

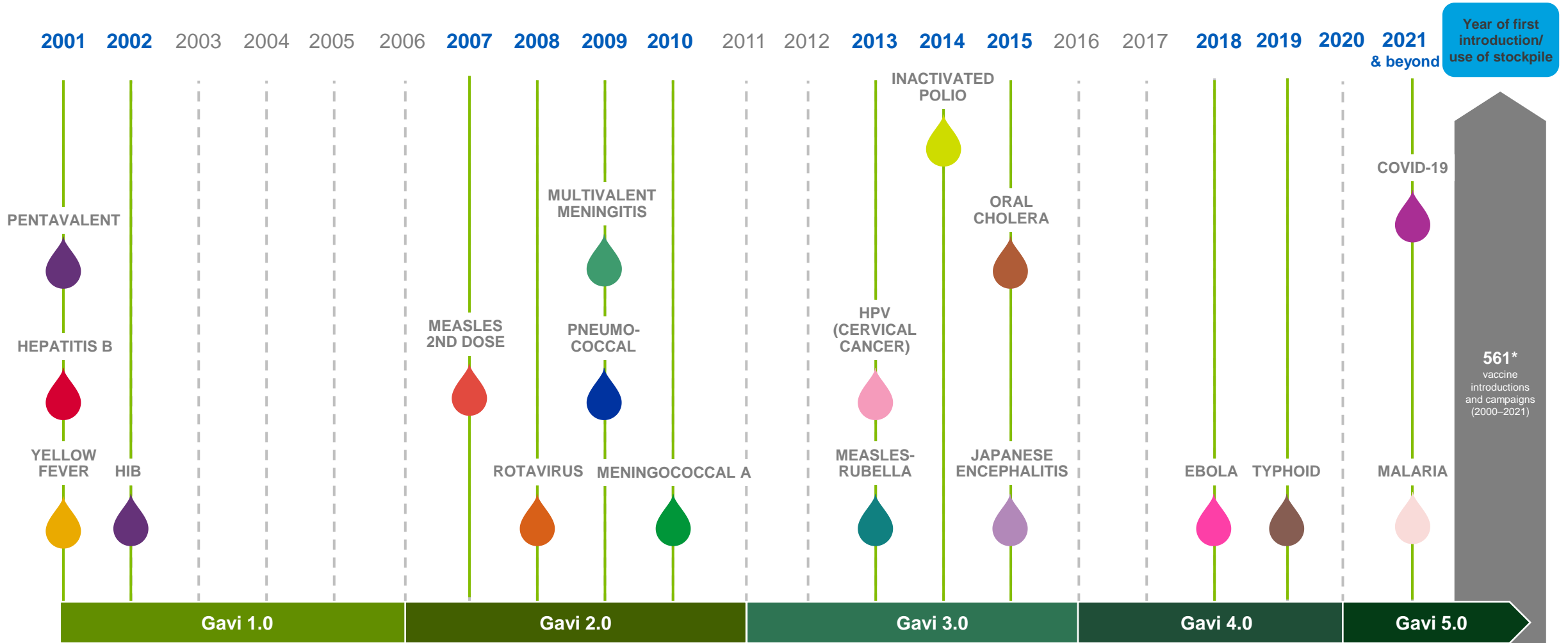
Malaria Vaccine Programme update

Dr. Stephen Sosler, Head, Vaccine Programmes
28 February 2024

gavi.org



Accelerating access: Gavi's vaccine portfolio



Year of first introduction/
use of stockpile

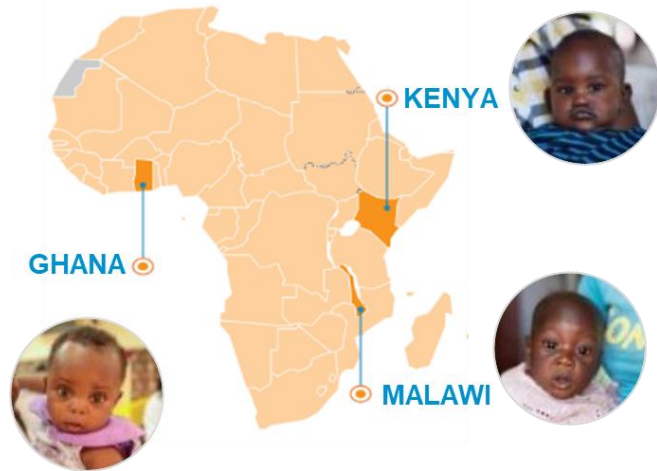
561*
vaccine
introductions
and campaigns
(2000–2021)

*Excluding COVID-19 vaccination

Summary findings from the Malaria Vaccine Implementation Programme

RTS,S/AS01 implementation 2019 - 2023

- **Over 2 million children reached** through implementation in routine immunization programmes in **Ghana, Kenya and Malawi** since 2019
- **Evaluation completed in 2023**



High impact results among children age-eligible for vaccination¹:
13% reduction in all-cause mortality
22% reduction in hospitalized severe malaria
17% reduction in hospitalization with positive malaria test



Vaccine uptake is high, with no reduction in ITN use, uptake of other vaccines, or change in health-seeking behavior



Community demand and health worker acceptability is high



The vaccine continues to demonstrate a **strong safety profile**, after more than 6 million doses provided.



Vaccine delivery is **equitable** by gender and socioeconomic status; vaccine is reaching children who are not using other forms of malaria prevention (access to malaria prevention measure grows up to 94%).

¹ The reduction in mortality was achieved during a period of vaccine scale-up with coverage of the three primary doses of 63% - 75% and coverage of dose 4 of 33-54% (across countries at ~30 months since introduction). Impact is expected to increase further with increased vaccine coverage.

Two available vaccines

- Product Choice: There is no evidence that one vaccine performs better than the other. Country decisions on which vaccine to introduce should be made on programmatic characteristics, such as affordability and supply considerations to allow scale-up



RTS,S/AS01 Malaria Vaccine

WHO recommended: since October 2021
WHO PQ: since July 2022



R21 Malaria Vaccine

WHO recommended: since October 2023
WHO PQ: since December 2023

WHO list of pre-qualified vaccines: <https://extranet.who.int/prequal/vaccines/prequalified-vaccines>

WHO recommendation: malaria vaccines

WHO recommends the programmatic use of malaria vaccines for the prevention of *P. falciparum* malaria in children living in malaria endemic areas, prioritizing areas of moderate and high transmission

- The malaria vaccine should be provided in a schedule of 4 doses in children from around 5 months of age¹ for the reduction of malaria disease and burden
- A 5th dose, given one year after dose 4, may be considered in areas where there is a significant malaria risk remaining in children a year after receiving dose 4
- Countries may consider providing the vaccine using an age-based, seasonal, or a hybrid of these approaches in areas with highly seasonal malaria or areas with perennial malaria transmission with seasonal peaks
- Countries should prioritize vaccination in areas of moderate and high transmission, but may also consider providing the vaccine in low transmission settings
- Vaccine introduction should be considered in the context of comprehensive national malaria control plans

¹ Vaccination programmes may choose to give the first dose at a later or slightly earlier age based on operational consideration. Studies with RTS,S/AS01 indicated lower efficacy if first dose was given around 6 weeks of age. However, it seems unlikely that efficacy would be substantially reduced if some children received the first dose at 4 rather than 5 months, and providing vaccination at an age younger than 5 months may increase coverage or impact

This recommendation now includes two malaria vaccines:

- **RTS,S/AS01**
WHO prequalified in 2022
- **R21/Matrix-M**
Currently under WHO pre-qualification review

WHO recommendation: malaria vaccine dose schedule and delivery

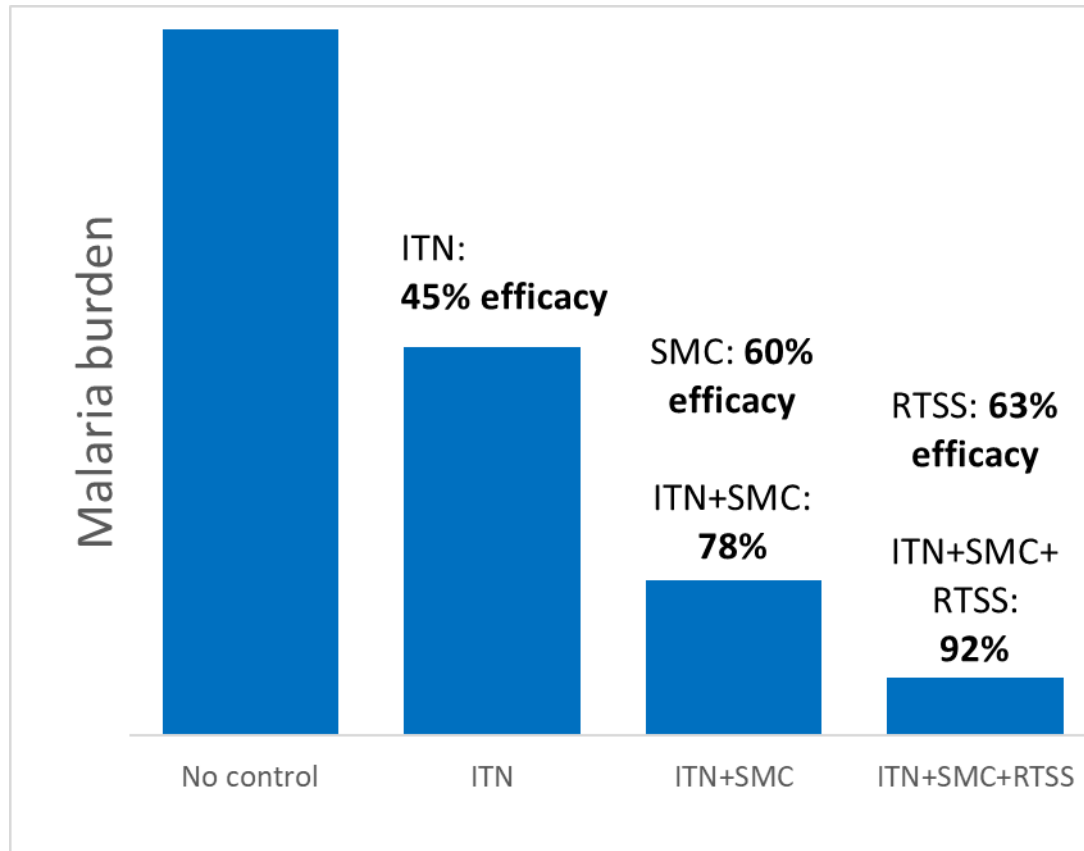
- In areas of perennial malaria transmission, the malaria vaccine should be provided as a 3-dose primary series, starting from around 5 months of age, with a minimal interval of 4 weeks between doses
- The fourth dose should be given to prolong protection. There can be flexibility to optimize delivery for dose 4:
 - Alignment with other second year of life vaccines
 - Administration prior to seasonal peaks to optimize efficacy
 - The optimal interval between dose-3 and 4 has not been established
- If malaria remains a significant public health problem in children a year after the fourth dose, then a fifth dose might be considered, depending on a local assessment of feasibility and cost-effectiveness

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Highest impact achieved when malaria interventions strategically used together

Reduction in malaria burden when interventions are strategically used together



Insecticide Treated Net (ITN) efficacy:
<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000363.pub3/full>

Seasonal Malaria Chemoprevention (SMC) efficacy: <https://journals.plos.org/plosmedicine/article/authors?id=10.1371/journal.pmed.1003727>

RTS,S/AS01 efficacy of seasonal vaccination **63% efficacious over 3 years**
<https://www.nejm.org/doi/full/10.1056/NEJMoa2026330>

Details on vaccine manufacturers and supply

RTS,S/AS01

- GlaxoSmithKline (GSK)

Manufacturer

- Contract between UNICEF and GSK was established in March 2023

Procurement Framework

- ~US\$10.00 per dose (EUR 9.30)

Market Pricing (2024)

- Limited overall supply of 18mds for 2023-25; will get focused on fewer countries enabling those countries to scale up with the RTS,S doses available
- Technology transfer of RTS,S to Bharat Biotech is underway, with prospects of increased supply and reduced prices

Overall volumes available

R21/Matrix-M

- Serum Institute of India (SII)

- Contract between UNICEF and Serum Life Sciences (SLS), subsidiary of manufacturer SII, was finalized this week, it is conditional to R21/Matrix M achieving WHO PQ.

- US\$ 3.90 per dose

- Sufficient supply to meet realistic and planned demand

Gavi supported Technical Assistance for Vaccine Introduction

Introduction planning

- Support microplanning
- Support phased introduction strategies
- Conduct & disseminate research to inform vaccine introduction
- Develop/strengthen platforms to reach children at new RI contact points

Training & Communication

- Develop training materials & conduct trainings at all levels of health system
- Support RCCE plans & IEC materials to promote vaccine confidence

Monitoring & planning

- Maintain/update monitoring tools
- Support comprehensive vaccine mgt. plans (reduce wastage & stock-outs)

Learning

- Document & disseminate lesson learnt (e.g.: to inform scale-up)



Coordinate & support

- NMCP & EPI coordination mechanism should be developed and/or maintained
- Supportive supervision aiming at continuous improvement of the programme

Co-financing implications for countries

Exceptional, time-limited approach for malaria vaccine¹ applicable to both RTS,S and R21

Co-financing status	Implications	Product choice implications
Initial self-financing country	<ul style="list-style-type: none"> Country contributes US \$0.20 per dose (no annual increase) 	<ul style="list-style-type: none"> No difference across RTS,S and R21
Preparatory transition country	<ul style="list-style-type: none"> Country co-financing starts at US \$0.20 per dose in the first year of introduction Increases by 15% annually (for example US \$0.23 in second year) 	<ul style="list-style-type: none"> No difference across RTS,S and R21
Accelerated transition country	<ul style="list-style-type: none"> Country contributes 20% co-financing in first year of introduction and increases co-financing by 10 percentage points annually (20% first year, 30% second year and so on) Country should reach 100% co-financing after 8 years 	<ul style="list-style-type: none"> Link to product market price. Higher price = higher co-financing

Country Application Approvals and Dose Allocations / Shipment

#	Country	Product	Doses (per first approved application)	Intro target	Decision Letter	Scale up/ additional application timeline	TA for implementation	1 st shipment and timeline
1	Ghana (MVIP, AT)	R21 / To be confirmed	2,880,000	Jan	Issued; revised DL to be issued basis of country plans	Approved in Sep '23 (43 districts and 1.4M doses)	NA	480K; 14 Nov
2	Kenya (MVIP, AT)	R21 / To be confirmed	1,770,000	Jan	Issued; ; revised DL to be issued basis of country plans	Applied in Jan '24 (12 additional sub counties)	NA	320K; 20 Nov
3	Malawi (MVIP)	RTS,S	2,250,000	Jan	Issued	Planned for H2 '24	NA	370K; 17 Nov
4	Burkina Faso	RTS,S	1,817,045	Feb 5	Issued	To be confirmed	Agreement signed (JHPIEGO)	658K, arrived
5	Niger	RTS,S	1,629,494	TBC	DL issued Jan 23 (incl. top up)	To be confirmed	Agreement signed (Dalberg)	285K; pending country confirmation
6	Cameroon (PT)	RTS,S	1,387,045	Jan 22	Issued	To be confirmed	Agreement signed (Dalberg)	331K; arrived
7	Sierra Leone	RTS,S	1,782,133	Mar	Issued	To be confirmed	Agreement signed (CHAI)	550K; arrived
8	Benin (PT)	RTS,S	976,517	April	Issued	To be confirmed	Agreement signed (AMP)	216K; arrived
9	Liberia	RTS,S	231,485	Apr 8	Issued	No immediate plans	Agreement signed (JHPIEGO)	112K; arrived
10	DR Congo	R21	1,437,942	Jul	Issued on Jan 19	Applied in Jan '24	Agreement signed (PATH/ CHAI)	Pending mfg. PO issue
11	Uganda	R21	1,457,046	Oct	Issued on Jan 19	Applied in Jan '24 (nationwide)	To be signed (PATH)	Pending mfg. PO issue
12	Burundi	R21 / To be confirmed	1,445,427	Jul	Issued; revised DL to be issued basis of country plans	To be confirmed	Agreement signed (Dalberg)	Pending PO issue
13	Mozambique	R21	1,687,115	Jul	Issued on Jan 23	Scale up planning underway	To be operationalised	Pending mfg. PO issue
14	Sudan	R21	924,812	TBC	AR being prepared	Scale up planning underway	To be operationalised	Pending mfg. PO issue
15	Nigeria (AT)	R21	3,000,440	Nov	Issued on Jan 19	Applied in Jan '24	To be operationalised	Pending mfg. PO issue
16	CAR	R21	452,083	Jul	Issued on Jan 23	To be confirmed	To be operationalised	Pending mfg. PO issue
17	South Sudan	R21	1,604,599	Jul	Issued on Jan 17	Scale up planning underway	To be operationalised	Pending mfg. PO issue
18	Chad	R21	553,306	May	Issued on Jan 18	Scale up app. planning underway	To be operationalised	Pending mfg. PO issue
19	Guinea	R21	1,347,326	TBC	To be issued	To be confirmed	To be operationalised	Pending mfg. PO issue
20	Cote d'Ivoire (AT)	R21	836,719 (for 2024)	TBC	To be issued	To be confirmed	To be operationalised	Pending mfg. PO issue

Malaria Vaccine Coordination Team (MVCT)

Organizations currently represented:



- Co-chaired by WHO and Gavi Secretariat, created in early 2022
- MVCT provides a platform for coordination and information sharing
- Initial focus on support to design of the Gavi malaria vaccine programme
- Overtime, expected to support the ongoing implementation of the Gavi programme & coordination among partners

Gavi Funding Guidelines provide an overview of the support available through Gavi & the process to apply

Gavi Support Guidelines

Main page with links to all relevant documents

[French](#) / [English](#)

Gavi Application Process Guidelines

[French](#) / [English](#)

Gavi Vaccine Funding Guidelines

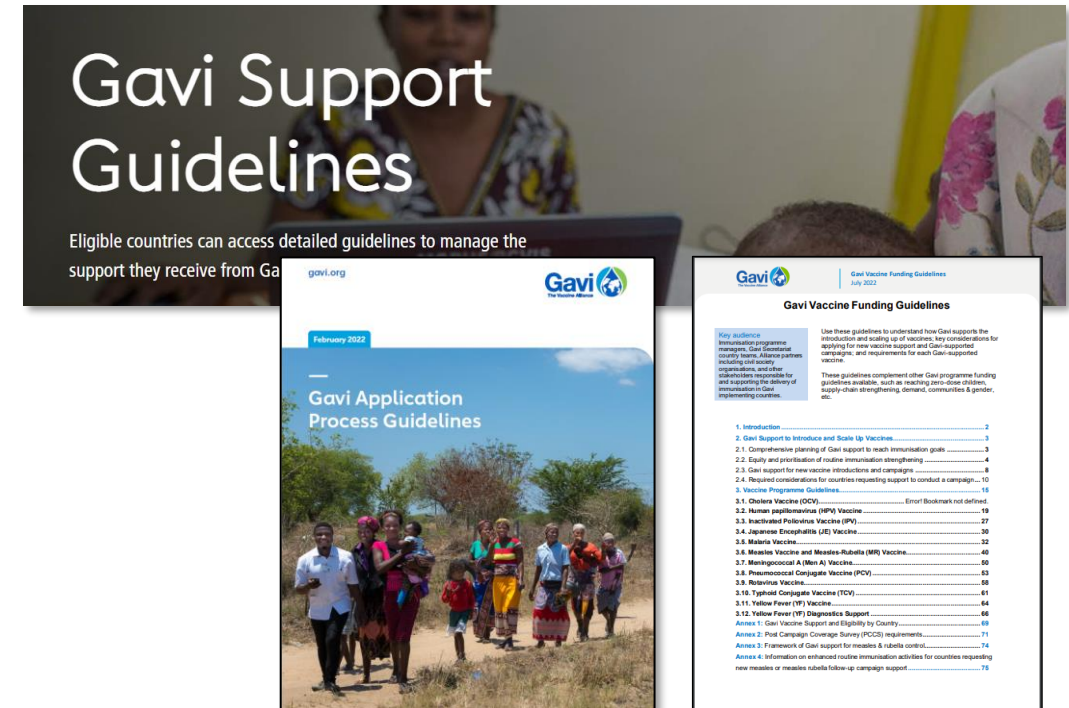
With malaria vaccine programme requirements in chapter 3.5

[French p.37](#) / [English, p.31](#)

Interim Malaria Vaccine Funding Guidelines

With interim guidelines ahead of formal guidelines in Q2, 2024

[English, p.31](#)



Tools and resources to support planning and implementation

Malaria vaccine introduction guide – advanced draft PDF shared via WHO country offices with countries planning introductions

- Available upon request (English and French)
- Published version online in late 2023 will reflect the recent WHO recommendation

Generic training materials for country adaptation – English versions to be shared 13 Oct (French versions week 23 Oct) with countries planning introduction

- Modules on malaria, vaccine characteristics (RTS,S/AS01) and storage conditions, schedule and contraindications, vaccine administration, recording and monitoring, communications, AEFI monitoring, and missed opportunities for vaccination

Other tools and resources will be posted on [TechNet-21 malaria vaccine page](#)

- Evidence available on both malaria vaccines
- Further examples and lessons from the pilot introductions
- Demand promotion planning guide and risk communications guidance
- Introduction readiness tracking tool in Excel

These will be shared via WHO country offices

And shortly made available online:

[WHO website](#) and/or

[TechNet-21 malaria vaccine page](#)

Useful links

- **TechNet-21 malaria vaccine page**

<https://www.technet-21.org/en/topics/programme-management/malaria-vaccine>

- **UNICEF Malaria vaccine questions and answers**

[Malaria vaccine questions and answers | UNICEF Supply Division](#)

- **Malaria Vaccine Implementation Programme**

<https://www.who.int/initiatives/malaria-vaccine-implementation-programme>

- **WHO Press release on R21 recommendation**

[WHO recommends R21/Matrix-M vaccine for malaria prevention in updated advice on immunization](#)

Thank you