, post-licensure studies for new vaccines will be crucial for widespread acceptability and adoption.

SDV = Single-dose vial; MDV = Multi-dose vial

4

Summary of recommendation

Tuberculosis

Tuberculosis: Summary of findings and guidance

Gavi VIS 2024 key findings

In 2022, TB remained the world's second leading cause of death from a single infectious agent with an estimated 1.3M deaths, while ~10.6M developed active TB disease.

- Immunocompromised patients (e.g. PLHIV*) are at most risk of developing severe disease
- Multi-drug resistant TB is on the rise and remains a public health crisis and a health security threat

Developing new safe, affordable, and effective TB vaccines is considered critical for eliminating TB

- Currently 16 vaccine candidates are in the clinical pipeline

A TB vaccine for adults and adolescents; high projected impact on mortality and value for money compared to other VIS candidates

- Represents a high-cost, high-impact investment; including campaigns and MICs amplifies this considerably

Guidance from Steering Committee

Support for investment case that would include routine immunisation at an adolescent time point (~15yo) and one-off catch-up campaigns for a narrow age range (~16-18yo)

- Need for an early assessment of market-shaping opportunities
- Early alignment and coordination with key stakeholders (e.g. through WHO's TB Vaccine Accelerator Council) and with Global Fund and WHO
- Need for co-financing from global partners to conduct one-off catch-up campaigns (SAGE to recommend approach) and strengthen the adolescent delivery platform

Guidance from PPC

PPC recognised the high public health impact of the vaccine and recommends an in-principle investment alongside a learning agenda

PLHIV= People living with HIV. RI = routine immunisation

TB: Summary of health impact, cost, and value for money Gavi-eligible, routine only[1]

Vaccination strategy: 2 doses via routine immunisation at 15 years old, Gavi-eligible only

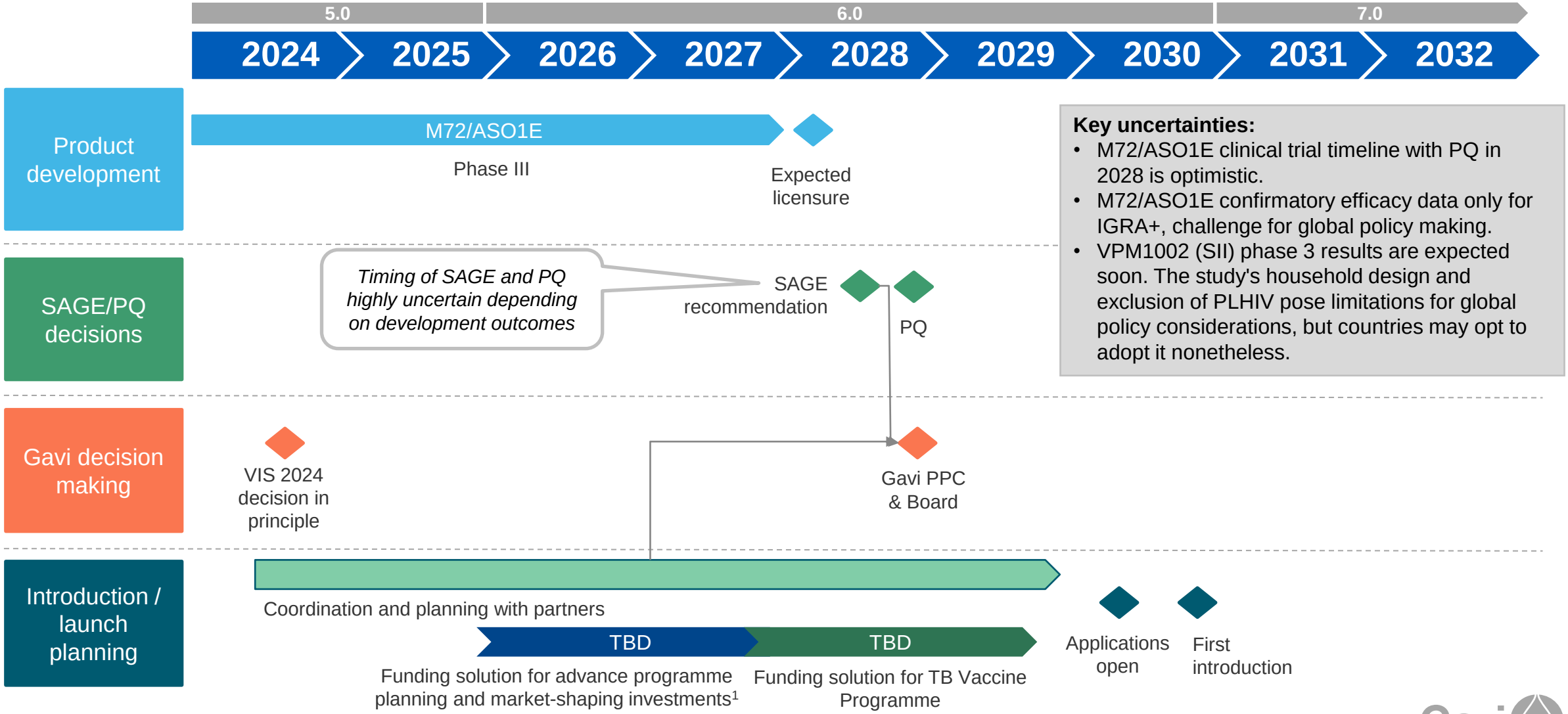
		Strategic period	*6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons	5.1M	74.6M	202M
		Total future deaths averted	6.4K-7.3K	82K-94K	201K-230K
		Total future DALYs averted	2M-2.2M	26M-30M	64M-73M
Procurement and Delivery Cost	**Gavi**	Gavi procurement costs	$10M-41M	$102M-422M	$277M – 1153M
		Gavi share of delivery costs[2]	$800K	$1.9M	$3.6M
		Total Gavi cost	$10.8M-41.8M	$103.9M – 423.9M	$280.6M – 1156.6M
	Country	Country procurement costs	$9M-32M	$127M-450M	$360M-1275M
		Country share of delivery costs	$45M	$562M	$1.5B
		Total Country cost	$54M – 77M	$689M-1.1B	$1.8B-2.7B
	Total	Total procurement costs	$19M – 73M	$229M - 872M	$637M – 2.4B
		Total delivery costs	$45M	$563M	$1.5B
		Total cost	$64M-118M	$ 793M – 1.4B	$2.1B – 3.9B
Value for money		Gavi cost per death averted	$1.6K-6.4K	$1.2K-5.1K	$1.4K-5.7K
		Gavi cost per DALY averted	$5.3-20	$4-16	$4.3-18
		Total cost (Procurement & Delivery) per death averted	$10K-18K	$9.6K-17K	$10K-19K
		Total cost (Procurement & Delivery) per DALY averted	$32-59	$30-54	$33-61

[1]Given the availability uncertainties, costs were excluded from 6.0 forecast. If the vaccine will become available in late 6.0, a specific funding solution will need to be assessed, including the need for potential market-shaping interventions to secure adequate capacities. [2]Includes Vaccine Introduction Grant (VIGs),

Potential learning agenda questions for TB

Objective	Key questions
Implementation & integration	• How can a potential new TB vaccine for adults and adolescents be seamlessly integrated into the existing non-vaccine TB healthcare services and PHC? • What is the feasibility of leveraging existing vaccination infrastructure and delivery platforms to streamline TB vaccine delivery for adults and adolescents?
Identification of Priority Groups	• How can countries effectively prioritize the deployment of TB vaccines at the national level, considering epidemiological data, biological factors, and socio-economic risk factors?
Cost-effectiveness	• What is the cost-effectiveness of introducing TB vaccination compared to continuing existing TB programmes (standard of care), as assessed through analyses of incremental costs and health benefits? • What strategies can be identified to support the long-term integration and scale-up of TB vaccination programmes?
Equity and Access	• What evidence gaps exist in understanding the social, structural cultural, behavioral, and ethical factors that impact the acceptance and uptake by older adolescents?
Total 6.0 cost: US$ 5M	

TB Development timeline – *estimated March 2024*



1 If the vaccine will become available in late 6.0, a specific funding solution will need to be assessed, including the need for potential market-shaping interventions to secure adequate capacities.

Tuberculosis market assessment and Gavi role

Healthy market framework attribute		Tuberculosis market description	Assessment[1]
Supply dynamics	Market sustainability & attractiveness	• **Significant burden in MICs with some level of uncertainty on demand and procurement mechanisms limiting market attractiveness** • Important **interlinkages** between **Gavi 6.0 MICs strategy** and potential market attractiveness	
	Geopolitical & regulatory risk	• **Expected licensure before 2030 for most candidates,** engagement with regulators and PQ started for a few candidates	
	Supplier base risk	• **3 vaccines candidates** in-scope for VIS assessment, although only one with disclosed Phase 2b efficacy data so far	
	Meeting country product preference	• **MDV presentation, 1 or 2-dose schedule**	
	Supply meets demand	• Potential **risk of supply constraints**	
Demand health		• **Pathway to SAGE recommendation clarified** through WHO TB ECVP, **alignment of specific candidates with ECVP to be confirmed**	

- **Market shaping challenges: Risk of supply not meeting demand** for the first few years after launch in most initial-year scenarios and for subsequent years depending on when additional investments are made, and **potential delays in terms of licensure, policy recommendation and/or WHO PQ for some candidates.**
- **Gavi market shaping role in addressing challenges:**
  - Clarify **likely demand scenario at launch and for subsequent years** based on design of an 'early' TB programme with Alliance partners, i.e. before PQ and a SAGE recommendation.
  - **As a function of launch scenario** (e.g., including campaigns or not), work with partners and manufacturers **to explore potential incremental market shaping intervention(s) to ensure supply at launch is adequate, and provide better visibility to manufacturers of potential additional investments needed to ensure timely and broader scale-up for subsequent years.**

MS: Market Shaping, PQ: Prequalification, SDV: Single-dose vial, MDV: Multi-dose vial

1. Green = health market attribute; Orange = somewhat healthy; red = unhealthy

5

Summary of recommendation

COVID-19

COVID-19 programme post 2025: Summary of findings and guidance

Gavi VIS 2024 key findings

Highly transmissible disease that has resulted >**770M confirmed cases and >6.9M deaths reported worldwide**

- Increased risk of severe disease, hospitalisation/ ICU admissions and death among vulnerable populations

Vaccination reduces mortality and morbidity among vulnerable groups

- However, there is uncertainty on country demand of revaccination and potential for scale back of programmes

COVID-19 continues to present new and unpredictable challenges

- Unknown demand and impact of variant specific vaccines due to changing landscape of burden, evolving viral mutation and immune escape
- Limited evidence available on long-term vaccine effectiveness of new/ updated variant specific vaccines
- High heterogeneity across country demand, vaccination uptake and coverage rate

Estimated health impact[1]: A COVID-19 vaccine could avert ~30 deaths per 100K vaccinated and ~1.2K DALYs per 100K vaccinated between 2026-2030 in Gavi 54

Guidance from SteerCo

No support for continued programme post-2025: COVID-19 2024-25 programme provides time for countries to re-adapt their vaccine programme in preparation for Gavi's de-escalating support

Country demand is likely to continue to decrease, especially if countries need to co-finance and make trade-off decisions between vaccine selection and use of resources

No support for a stockpile

Guidance from PPC

PPC noted the recommendation to discontinue the COVID-19 programme from 2026, considering decreased demand from countries and trade-offs for the 6.0 strategic period.

SOURCE: C-19 impact estimates generated by Imperial College, assuming a low-demand scenario of Gavi's COVID-19 demand planning team for 2024 that approximately 17% of high-risk individuals will receive a revaccination dose annually from 2026-2030. (Baseline endemic-type scenario: gradual viral evolution with increased immune escape, constant rate of transmission, severity remains consistent with omicron variant).

Gavi Board approved in June 2023 a continued COVID-19 vaccine programme through 2025

Objective 1

Maximise health impact by continuing to support COVID-19 vaccine delivery for high priority user groups per the SAGE Roadmap (March 2023).

- Older adults, immunocompromised people, pregnant persons, adults with comorbidities, and HC workers.
- Paediatric and adolescent COVID-19 vaccines in 2024-2025 will be supported only for immuno-compromised individuals that fall under these groups.

Objective 2

Continue to support health system strengthening and integration of COVID-19 vaccination into routine immunisation, primary healthcare, and other healthcare services

- Depending on country context and WHO recommendations; and where supported by national commitments and existing delivery platforms to achieve mutual benefits for COVID-19 and routine immunisation.

All AMC 91 countries are eligible for support

Gavi-eligible 54 (**Gavi 54**) countries are eligible for full vaccine procurement without co-financing obligations.

COVAX AMC

The AMC 37 (the former- and never-Gavi eligible countries which received COVAX support) are eligible for 50% vaccine procurement support and for delivery support through existing CDS resources. This support refers to COVID-19 vaccine procurement, inclusive of procurement associated costs.

2024-25 COVID-19 programme underway

2024

Focus: high-priority groups

Demand:

- Requests for 83M doses from 58 countries & territories
- **68 million doses approved**, inclusive of 50% reduction for AMC37 countries

Products: Variety, including XBB and ancestral strains

2025

Focus: high-priority groups

Demand:

- One application window in June-July 2024
- Estimated demand **~30-40M doses**, with high uncertainties

Products: Programmatically suitable PQed or EULed

Vaccine procurement		Delivery		Technical Assistance
~US$ 813 million	+	~US$ 220* million	+	~US$ 47 million

Follow SAGE recommendations on priority groups, vaccination schedule, and vaccine recommendations for platforms and portfolio

Gavi The Vaccine Alliance

Investment Options Summary

Increasing investment and impact

1. Do not extend current programme post-2025

Cost: US$ 0M, *potential operational costs to sunset programme*

Recommended by Steering Committee

2. Continued programme with base support as per standard Gavi policies

Cost to Gavi (procurement): US$ 47-108M
Cost to Countries (procurement): US$ 2M
Cost to countries (delivery): US$ 42M
No continued learning agenda

3. Continued support in line with current C-19 programme

Cost to Gavi (procure.): US$ 222-496M
Cost to Countries (delivery): US$ 154M
No continued learning agenda

Not recommended

A stockpile was not recommended by Steering Committee as it would require:

- Very flexible arrangements with manufacturers to ensure that correct vaccine is available
- Broad protective vaccines are still 5+ years in the future
- Stockpile to tackle a significant outbreak would need to be very large

Gavi The Vaccine Alliance

6

Summary of recommendation

Hepatitis E

Hepatitis E: Summary of findings and guidance

Gavi VIS 2024 key findings

Increased frequency of outbreaks in internally displaced populations (IDP) camps – often fatal for pregnant people

- Approximately 4-5 reported outbreaks are notified per year from countries (Gavi55 + MICs)

High value for money investment aligned with global partner activities on Hepatitis E

- MSF stockpile already deployed twice in S. Sudan
- BMGF commitment to fund a 3-year stockpile to support evidence generation
- Gavi can ensure continued availability of a small stockpile for outbreaks and equitable access where other countermeasures are challenged

Gavi signaling could contribute to the existing vaccine becoming prequalified

- Vaccine prequalification expected by 2028

Guidance from Steering Committee

Support for investment in stockpile when PQ'd vaccine available (~2028)

- Provide a strong signal to BMFG and MSF to continue their pilot stockpiles with existing vaccine until vaccine is PQ'd to ensure that there is no gap in access

Guidance from PPC

PPC recommends an in-principle stockpile investment alongside a learning agenda from 5.1

Hepatitis E: Summary of health impact, cost, and value for money assuming availability of a Gavi stockpile as of 2029

Vaccination strategy: 3 doses to individuals >15y of age, including pregnant people; 100k doses per year

		Strategic period	*6.0* **2026-2030**	*7.0* **2031-2035**	*6.0 & 7.0 & 8.0* **2026-2040**
Impact		Fully vaccinated persons	21K – 106K	53K – 266K	128K – 640K
		Total future deaths averted	200 – 1K	500 – 2.5K	1K – 6K
		Total future DALYs averted	10.3K – 51.4K	25.7 – 128.5K	62K – 308K
Procurement and Delivery Cost	**Gavi**	Gavi procurement costs	US$ 447K – 2M	US$ 1M – 6M	US$ 3M – 14M
		Gavi share of delivery costs[1]	US$ 57K – 286K	US $143K – 716K	US$ 343K – 2M
		Total Gavi cost	US$ 500K – 2.5M	US$ 1M – 7M	US$ 3M – 16M
	Country	Country procurement costs	$ 0	$ 0	$ 0
		Country share of delivery costs	$ 0	$ 0	$ 0
		Total Country cost	$ 0	$ 0	$ 0
	Total	Total procurement costs	US$ 447K – 2M	US$ 1M – 6M	US$ 3M – 14M
		Total delivery costs	US$ 57K – 286K	US $143K – 716K	US$ 343K – 2M
		Total cost	US$ 500K – 2.5M	US$ 1M – 7M	US$ 3M – 16M
Value for money		Gavi cost per death averted	US$ 2.5K	US$ 2.6K	US$ 2.7K
		Gavi cost per DALY averted	US$ 49	US$ 51	US$ 52
		Total cost (Procurement & Delivery) per death	US$ 2.5K	US$ 2.6K	US$ 2.7K
		Total cost (Procurement & Delivery) per DALY	US$ 49	US$ 51	US$ 52

1. Based on Gavi Modellers' estimated outputs

Total costs same as Gavi costs as Gavi typically covers procurement and Ops costs for stockpiles for Gavi-supported countries

Gavi The Vaccine Alliance

Potential learning agenda questions for Hepatitis E

Objective	Key questions
Feasibility	• What are the financial and programmatic (surveillance, lead-times, logistics) needs for vaccine delivery in outbreak settings (to include a variety of contexts, including internally displaced populations, epidemics in African region or endemic contexts in South East Asia)? • What is the relative feasibility against WASH interventions?
Demand	• What is the demand for the vaccine in Gavi countries? When would vaccination be an appropriate intervention measure, considering other countermeasures? To consider both endemic and epidemic settings.
Diagnostics	• What rapid diagnostic test (RDT) deployment, testing and confirmation strategies should be used in different settings of interest (e.g. IDP camps, areas with unimproved or no WASH facilities) for timely and accurate detection of and response to outbreaks through evidence based targeted vaccination campaigns? • How can Gavi's yellow fever network be leveraged for improving access and use of Hep E diagnostics? • What kind of capacity assessments and capacity building, including data management and reporting, trainings, should be undertaken prior to deployment of Hepatitis E RDTs? • Which tests are demonstrated to accurately detect Hep E, and what is their diagnostic accuracy?

Total 6.0 cost: ~US$ 3.5M

Hepatitis E vaccine: Gavi historical considerations and key changes to vaccine context

VIS 2013 decision and key findings

Not short-listed :

- Low health impact
- Sub-optimal product profile with uncertain supply prospects

VIS 2018 decision and key findings

Not short-listed :

- Removed due to unavailability of burden of disease data
- Health impact considered too low
- No proof-of-concept of use in outbreak settings
- Lack of clinical data in pregnant women

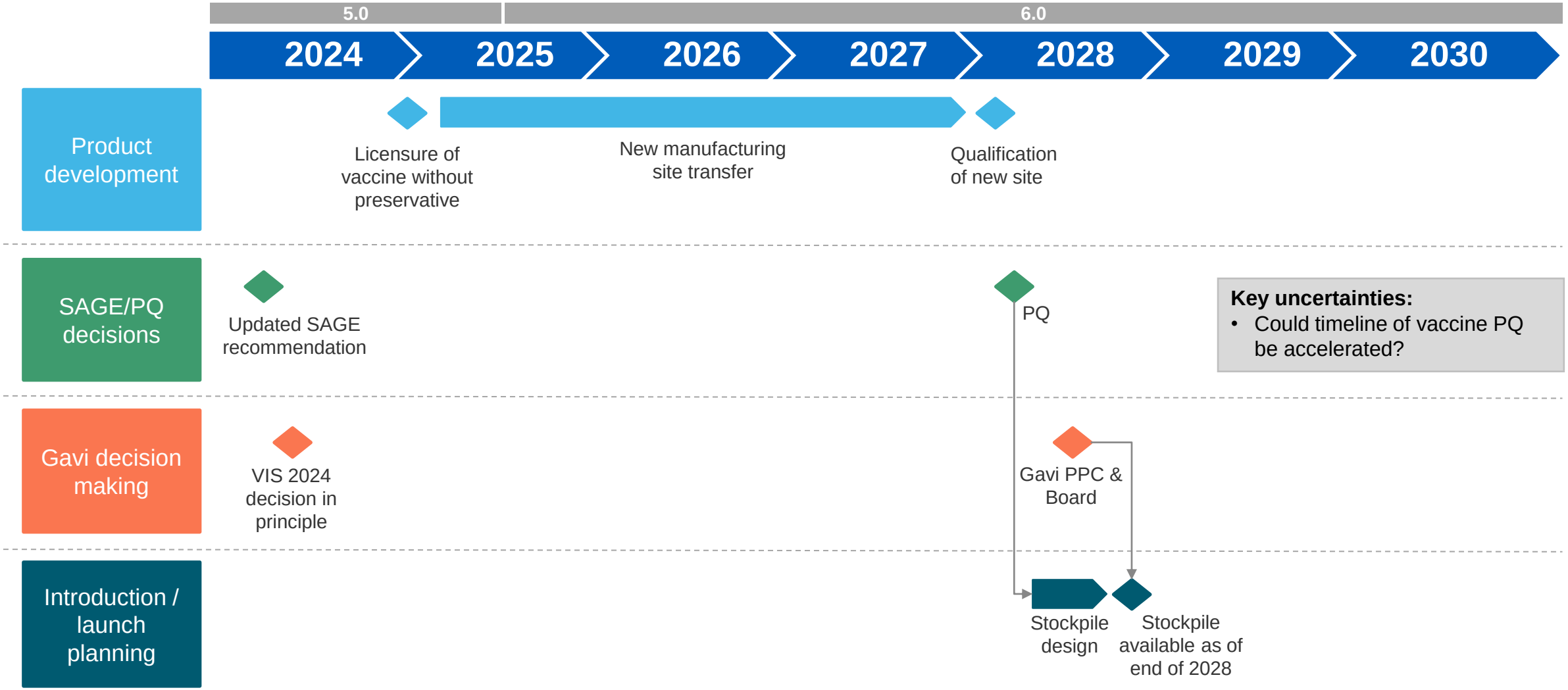
Changes to context since

- First use of vaccines in an outbreak settings in South Sudan by MSF in 2022 and 2024
- Updated SAGE recommendation permissive of 2-dose regimen in outbreaks and assessment of risk-benefit of vaccination in pregnant people (March 2024)

Upcoming data and updates:

- New output from IHME (seroprevalence)
- Data on vaccine effectiveness in outbreak setting (2024)
- Clinical trial results of vaccine efficacy on pregnant women in Bangladesh
- Data on vaccine efficacy on children (2026)
- Expected PQ of vaccine in coming years (2027/2028)

Hepatitis E Vaccine Development timeline – *estimated March 2024*



7

Summary of recommendation

Mpox

Mpox: Summary of findings and guidance

Gavi VIS 2024 key findings (April 2024)

Mpox is associated with historical transmission in west and central Africa for decades, and led to a multi-country (PHEIC) outbreak in 2022

- Populations in contexts with recurring outbreaks and lack of access to countermeasures considered at high risk (such as in some Gavi-eligible countries)

Uncertain projected impact on mortality and value for money

- Poor surveillance and epidemiological data from Africa to inform demand

Gavi could address inequity in access to vaccines by LMIC (vs HIC) observed in recent PHEIC

- Gavi could contribute to the use-case of vaccines for mpox as those available currently are for smallpox – no vaccine prequalified for mpox yet

Guidance from Steering Committee

- In December 2023, the Board did not prioritise Mpox for shortlisting, but did recommend continued monitoring via living assessment and to explore potential investments in learning agendas to address evidence gaps
- In January 2024, the VIS Steering Committee asked Secretariat to reconsider mpox based on new evidence from DRC outbreak

Support for investment in a learning agenda to start in 5.1, and a future stockpile as soon as vaccine is pre-qualified

- Underlying principle for action: Equity issues with regards to access to countermeasures and risk to children
- Important to coordinate with other partners for clear delineation of roles to ensure equitable access to vaccines and prioritisation of vaccine PQ

Guidance from PPC

PPC recommends an in-principle stockpile investment alongside a learning agenda from 5.1 and agreed with the recommendation that the Alliance coordinate dose donations to address the ongoing mpox outbreak in DRC, building on experience and learnings from COVAX

PHEIC – Public health emergency of international concern; HIC – High income Countries; LMIC – Low- and Middle-Income Countries

Summary of 3 Gavi investment options for mpox

1. No investment – "Wait and monitor"

- No financial commitment
- Continue monitoring through Living Assessment

2. Investment in accelerated learning agenda starting from 5.1 and active role in partner activities

- **Funding for a learning agenda** to address research and evidence gaps as identified by WHO and partners around disease burden, vaccine use-case, vaccine impact and feasibility questions, including potential phase 4 / implementation studies
- Active engagement with partners and manufacturers on activities that support (i) Evidence generation towards PQ of vaccine and (ii) Access to supply including donations

5.1 learning agenda: $0.5M

6.0 Learning agenda: $3.5M

3. In-principle commitment to stockpile

In addition to option 2:

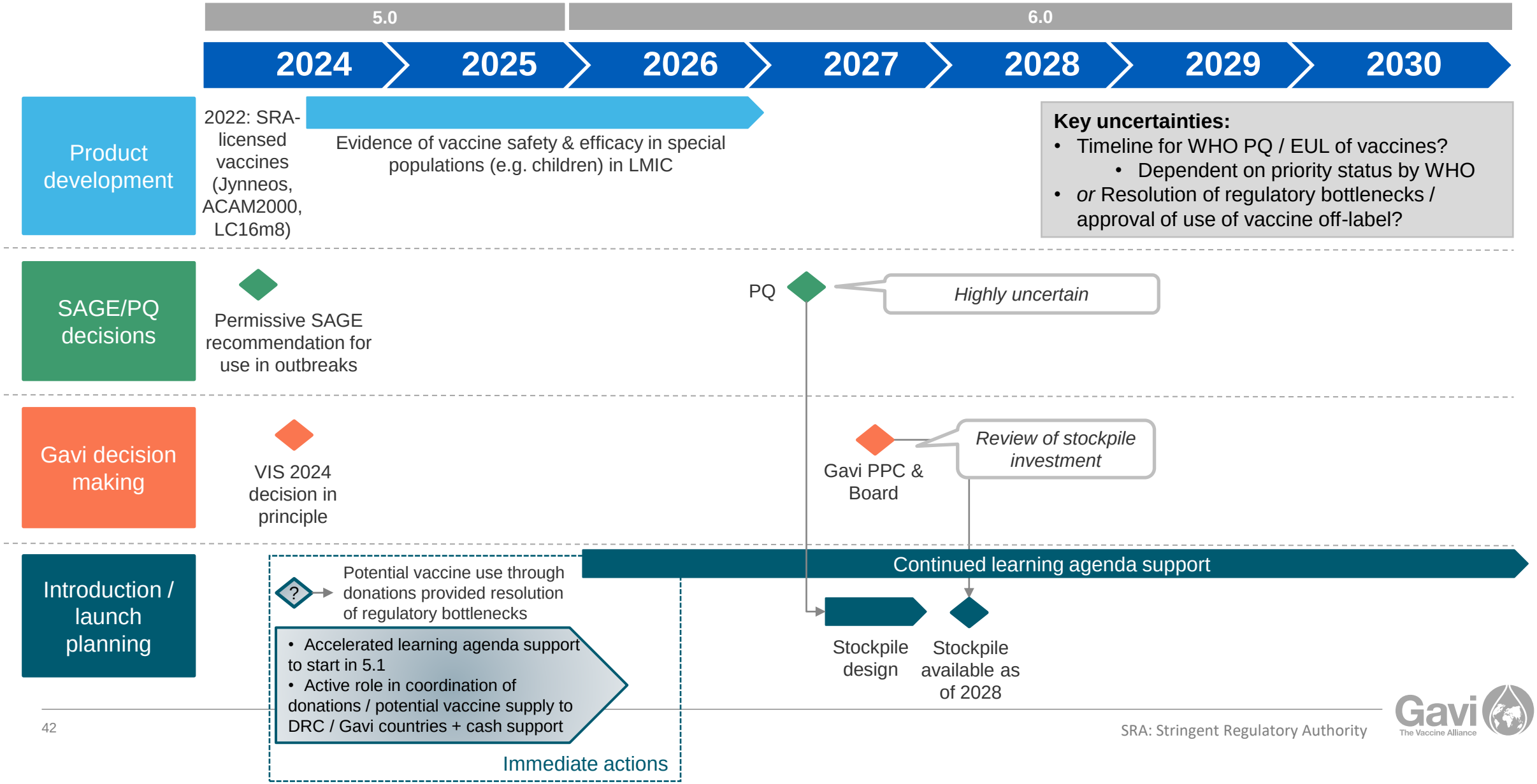
- **Signal intention to procure vaccine for stockpile**, conditional on PQ of vaccines
- Estimated **100k doses per year** for 6.0

$24.1M from 6.0

Recommended by PPC

Gavi The Vaccine Alliance

Mpox Vaccine Policy Development timeline – *estimated March 2024*



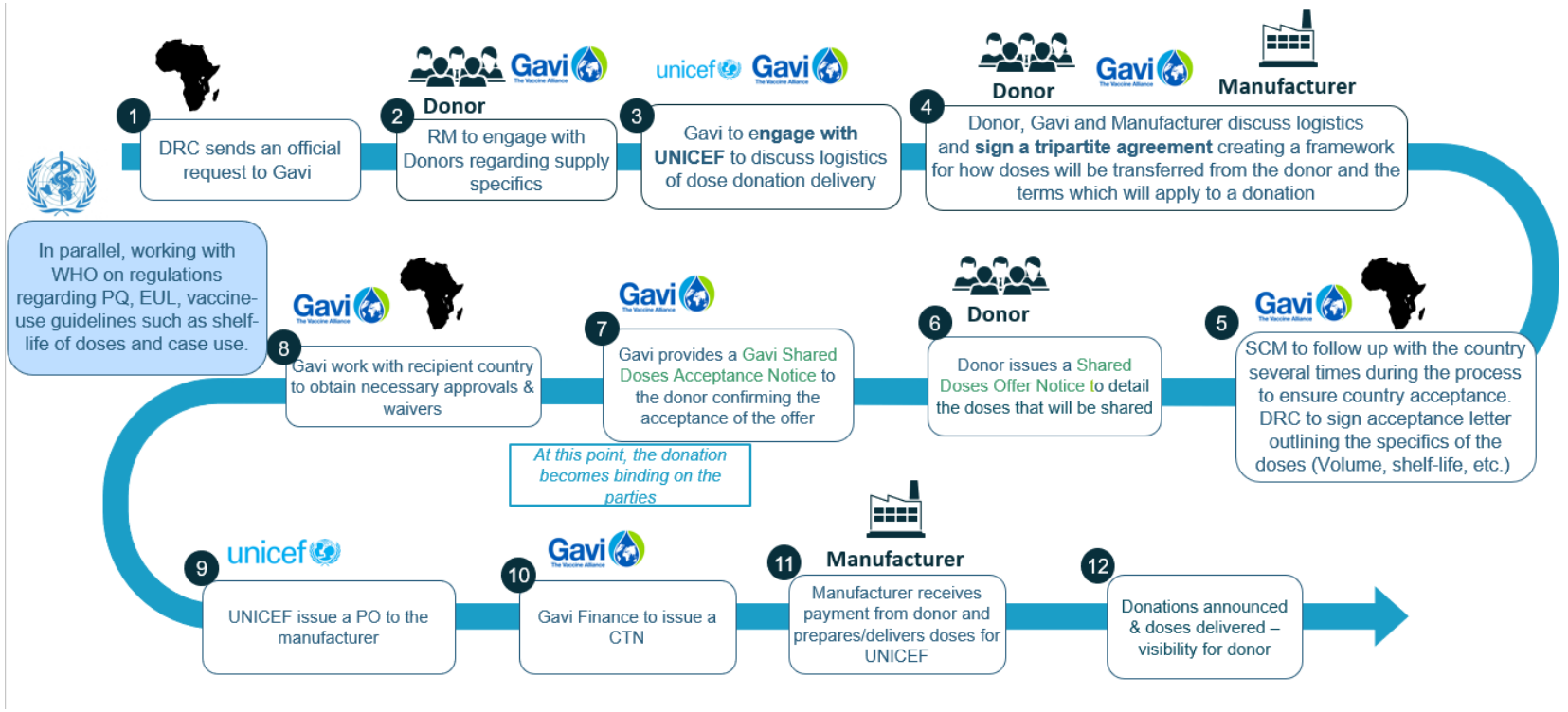
SRA: Stringent Regulatory Authority

Potential learning agenda questions for mpox

Objective	Key questions
Burden of disease	• Understanding of the epidemiology in endemic settings, including role of children in disease transmission *CEPI also addressing burden of disease – fund complementary studies*
Vaccine use-case	• Support evidence generation efforts of vaccine safety and efficacy in endemic settings, including in key populations such as children and potentially pregnant women, to inform appropriate vaccination strategies and potential use-case of vaccine. • What is the impact of the vaccine in endemic settings where multiple modes of transmission are observed (e.g., DRC)? – modeling study
Diagnostics	• What diagnostics tests deployment, testing and confirmation strategies should be used at the point of care (POC) in endemic settings for timely and accurate detection of and response to outbreaks through evidence based targeted vaccination campaigns? • What kind of capacity assessments and capacity building, including data management and reporting, trainings, should be undertaken prior to deployment of mpox rapid diagnostic tests?
Total 6.0 cost: ~US$ 3.5M	

Gavi learning agenda funds should be flexible to respond to the needs as identified by coordinated mpox partners

Potential Mpox dose donations process overview



Lessons learned from COVAX would inform our ability to execute this role and it would hinge on the following factors:

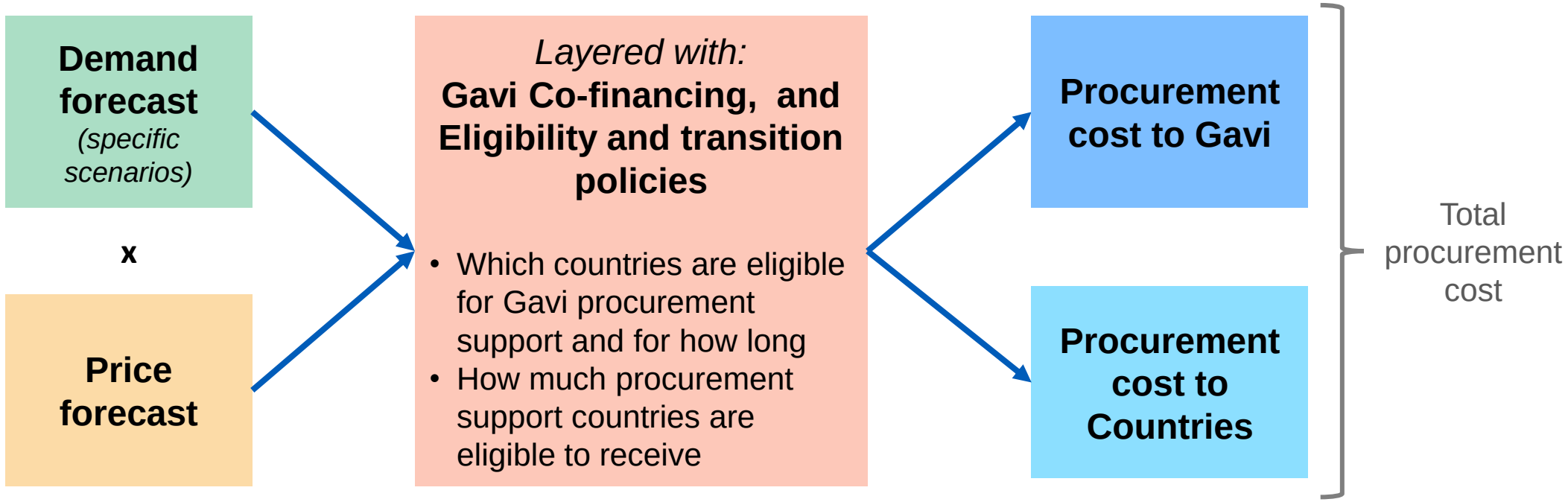
- Assessing country-specific demand
- Official country request
- Successful supply matching, dependent on readiness of Tripartite agreements and specifications of doses
- Resolving regulatory requirements
- Ensuring operational ease (e.g., adequate shelf-life and deploy-ability) and working with an implementing partner

8a

Costs

Vaccine Procurement Costs

Procurement costs are calculated using the demand and price forecasts, applying Gavi co-financing and eligibility policies



Gavi policies are currently under review to be discussed by PPC in parallel. In preparation for these discussions, VIS assumptions use current policies.

Summary of total procurement costs (US$ M)

Cost to	Vaccine	2026-2030 (6.0)	2031-2035 (7.0)	2036-2040 (8.0)	2026-2040
Gavi	Tuberculosis	10 - 41	102 - 422	165 - 690	277 - 1153
	+ campaigns (16-18y)	82 - 312	97 - 370	46 - 174	225 - 856
	Shigella	-	58 - 143	195 - 519	252 - 662
	GBS	-	187 - 300	304 - 544	491 - 844
	Dengue	0 - 1	1 - 3	1 - 2	2 - 6
	+ campaigns	3 - 9	2 - 8	0 - 0	5 - 17
	Hepatitis E	0 - 2	1 - 6	1 - 6	3 - 14
	Mpox	5 - 25	7 - 24	8 - 27	21 - 76
	COVID-19 post-2025	0 - 108	0 - 0	0 - 0	0 - 108
	Total	101 - 499	455 - 1276	719 - 1962	1275 - 3737
	Total w/o TB 6.0 and COVID	9 - 38	455 - 1276	719 - 1962	1183 - 3276
Country	Tuberculosis	9 - 32	127 - 449	224 - 793	361 - 1275
	+ campaigns (16-18y)	-	-	-	-
	Shigella	-	80 - 191	306 - 767	386 - 958
	GBS	-	180 - 295	353 - 616	533 - 912
	Dengue	0 - 1	4 - 14	3 - 10	7 - 25
	+ campaigns	-	-	-	-
	Hepatitis E	-	-	-	-
	Mpox	-	-	-	-
	COVID-19 post 2025	-	-	-	-
	Total	10 - 36	391 - 949	886 - 2186	1286 - 3171
	Total w/o TB 6.0 and COVID	0 - 1	391 - 949	886 - 2186	1277 - 3137
Total		111 - 534	845 - 2225	1605 - 4149	2561 - 6908
Total w/o TB 6.0 and COVID		9 - 39	845 - 2225	1605 - 4149	2460 - 6413

Notes: Procurement costs are ‘fully loaded’ including syringe, safety box and freight. GBS costs have been removed from 6.0 due to anticipated regulatory delays.

8b

Costs

Delivery costs

Delivery costs are estimated using best-available modelling and the Gavi portion is estimated based on current policies

1. Estimate the total delivery cost per dose to implement the vaccine

- Based on a modelling study by Portnoy et al., “Producing Standardized Country-Level Immunization Delivery Unit Cost Estimates” (2020)
- EPI vaccines cost on average $1.87 to deliver, but the data is provided per country, with the range $0.64–4.38.
- Assumes +25% for GBS, +50% for COVID-19 and Dengue
- TB based on specific modelling for VIS, also by Allison Portnoy

2. Estimate what proportion of costs Gavi assumes

Layered with:

Gavi Health Systems and Immunisation Strengthening (HSIS) Policy

- Which countries are eligible for Gavi delivery support and for how long
- How much delivery support countries are eligible to receive

Delivery cost to Gavi
Represents the Vaccine Introduction Grant and Campaign operational costs

Delivery cost to Countries

Total delivery cost

Current costings do not take into account Gavi HSS support, technical assistance costs to countries or to partner organisations

Current policy for VIGs and operational support

Financial Support for New Introductions and Campaigns		
Transition Phase	**Vaccine Introduction Grants (VIGs)**	**Operational Support for Campaigns Grants (Ops)**
Initial Self-Financing	US $ 0.80 per infant in the birth cohort (i.e., live births in the year of introduction) or a lump sum of $100,000, whichever is higher	US $ 0.65 per targeted person
Preparatory Transition	US $ 0.70 per infant in the birth cohort or a lump sum of $100,000, whichever is higher	US $ 0.55 per targeted person
Accelerated Transition	US $ 0.60 per infant in the birth cohort or a lump sum of $100,000, whichever is higher	US $ 0.45 per targeted person

Some **vaccine-specific rules** for the calculating of VIGs and operational support for campaigns apply:

- Preventive cholera campaigns: operational support is calculated per dose rather than per targeted person; countries are expected to use in particular the second campaign round to conduct integrated activities to reach under-immunised populations.
- HPV introductions are eligible for a VIG of US $2.40 per targeted girl in the routine cohort or a lump sum of US $100,000, whichever is higher, and regardless of the country's transition phase.
- Malaria vaccine introduction: The VIG amount is calculated based on the sub-national birth cohort in the areas targeted for the vaccine introduction; please refer to section 3.5 for more details on the calculation.
- Measles or measles-rubella follow-up campaigns: Gavi provides flexibility for countries requesting measles or MR follow-up campaign support to apply for operational cost support calculated on the basis of the national 9-59 month population, with the flexibility of the funds to be used for tailored strategies, e.g. national campaigns, subnational campaigns or enhanced routine immunisation activities targeted at reaching missed children. Differentiated use of funding for operational costs to reach zero dose children is expected. Please refer to the measles-rubella section 3.6 below.

For some vaccines, potential for higher introduction and delivery costs than current portfolio vaccines

Delivery costs similar to current portfolio vaccines

Potential for increased introduction/ campaign costs compared to current portfolio vaccines

Vaccine	Introduction / campaign requirements
Hepatitis E	• Planned preventative campaigns, similar to campaigns currently supported by Gavi
Mpox	• Planned preventative campaigns, similar to campaigns currently supported by Gavi
Shigella	• Can be delivered using existing EPI platform
Dengue	• Will likely be delivered at new timepoint, at age between 2-16 years old depending on country seroprevalence data • Will necessitate establishment and strengthening of systems to enable equitable delivery of vaccine to appropriate levels of health system
GBS	• No consistent routine immunisation platform during pregnancy (can leverage maternal tetanus programmes where established) • Requires integration between EPI and ANC at multiple levels of health system for efficient delivery
TB	• No health platform that reaches 15 yo., will require developing new ways to reach adolescents • Requires integration between EPI and TB programmes at multiple levels of health system for efficient delivery

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Summary of VIGs and Ops costs (US$ M)

Vaccine	2026-2030 (6.0)	2031-2035 (7.0)	2036-2040 (8.0)	2026-2040
Tuberculosis	0.8	1.9	0.9	3.6
+ campaigns (16-18y)	18.8	23.8	11.6	54.2
Shigella	0	1.1	1.3	2.4
GBS	0	2.1	0.9	3.0
Dengue	0.1	0.1	0	0.2
+ campaigns	0.4	0.4	0	0.8
Hepatitis E	0.05 – 0.28	0.14 – 0.71	0.14 – 0.99	0.34 – 2
Mpox	0.3	0.3	0.3	1
COVID-19 post-2025	0	0	0	0
Total	**20.4 – 20.6**	**29.8 – 30.4**	**15.1 – 16**	**65.1 – 66.8**
Total w/o TB in 6.0	**0.8 – 1**	**4.1 – 4.7**	**2.6 – 3.5**	**7.3 – 9**

Note: Procurement costs are 'fully loaded' including syringe, safety box and freight. GBS costs in 7.0 are the sum of previously estimated VIGs for 6.0 and 7.0, given anticipated regulatory delay.

Summary of total delivery costs (US$ M)

Vaccine	2026-2030 (6.0)	2031-2035 (7.0)	2036-2040 (8.0)	2026-2040
Tuberculosis	45	564	900	1,509
+ campaigns (16-18y)	195	232	106	534
Shigella	0	80	271	351
GBS	0	103	237	340
Dengue	1	5	2	8
+ campaigns	4	1	0	5
Hepatitis E	0.05 – 0.28	0.14 – 0.71	0.14 – 0.99	0.34 – 2
Mpox	0.3	0.3	0.3	1
COVID-19 post-2025	0 – 42	n/a	n/a	0 - 42
Total	**246 – 288**	**986 – 987**	**1,515 – 1,517**	**2,748 – 2,792**
Total without TB 6.0 and COVID	**5**	**986 – 987**	**1,515 – 1,517**	**2,507 – 2,509**

Note: Procurement costs are 'fully loaded' including syringe, safety box and freight. GBS costs in 7.0 include the previously estimated VIGs for 6.0, given anticipated regulatory delay and delayed country introductions.

8C

Total costs

Total costs (US$ M) of VIS 2024 vaccines (procurement and delivery) for Gavi-eligible countries

Cost to	Vaccine	2026-2030 (6.0)	2031-2035 (7.0)	2036-2040 (8.0)	2026-2040
Gavi	Tuberculosis	55 - 86	666 - 986	1065 - 1590	1786 - 2663
	+ campaigns (16-18y)	277 - 508	330 - 602	152 - 280	759 - 1390
	Shigella	-	137 - 223	466 - 790	603 - 1013
	GBS	-	290 - 404	541 - 780	831 - 1184
	Dengue	1 - 2	6 - 8	2 - 4	9 - 14
	+ campaigns	6 - 13	3 - 9	0 - 0	10 - 22
	Hepatitis E	0 - 3	1 - 7	1 - 7	3 - 16
	Mpox	11 - 51	15 - 49	17 - 54	43 - 154
	COVID-19 post-2025	0 - 108	0 - 0	0 - 0	0 - 108
	Total	**352 - 770**	**1448 - 2287**	**2244 - 3506**	**4044 - 6563**
	Total w/o TB 6.0 and COVID-19	**19 - 68**	**1448 - 2287**	**2244 - 3506**	**3711 - 5861**
Country	Tuberculosis	9 - 32	127 - 449	224 - 793	361 - 1275
	+ campaigns (16-18y)	-	-	-	-
	Shigella	-	80 - 191	306 - 767	386 - 958
	GBS	-	180 - 295	353 - 616	533 - 912
	Dengue	0 - 1	4 - 14	3 - 10	7 - 25
	+ campaigns	-	-	-	-
	Hepatitis E	-	-	-	-
	Mpox	-	-	-	-
	COVID-19 post 2025	0 - 44	-	-	0 - 44
	Total	10 - 78	391 - 949	886 - 2186	1286 - 3213
	Total w/o TB 6.0 and COVID-19	0 - 1	391 - 949	886 - 2186	1277 - 3137
Total		**362 - 848**	**1839 - 3236**	**3129 - 5693**	**5330 - 9777**
Total w/o TB 6.0 and COVID-19		**20 - 69**	**1839 - 3236**	**3129 - 5693**	**4988 - 8999**

Note: Procurement costs are ‘fully loaded’ including syringe, safety box and freight

Related costs

Budget area		Background assumptions
Vaccine Procurement		Based on refined demand forecast x price forecast and including devices and delivery
Vaccine introduction grants/ Ops		Based on current rules
Health System Strengthening Support (HSS)		Depending on outcome of HSS Strategy
Partner Engagement Funding (PEF)	Foundational Support	Driven by 6.0 discussions
	Technical Assistance	
	Strategic Focus Areas	
Learning agenda / Reporting and Monitoring		Under PEF
Secretariat Operations		Developed separately

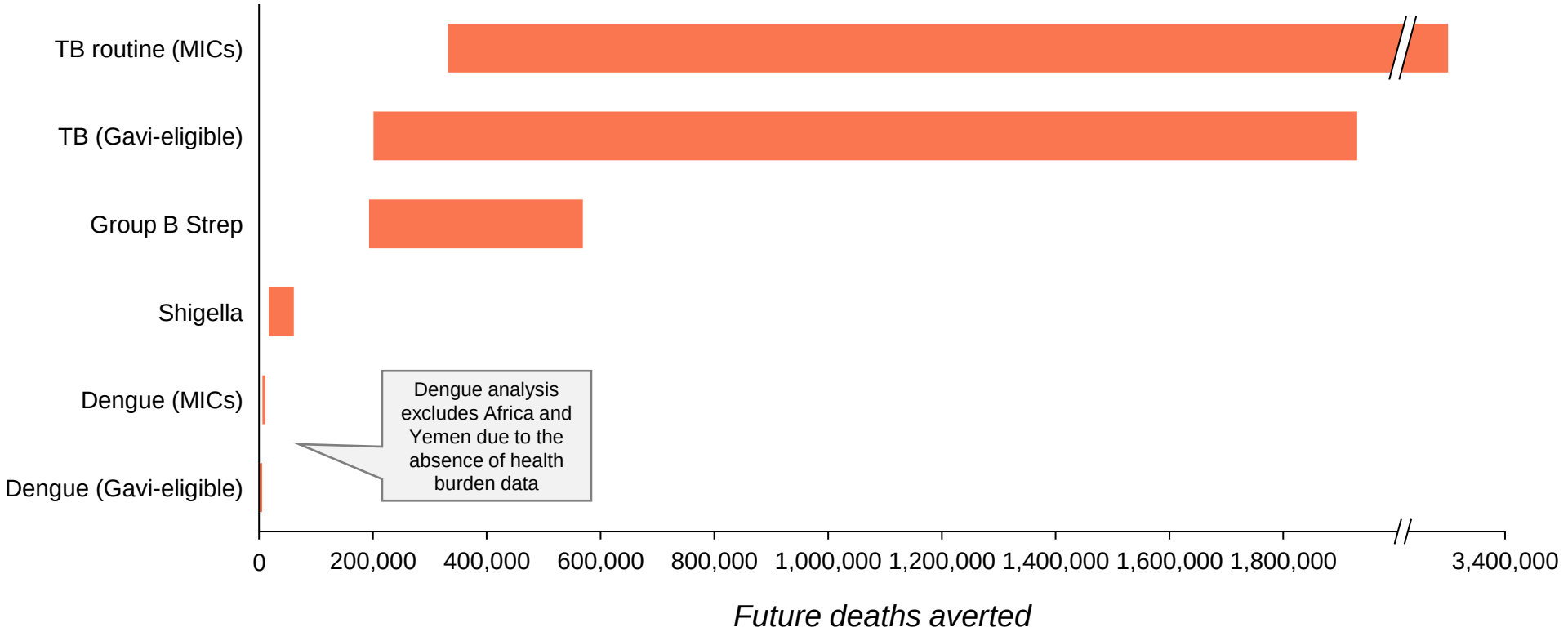
9

Comparison to existing portfolio

The range of potential impact per VIS vaccine is driven by multiple models, scenarios and sensitivity analyses

Vaccine	Parameters defining the range of potential impact
Shigella	• 2 models (BMGF IPM & Bagamian) • Sensitivity analysis conducted on vaccine efficacy (high / baseline / low) and duration of protection (5 years / 2 years)
GBS	• 2 models (BMGF IPM & LSHTM) • Primary scenario is antenatal vaccination with 1 dose • Sensitivity analysis conducted on vaccine efficacy (high / baseline / low)
Dengue	• 1 model (Imperial) • Primary scenario is routine vaccination for 6yo + campaign for 7-9yo; alternative scenarios include routine-only vaccination • Sensitivity analysis examined whether vaccines protect against symptoms only or also against infection and onward transmission
TB	• 1 model (LSHTM) • Primary scenario is routine vaccination with 2 doses for 15yo; alternative scenario is routine vaccination with 1 dose for 14yo
Hepatitis E	• Exploratory model (BMGF IPM) • Considered 2-dose and 3-dose regimens, for >15yo and >2yo in outbreak settings • Sensitivity analysis explored a range of triggers for vaccine deployment (10 cases / 50 cases)
Mpox	• Exploratory model (UNIMED, Nigeria) • Sensitivity analyses conducted on outbreak type (Nigeria, DRC) and vaccine efficacy (80% / 60%)
COVID-19	• 1 model (Imperial) • 1-dose annually, routine, 60yo+ and HCWs • Impact evaluated in both baseline (endemic) and worse-case (epidemic) risk scenarios

VIS 2024 candidate vaccines: Future deaths averted attributable to vaccination in 2026-2040



Vaccine impact for VIS candidate vaccines are based on the investment case (2026-2040). Large TB range is driven by difference in scenarios with and without campaigns.

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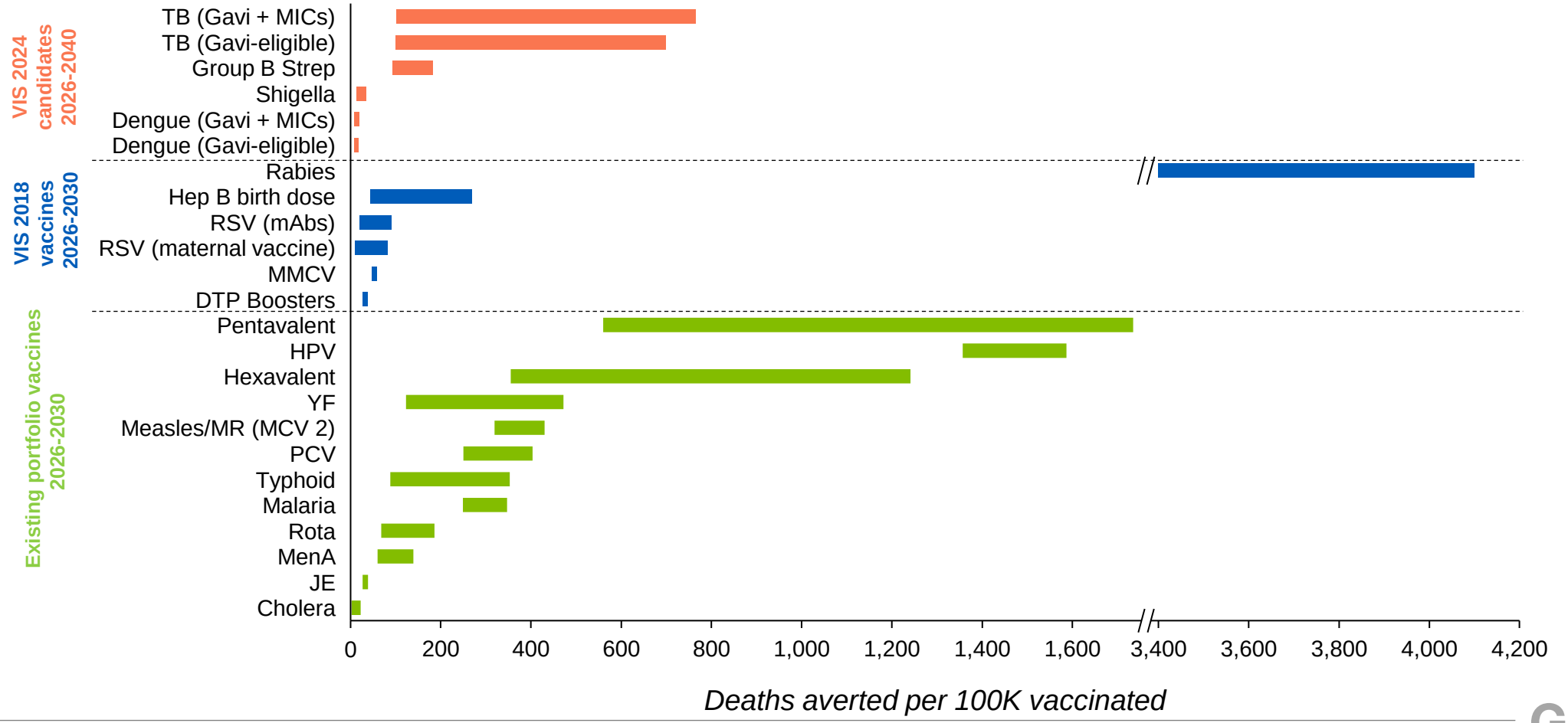
VIS 2024 candidate vaccines vs. Current portfolio of Gavi-supported vaccines: Deaths averted per 100K vaccinated

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.

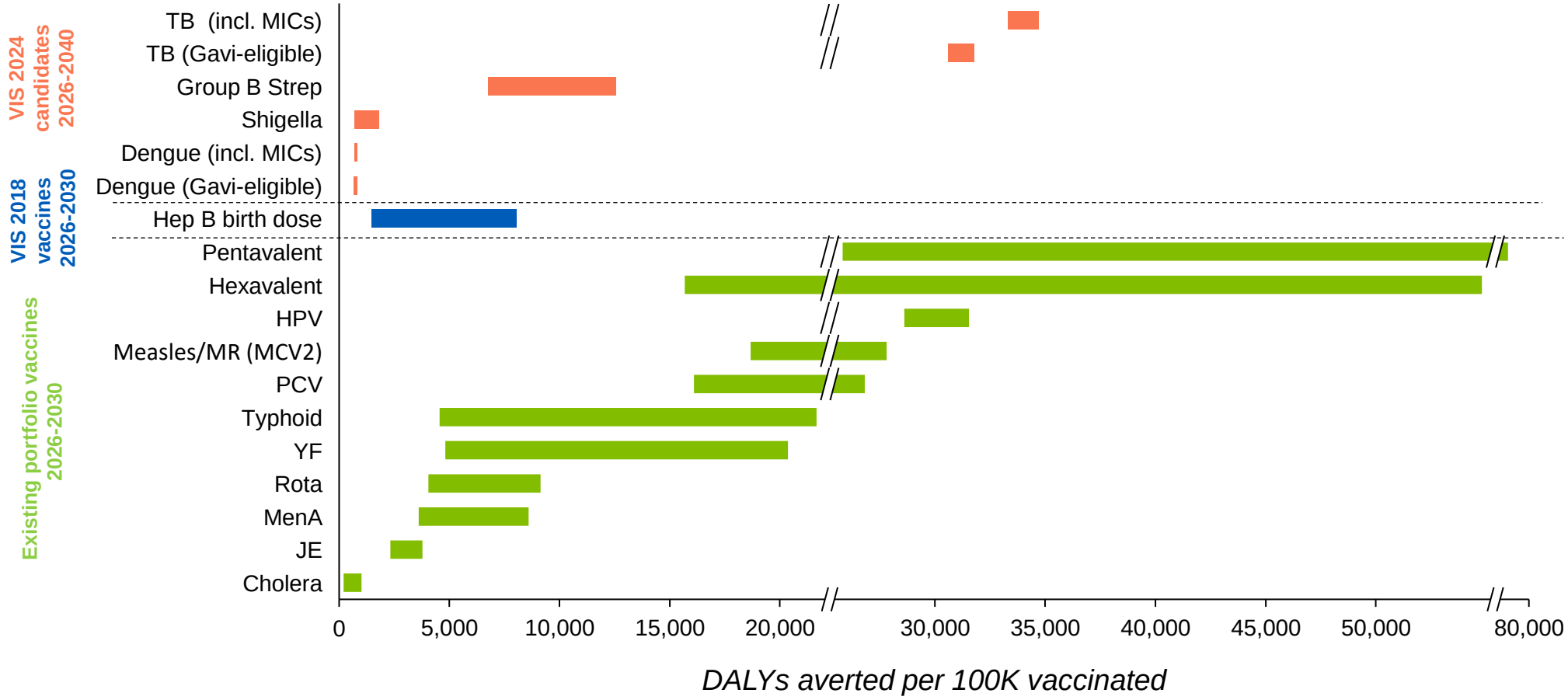


Vaccine impact for current GAVI portfolio vaccines is based on Gavi operational forecasting version 21.1 (2026-2030). Vaccine impact for VIS candidate vaccines are based on the investment case (2026-2040).
The future deaths averted are not available for vaccines against rubella.
Estimates of impact were unavailable through the VIMC for malaria, MMCV, rabies, RSV, and the 1st DTP booster. Indicative estimates were therefore derived based on the respective investment cases.

Gavi The Vaccine Alliance

VIS 2024 candidate vaccines vs. Current portfolio of Gavi-supported vaccines: DALYs averted per 100K vaccinated

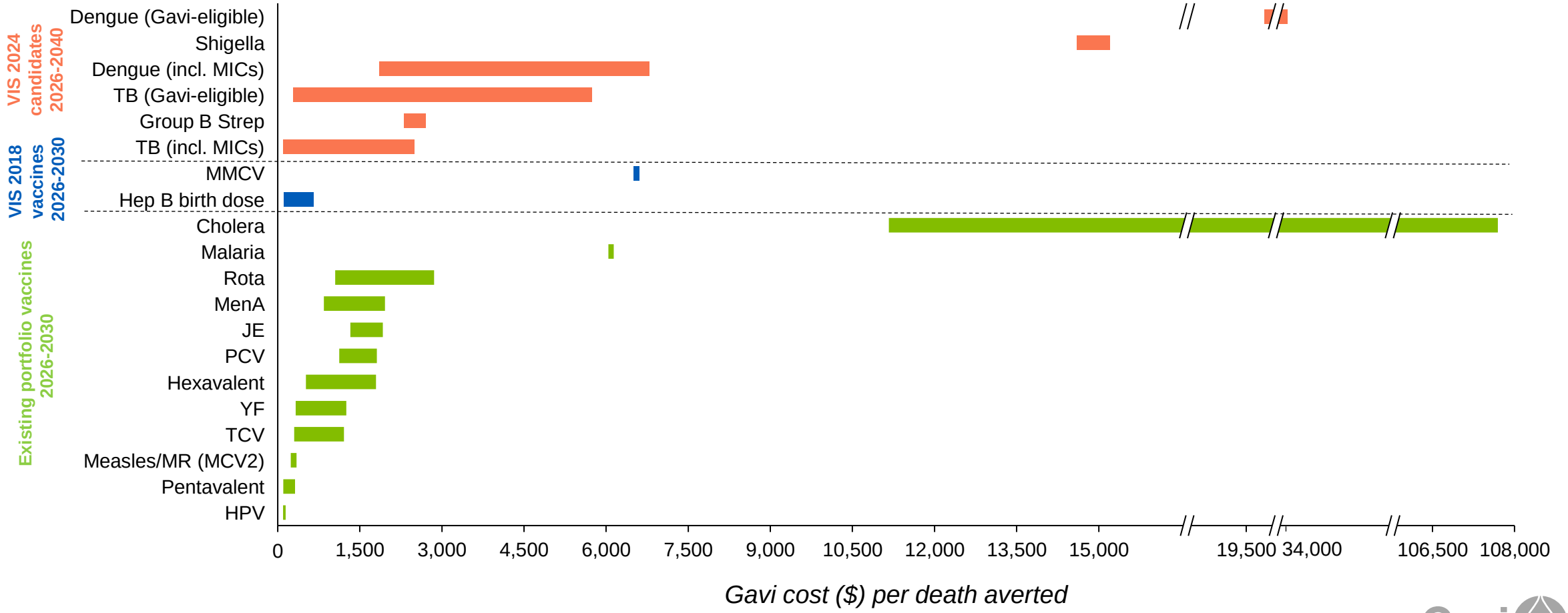
Note: Many of Gavi's current portfolio vaccines have been widely introduced and scaled in Gavi-supported countries. Many VIS candidates will still be in a period of introduction and ramp-up between 2026-2040.



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.

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

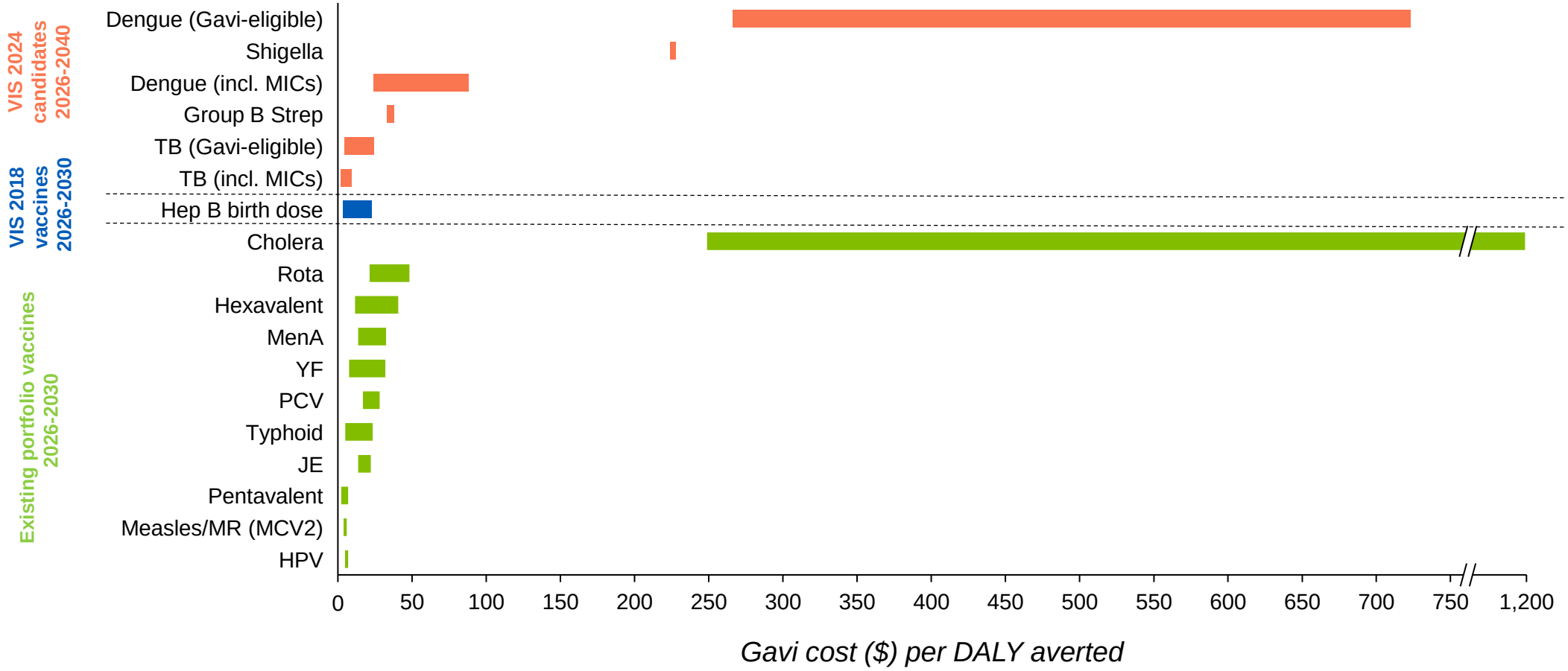
Note: Many of Gavi's current portfolio vaccines have been widely introduced and scaled in Gavi-supported countries. Many VIS candidates will still be in a period of introduction and ramp-up between 2026-2040.



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, RSV, 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.

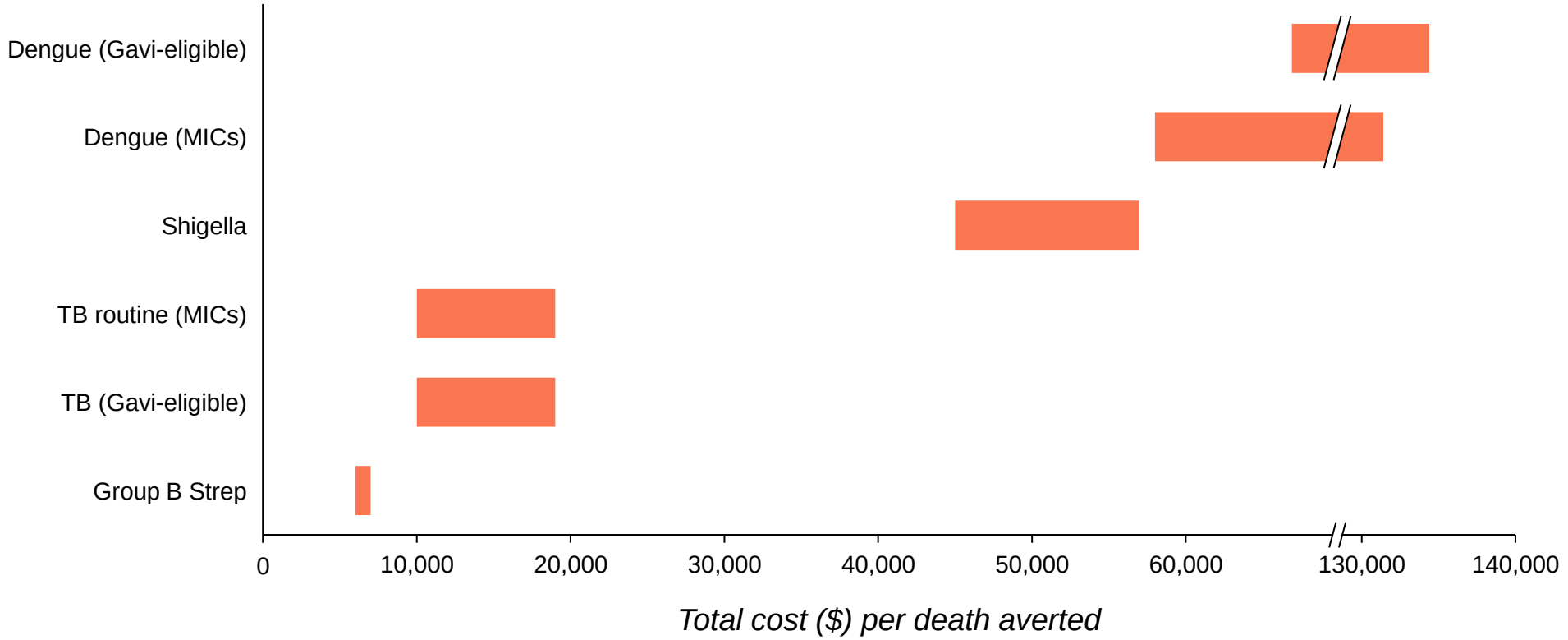
VIS candidate vaccines vs. Current portfolio of Gavi-supported vaccines: Gavi cost (Procurement + Delivery US$) per DALY averted

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.

VIS 2024 candidate vaccines: Total cost (Procurement + Delivery US$) per death averted



Value for money for VIS candidate vaccines are based on the investment case (2026-2040). Total cost takes into account procurement and delivery costs to Gavi and country. Comparator to current vaccine portfolio not currently available.

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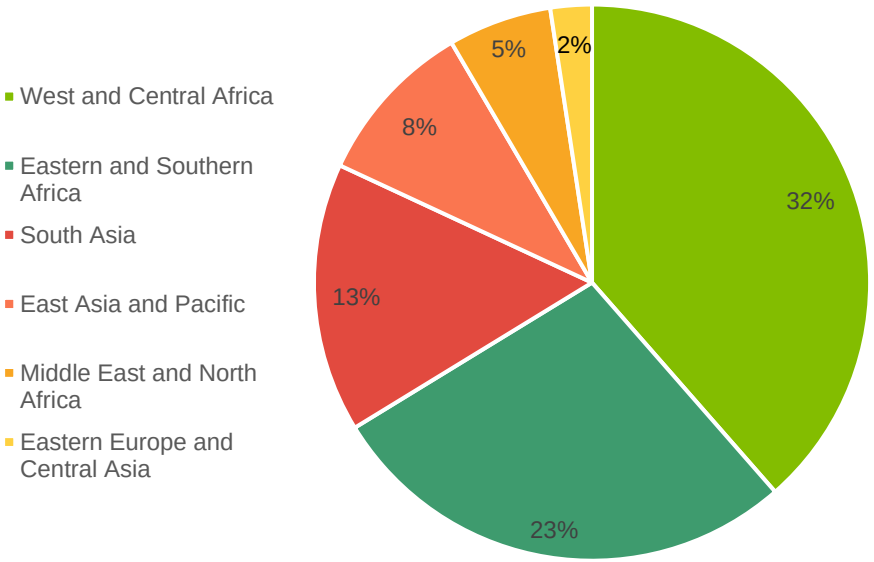
VIS 2024 Phase III: Country Survey

Responses from 40 countries, >60% from AFRO region

Responses by region (all stakeholders)



83 individual responses, 80% from Gavi-eligible countries, 19% from MICs and 1% from non-Gavi country

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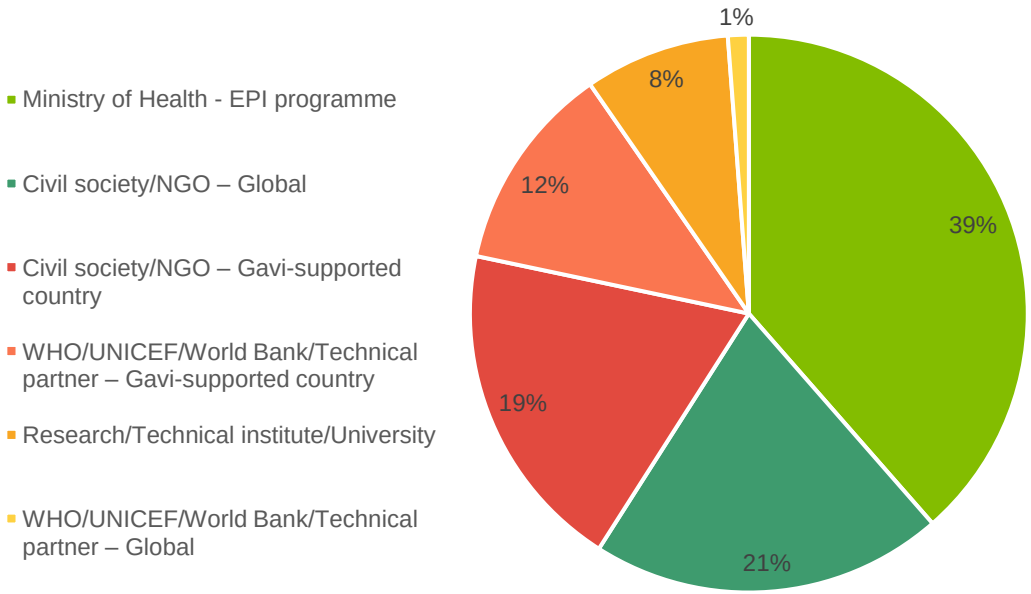
Stakeholders



Results were analysed and reported by MoH and Other stakeholders.

Limitations:

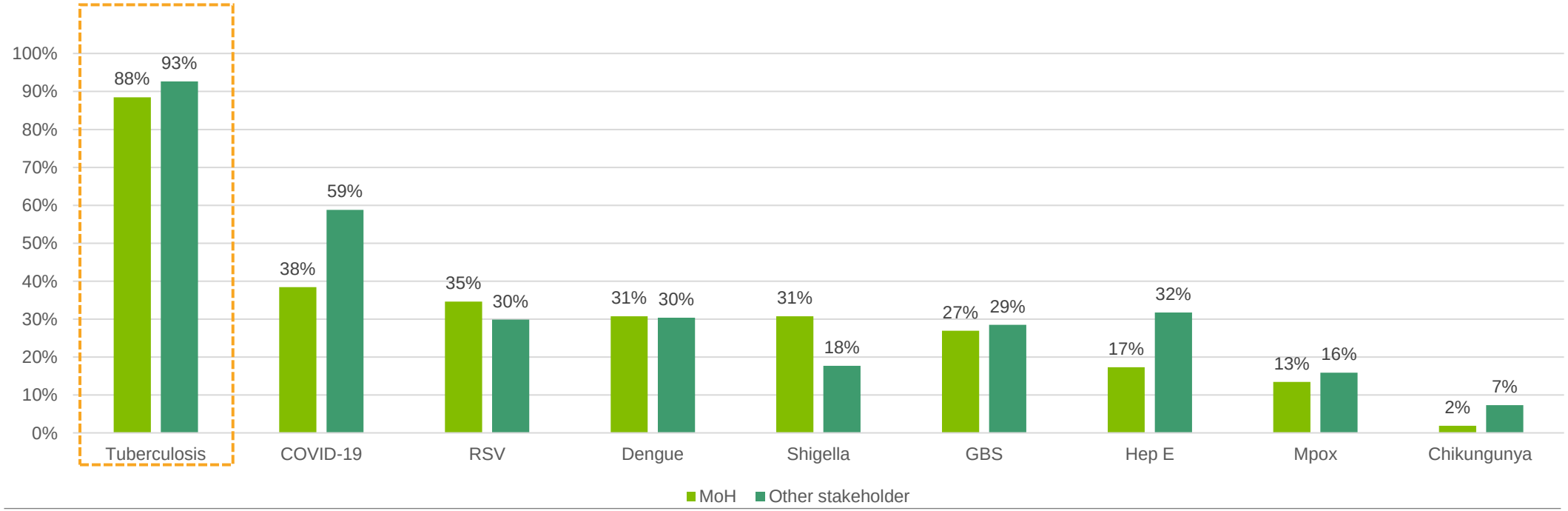
- Data collected was based on individual inputs, so outputs do not represent official country positions
- Number of responses varied per question

Source: VIS-24 Phase III country survey
Regional classification based on UNICEF: https://data.unicef.org/regionalclassifications/

TB was selected as a disease of public health importance by the majority of respondents

- 67% MoH and 86% Other stakeholders indicated that a TB vaccine would be considered as a valuable control measure against the disease.
- All other endemic diseases were viewed by MoH respondents to be at a similar level of importance
- Among the epidemic diseases, Hep E (17%) and Mpox (13%) were regarded at a similar level of importance by MoH

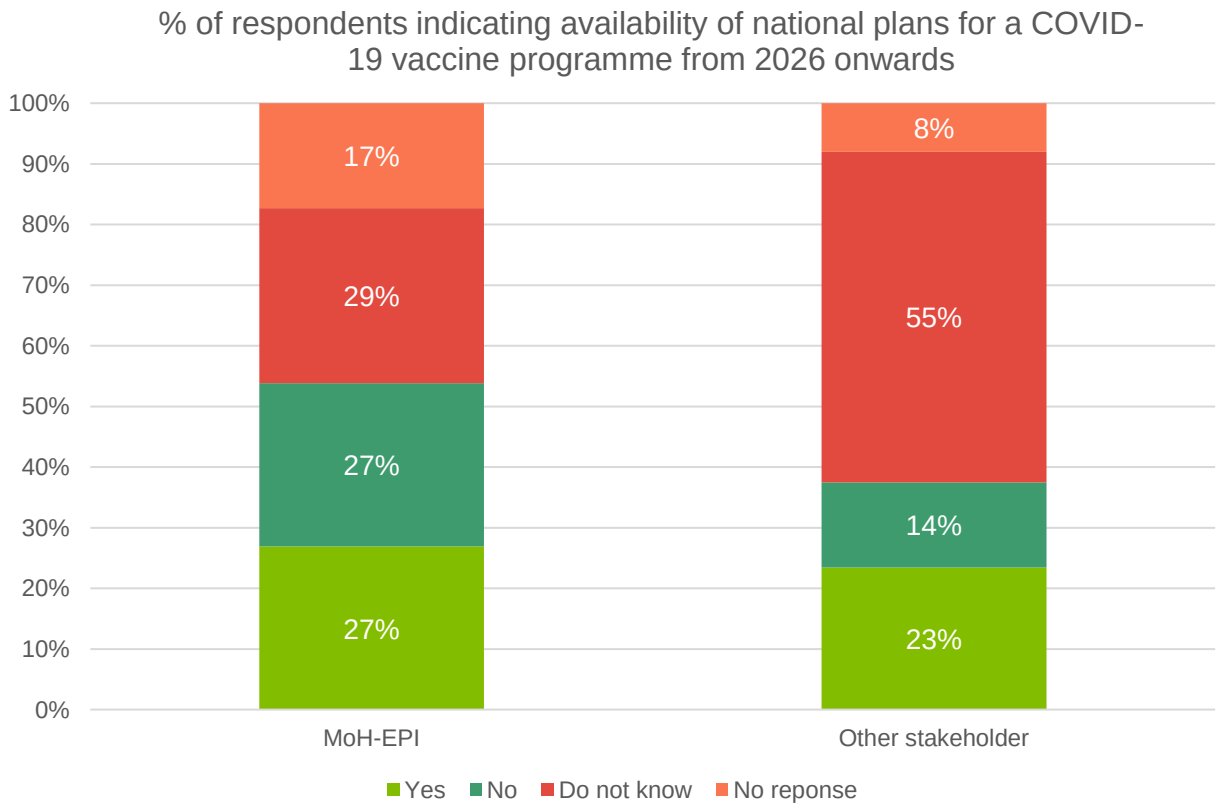
% of respondents indicating which diseases are of public health importance in their country



Source: VIS-24 Phase III country survey

Respondents showed uncertainty regarding their country's plans for COVID-19 from 2026

- According to MoH responses, only 7/26 (27%) countries have a national COVID-19 plan from 2026



Comments received from different countries regarding future COVID-19 country plans:

- Countries will continue to monitor the epidemiology of COVID-19 and the performance of the vaccination programme to adjust the plan.
- Since WHO declared COVID-19 is no longer a public health threat, interest in COVID-19 has decreased drastically.
- A roadmap for the integration of COVID-19 vaccines into the Primary Healthcare Services is being developed.
- Vaccination against COVID-19 is declining in the country due to the decrease in cases. The country has not decided whether to carry out the COVID-19 vaccination program in 2026.

Source: VIS-24 Phase III country survey

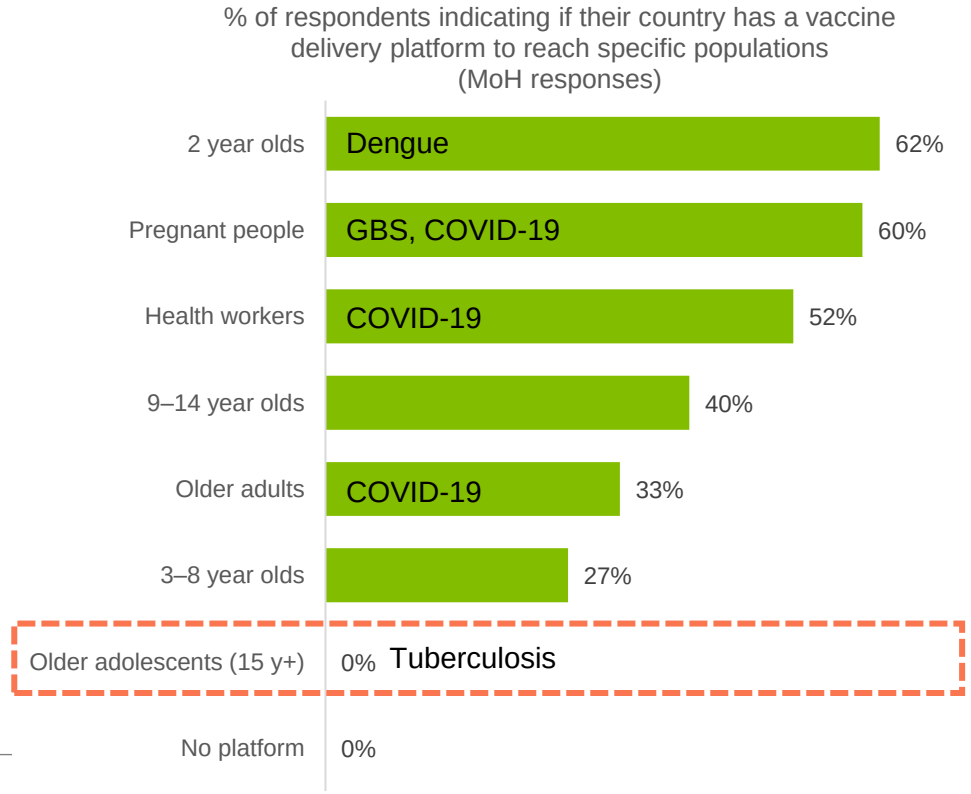
Demand for hepatitis E and mpox vaccine stockpiles would be better informed by reliable surveillance and burden data

- 23% of respondents from the MoH would be interested in a **hepatitis E stockpile**
  - Risk concentrated in vulnerable populations with limited access to clean water
- To inform the demand for a hepatitis E stockpile, respondents highlighted: a) need for diagnostic tests and a prequalified vaccine; b) improved/reliable surveillance and burden data; c) vaccine efficacy and cost-efficiency; d) ease of administration and vaccine storage conditions; and e) increased community awareness of vaccine.
- Overall, respondents from 15/25 countries in AFRO region (Cameroon, Central African Republic, Congo, DRC, Ethiopia, Ghana, Lesotho, Nigeria , Sierra Leone, Togo, Uganda) expressed an interest in a **mpox vaccine stockpile**
- To inform the demand for a mpox stockpile, respondents highlighted: a) need for improved/reliable surveillance, burden and outbreak data; b) data on vaccine safety, target population, and access to a prequalified vaccine; and c) increased community awareness.

Source: VIS-24 Phase III country survey

Majority of respondents indicated their country has immunisation touchpoints for different target populations, except for older adolescents (≥15 years)

- Operational challenges of reaching populations outside EPI include limited human resources, limited funding for vaccine procurement and delivery, and limited cold chain
- Communication, community-led capacity building and socio-cultural considerations were reported as essential in reaching specific populations with new vaccines



Comments received from different countries regarding challenges in reaching specific populations:

- Demand generation required in the communities
- Lack of awareness among the target population, health workers, program managers on disease and vaccine benefits
- Need to coordinate with health programs to reach specific populations
- Resource constraints
- Vaccine hesitancy
- Lack of financial support to build capacity of community volunteers
- Limited training of technical staff in Health Education
- No support on changing societal behavior

Source: VIS-24 Phase III country survey

* Shigella is the only vaccine targeting infants