Ministry of Health

REPUBLIC OF KENYA

[illegible] RTS,S/AS01 [illegible]

5th Mar 2025

[illegible]

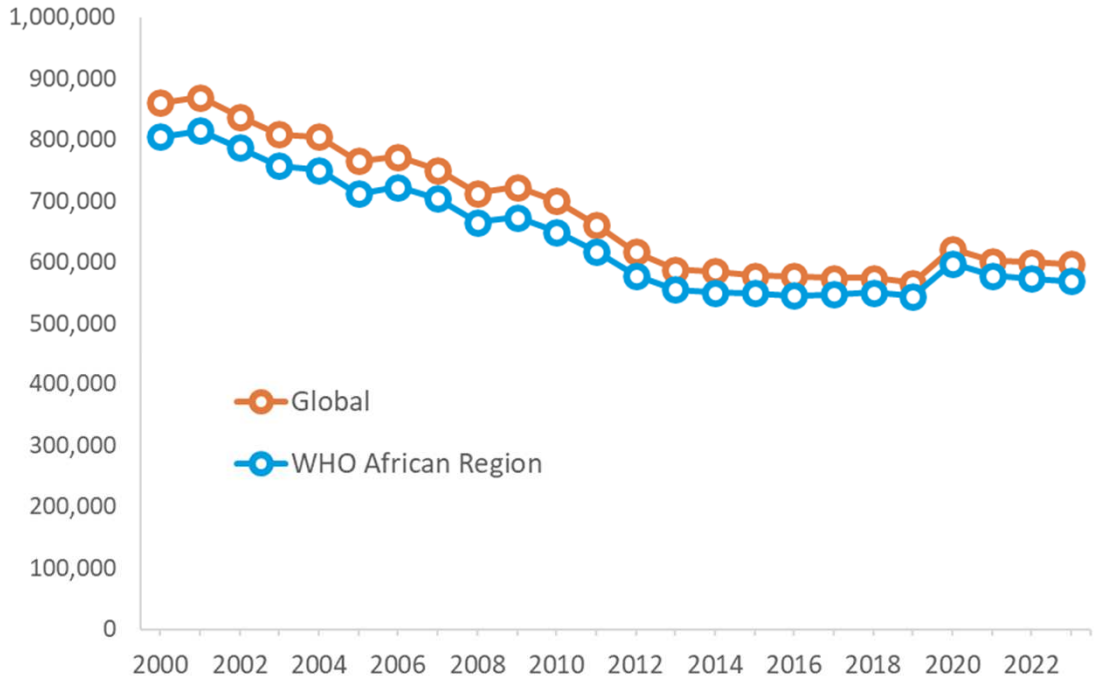
Vaccinate to Protect.
Ministry of Health

Outline

1. Malaria burden
2. Pilot Implementation
3. Malaria vaccine rollout
4. Lessons from subnational roll out.

Malaria remains a primary cause of childhood morbidity and mortality, particularly in Africa

Estimated malaria deaths globally and in the WHO African Region, 2000-2023
Source: WMR 2024



In 2023:

263 million cases

597,000 deaths

~94% in African Region

>432,000 child deaths in Africa

Major cause of pediatric hospitalization and death

Progress is further threatened with changes in global health funding: Disruptions to PMI alone may result in 105,000 additional deaths in 2025[1]

Source: World Malaria Report 2024;
1 Malaria Atlas Project. (n.d.). PMI 2025 project resources. https://malariaatlas.org/project-resources/pmi-2025/

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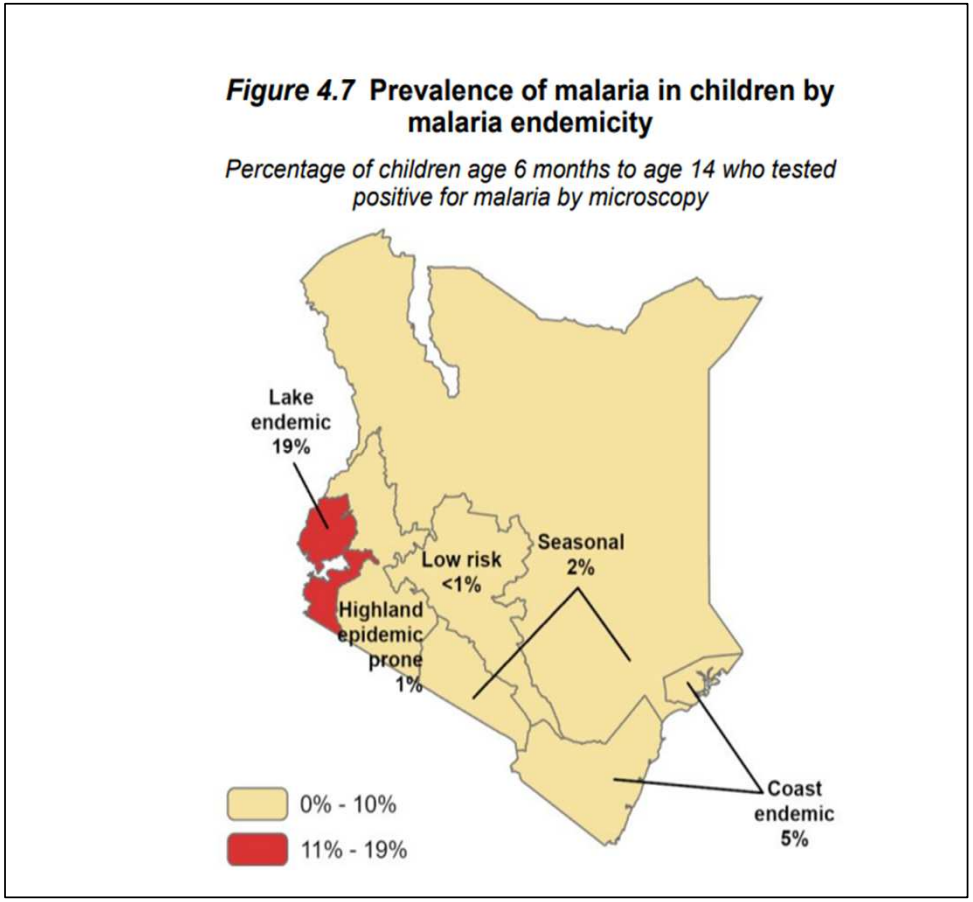
Malaria in Kenya

- Malaria is a significant public health problem in Kenya.
- More than 70% of the population is at constant risk from malaria, especially children and pregnant women.
- In the past 10 years, there has been a concerted effort by the government and malaria partnerships to fight the disease through prevention and treatment interventions.

Zone	Transmission	Geographic Coverage
Endemic Zone	High, year-round	Western Kenya (Lake Victoria basin), parts of Nyanza and Western regions
Seasonal Zone	Moderate, seasonal peaks	Rift Valley, parts of Coast, and Eastern regions with seasonal rainfall
Epidemic Zone	Low, unstable	Highlands of Rift Valley and parts of Central Kenya
Low Risk Zone	Very low or no transmission	Nairobi, parts of Central Kenya, and arid/semi-arid areas like Northern Kenya



RTS,S/AS01 malaria vaccine: 30+ years of development

Malaria vaccine update (as of 4 Nov 2025)

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2015: WHO deploys RTS,S/AS01

Following review of data by the Strategic Advisory Group of Experts on Immunizations (SAGE) and the Malaria Policy Advisory Group (MPAG), WHO recommended:

- Pilot implementation of RTS,S/AS01 with phased, sub-national introduction through routine immunization programmes to inform policy on public health use of vaccine
- Pilot evaluations designed to address outstanding questions:
    1. Feasibility of reaching children with 4 doses
    2. Safety in the context of routine use, emphasis on meningitis and cerebral malaria
    3. Impact on mortality (including gender specific) and severe malaria
- The goal was to inform the WHO policy recommendation on the use of the RTS,S/AS01 vaccine in young children

WHO position paper 2016

The RTS,S/AS01 vaccine considered in this position paper has been evaluated in a large Phase 3 trial, and received a positive regulatory assessment. However, a number of uncertainties need to be resolved in order to assess the advisability of introducing the RTS,S/AS01 vaccine for routine use. A highly critical issue is the extent to which the protection demonstrated in children aged 5–17 months in the Phase 3 trial can be replicated in the context of routine health systems, particularly in view of the need for a 4-dose schedule that requires new immunization contacts. WHO therefore recommends further evaluation of RTS,S/AS01 in a series of pilot implementations, addressing several gaps in knowledge, before considering wider country level introduction.[48]

Extract from Malaria vaccine: WHO position paper – January 2016

Malaria Vaccine Implementation Programme

- Funded by Gavi, Global Fund, and UNITAID
- WHO - programme oversight, coordination; scientific and technical leadership
- PATH - qualitative and economic studies and supported communication
- GSK donated 10M RTS,S vaccine doses
- UNICEF vaccine delivery
- Contributions from >30 partners

World Health Organization

PATH

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

gsk

unicef

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Ghana, Kenya Malawi

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REPUBLIC OF GHANA

Evaluation partners
Commissioned by WHO

Ghana

UNIVERSITY OF GHANA SCHOOL OF PUBLIC HEALTH

UNIVERSITY OF HEALTH AND ALLIED SCIENCES

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
UNIVERSITY OF GHANA, LEGON

Kenya

CDC

KEMRI | Wellcome Trust

CDC Foundation
Together our impact is greater

Malawi

UNIVERSITY OF MALAWI
COLLEGE OF MEDICINE

UNC PROJECT
Lilongwe, Malawi

Funders

Gavi
The Vaccine Alliance

The Global Fund

Unitaid

External monitor

Pharmalys
Clinical Research

ClinWin Research Services
Quality. Efficiency. Ethics

Reference laboratories

MRC Unit The Gambia

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES
Division of the National Health Laboratory Service

Partners qualitative study Commissioned by PATH

UNIVERSITY OF HEALTH AND ALLIED SCIENCES

CDC

LSTM

Malawi-Liverpool-Wellcome Clinical Research Programme

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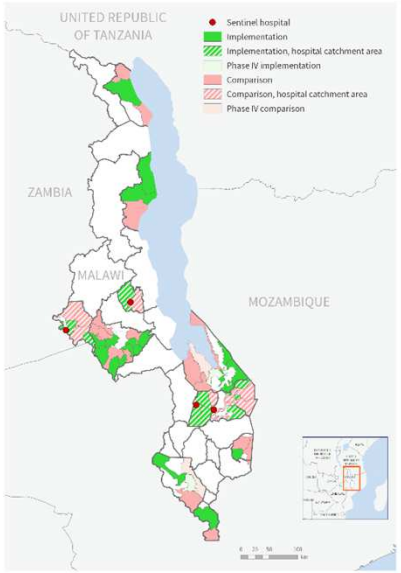
RTS,S/AS01 E-MVIP Malaria Vaccine Implementation Programme 2019-2023

Malawi

First introduced: 23 April 2019

Expanded: 29 Nov 2022

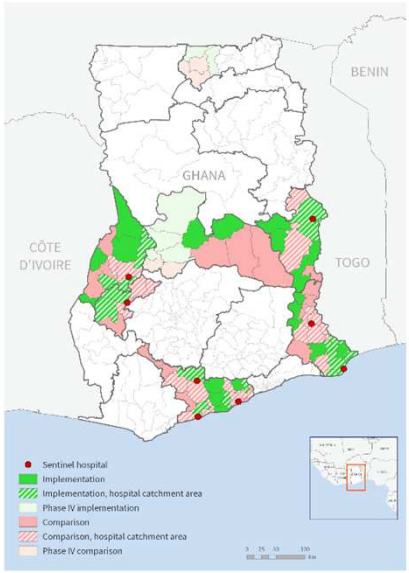


Annual incidence (2023):306 cases per 1000 children

Ghana

First introduced: 30 April 2019

Expanded: 20 Feb 2023

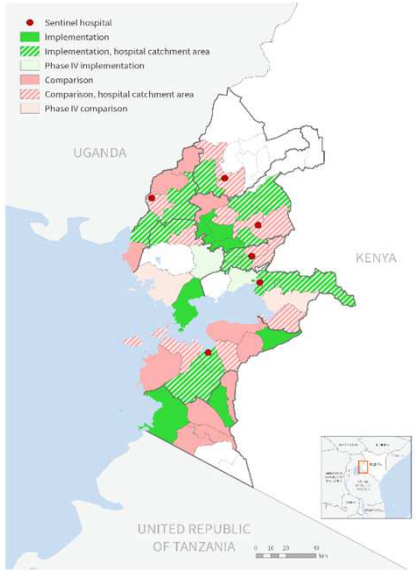


Annual incidence (2023):395 cases per 1000 children

Kenya

First introduced: 13 Sept 2019

Expanded: 7 March 2023



Annual incidence (2023):267 cases per 1000 children

MVIP initial vaccinating district

MVIP comparator district

Non MVIP district

Measure feasibility, safety, impact of vaccine in routine use

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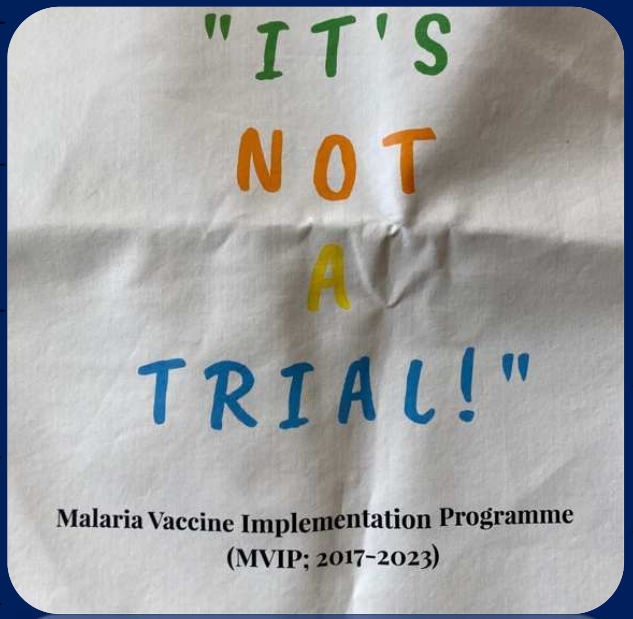
The Malaria Vaccine Implementation Programme: WHO flagship programme



Credit: WHO/F.Combrink

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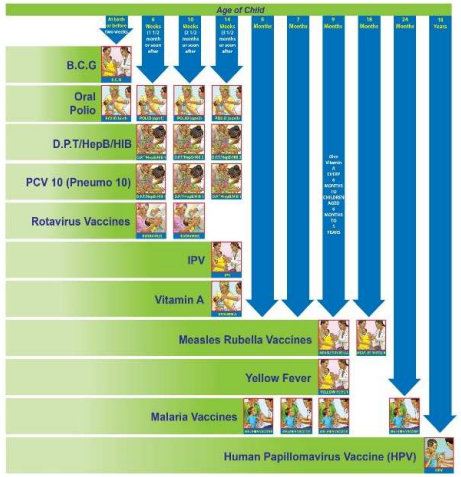
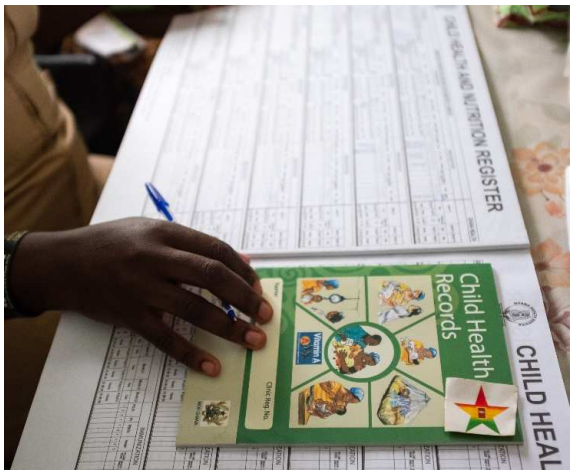
Vaccine implementation began in 2019 in phased introductions

By Ministries of health through country's routine Expanded Programme on Immunization (EPI)



Integration in routine schedule

Service delivery



Recording & reporting in DHIS2

Community engagement

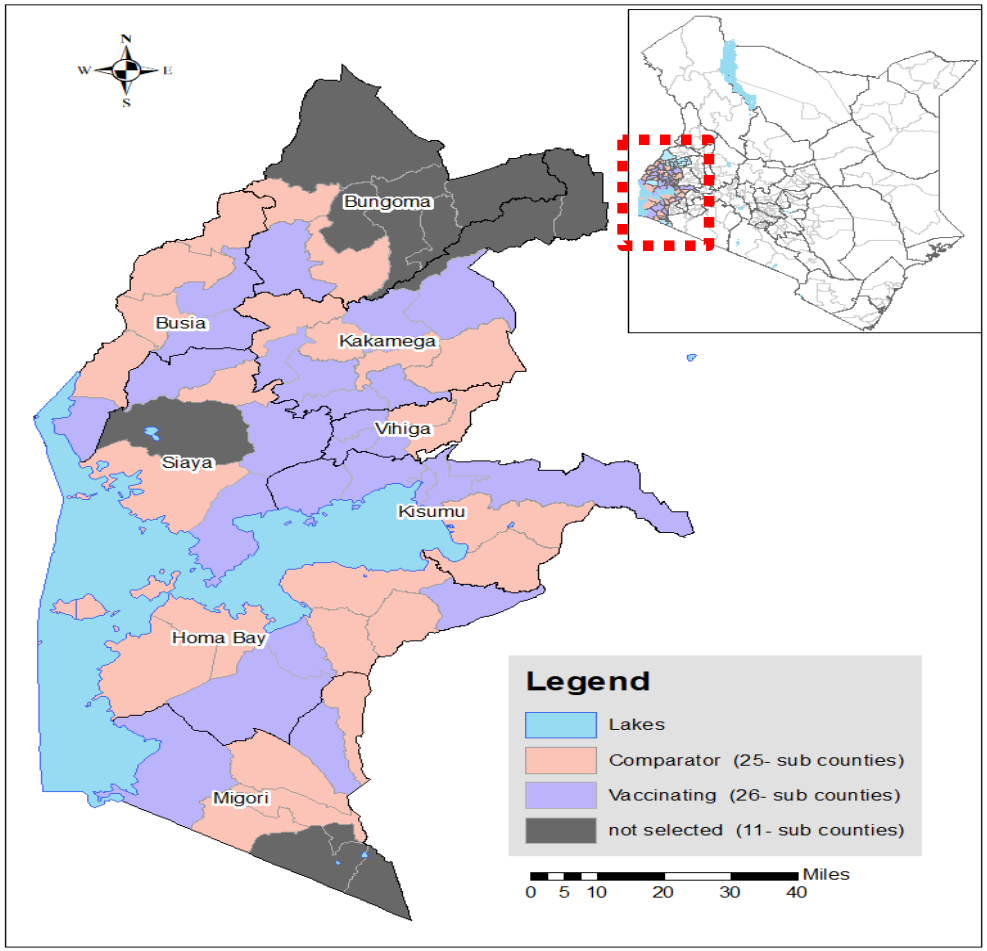
Logistics together with other vaccines

Integrated messaging

Kenya malaria vaccine launch Sept 13, 2019

Malaria vaccine introduction in Kenya

- Malaria vaccine (MV) introduced into national routine immunization programme:
  - In 8 high burden counties[1]
  - In 26 selected sub-counties (purple on map)
  - 603 implementing facilities
  - Annual target of 143,388 children (monthly – 11,949)
- First child vaccinated on 13th September 2019



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1 Bungoma, Vihiga, Kakamega, Busia, Kisumu, Homa Bay, Siaya and Migori

Malaria vaccine in childhood vaccination schedule

Child's age	Birth	6 wks	10 wks	14 wks	5 mo	6 mo	7 mo	8 mo	9 mo	12 mo	15 mo	18 mo	22 mo	24 mo
BCG	1													
Oral polio	0	1	2	3										
DTP-HepB-Hib (penta)		1	2	3								4		
Pneumococcal conj.		1	2	3										
Rotavirus		1	2											
Inactivated Polio				1					2					
Meningococcal A conj.												1		
Measles-Rubella									1			2		
Yellow Fever									1					
Ghana						1	2		3			4		4
Kenya						1	2		3					4
Malawi					1	2	3						4	
Vitamin A						1				2		3		4
Growth Monitoring	•	•	•	•	•	•	•	•	•	•	•	•		•
Deworming										1				2
ITN distribution												•		
PMC			1	2	3	3	4		5			6		

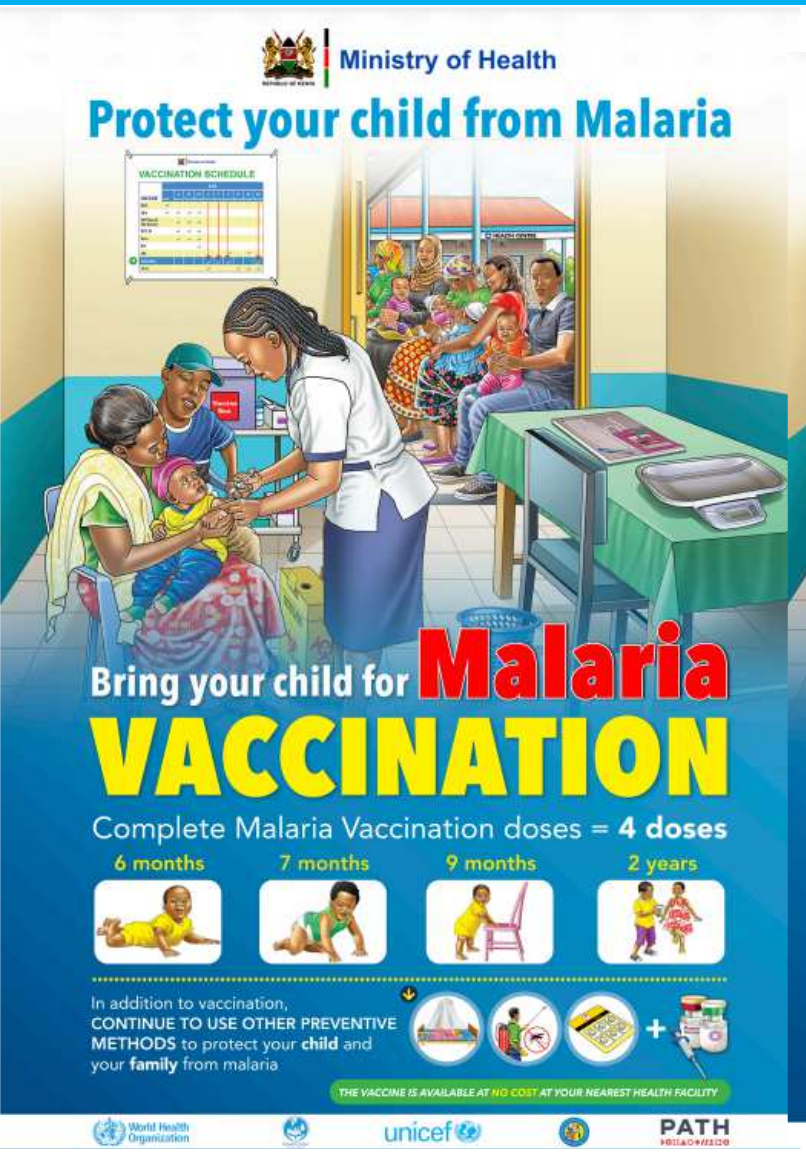
Illustration of malaria vaccine integration into childhood immunization schedule

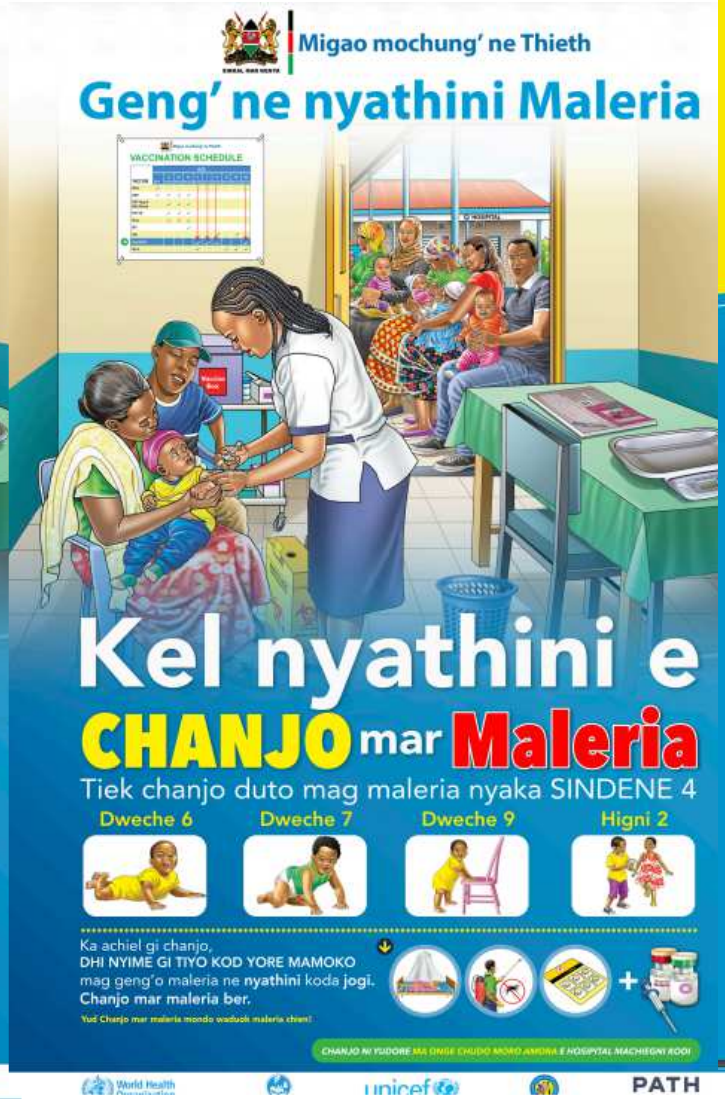
Ghana introduced the malaria vaccine with dose 4 scheduled at 24 months of age; in March 2023, the national immunization programme shifted dose 4 timing to 18 months

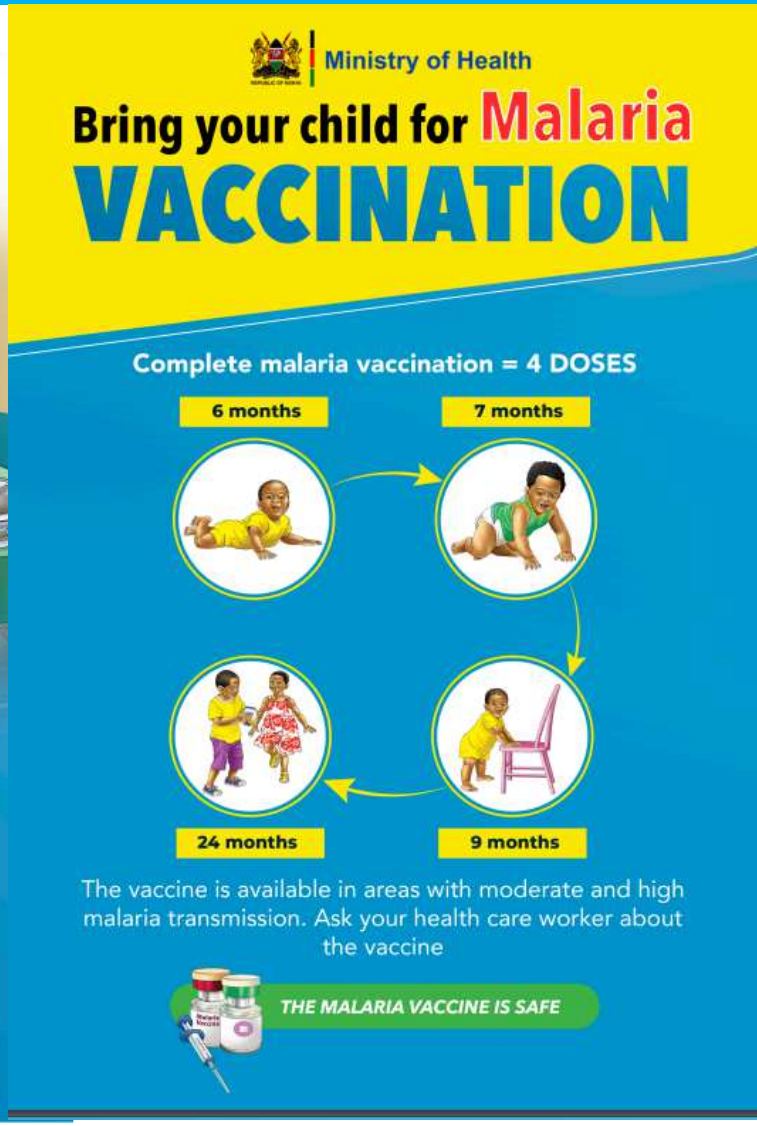
Opportunities for integration with other child health services

Pilot supported with Evidence based high quality communication materials

EVIDENCE BASED IEC MATERIALS IN LOCAL LANGUAGES







First child to receive the vaccine in Kenya doing well over the years

Summary results from the MVIP evaluation, 46 months of vaccine scale-up through routine immunization system, 2019 - 2023

- **Vaccine confirmed to be safe**
- **High uptake and high impact*:**

→ **13% vaccine-attributable reduction in all-cause mortality** excluding injury [0.87 (95% CI: 0.77, 0.97)]

→ **22% reduction** in hospitalized severe malaria [0.78 (95%CI: 0.64, 0.97)]

- **Impact measured during scale-up when ~70% had received 3 doses, and ~40% had received 4 doses**
- No reduction in ITN use, care-seeking behavior, uptake of other vaccines
- Equitable; extends reach of malaria preventive tools

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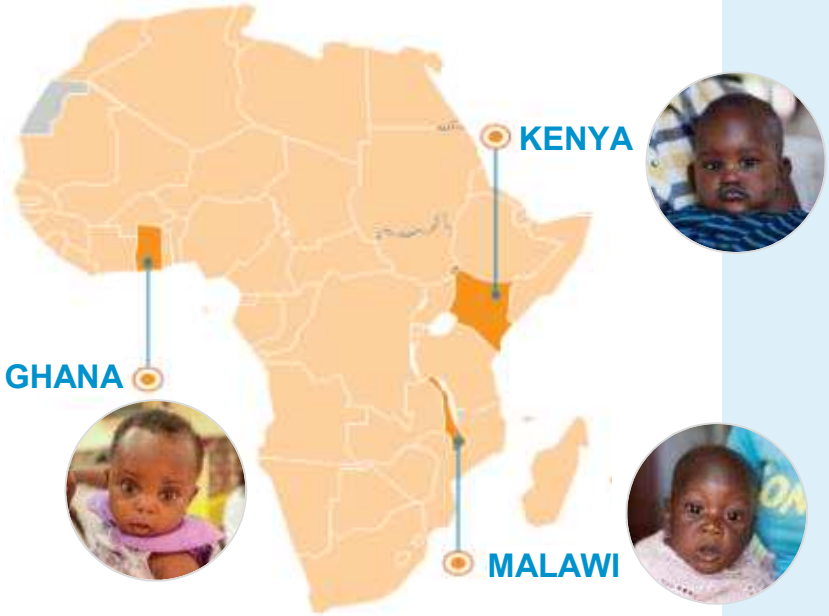
*Statistical Analysis Report available: Immunization, Vaccines and Biologicals (who.int)

2019-2023:

> 2 million children vaccinated with RTS,S

> 6 million doses administered

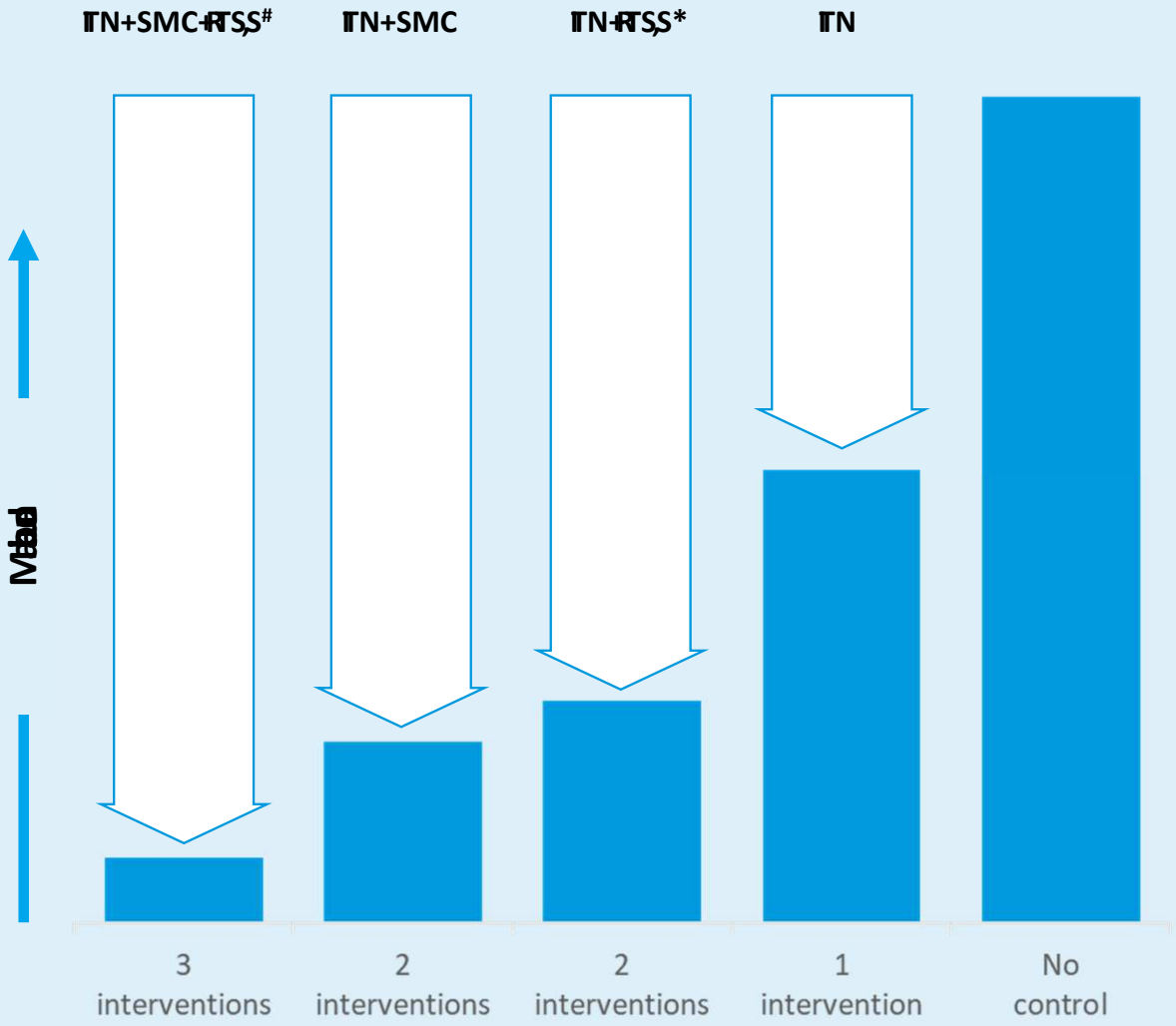


Funded by Gavi, Global Fund, Unitaid

~~Highest impact achieved~~ when mix of malaria interventions used together

We will not reach the goal of driving malaria illness and death down, without applying a mix of available interventions

- Case management
- Vector control (ITNs, IRS, LSM)
- Chemoprevention (SMC, IPTp, PMC, MDA)
- Vaccines (RTS,S, R21)



Source:Professor Paul Milligan, LSHTM

seasonal vaccination, over 3 years
*assumes seasonal vaccination equivalent to efficacy of 4 SMC cycles

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Lessons from the pilot implementation have been published

- **Ensure update of all recording and reporting tools** to include the new vaccine, and then distribute to all administrative levels before the new vaccine is introduced
- **Pre-assessment of cold chain capacity** and scale up as needed before introducing the new vaccine is key to improving vaccine supply and management
- **Investment in HW trainings** in terms of sufficient time, resources, and ensuring that all key health workers at all levels are trained to optimize impact
- Plan for **refresher training** with the expectation of staff turnover and the need to readdress priority topics
- Early training and **involvement of community health volunteers**
- Ensure **robust defaulter tracing mechanisms** are in place as an essential tool in reducing vaccine dropout rates
- Ensure a **"dialogue" with the community** through continuity of advocacy, communication, and social mobilization activities after the initial introduction phase, to reduce dropout rates and ensure children complete the four-dose malaria vaccine immunization schedule.
- Conduct **regular onsite supervisory visits** with written feedback before, during, and after introducing the new vaccine to improve and consolidate staff capacity in deploying and administering it.
- In light of the proliferation of misinformation and anti-vaccination sentiments, **rumors and misinformation must be actively addressed** using social media, key influencers, or other methods to spread the correct messages before introduction

- **Early involvement of subnational levels** from the early planning phase of the new vaccine introduction should be encouraged to develop detailed subnational plans and budgets, which will improve the rollout of the vaccine at the service delivery level

Jalang'o et al. Malaria Journal (2025) 24:244
https://doi.org/10.1186/s12936-025-05484-6

Malaria Journal

RESEARCH Open Access

Subnational introduction of the RTS,S/AS01$_E$ malaria vaccine into routine immunization: experience and lessons from the three pilot countries

Rose Jalang'o[1†], Kwame Amponsa-Achiano[2†], Mike Chisema[3†], Keziah Malm[4], Lydiah Khalayi[1], Brenda Mhone[3], Wahjib Mohammed[4], Franklin Asiedu-Bekoe[5], Adam Haji[6], Josephine Njoroge[6], Boston Zimba[7], Esther Chirwa[7], Peter O. Tweneboah[8], Jackson Sillah[9], Mgaywa G. M. D. Magafu[10], Cynthia Bergstrom[11], Tracey Goodman[11], Jenny Walldorf[11], Kristen Kelleher[11], Eliane Pellaux-Furrer[11], Mary J. Hamel[11], Michael R. Adjei[8†] and Rafiq N. A. Okine[12*†]

https://doi.org/10.1186/s12936-025-05484-6

Table 1 Key recommendations for new vaccine introductions based on MVIP experience

WHO Health System component	Programmatic areas	Key components for future vaccine introductions
Leadership/Governance	Programme coordination	Establish national and subnational coordination mechanisms early to ensure smooth rollout and adequate lead time to address bottlenecks Establish malaria vaccine technical working groups and subcommittees Ensure optimal participation from national malaria and immunization programmes Map funding gaps, identify potential partners, and mobilize additional resources to address them
Service delivery	Communication, Advocacy, and Social Mobilization	Use data and information to understand the community context Early stakeholder mapping and engagement to build champions and mitigate risks Ensure health messages effectively communicate the importance of vaccination across the four-dose schedule, tailoring them for healthcare workers, caregivers, and other stakeholders Develop and communicate clear messaging on vaccine benefits and use alongside other malaria prevention interventions Leverage social media to strengthen public education using short messages and infographics Monitor and evaluate communication activities and course correct as needed

RESEARCH Open Access

POST introduction evaluation (PIE) of the malaria vaccine introduced in three pilot countries (Ghana, Kenya, and Malawi) in 2021

Jenny A. Walldorf[1], Gillian F. Mayers[2], Kwame Amponsa-Achiano[3], Rose Jalang'o[4], Mike Chisema[5], Lydia Khalayi[4], Josephine Njoroge[6], Adam Haji[6], Peter O. Tweneboah[7], Emmanuel T. Sally[3], Donnie Mategula[8,9,10], Brenda Mhone[5], Boston Zimba[11], Esther Chirwa[11], Naziru Tanko Mohammed[3], Michael Rockson Adjei[7], Jackson Sillah[12], Eliane Pellaux-Furrer[1], Mgaywa G. M. D. Magafu[13] and Rafiq N. A. Okine[14*]

https://doi.org/10.1186/s12936-025-05590-5

Oct 2021 - WHO [illegible] *P. falciparum* [illegible]

Oct 2023 – WHO [illegible]

WHO recommends groundbreaking malaria vaccine for children at risk

Historic RTS,S/AS01 recommendation can reinvigorate the fight against malaria

6 October 2021 | News release | Geneva |Reading time: 3 min (859 words)

The World Health Organization (WHO) is recommending widespread use of the RTS,S/AS01 (RTS,S) malaria vaccine among children in sub-Saharan Africa and in other regions with moderate to high *P. falciparum* malaria transmission. The recommendation is based on results from an ongoing pilot programme in Ghana, Kenya and Malawi that has reached more than 900 000 children since 2019.

"This is a historic moment. The long-awaited malaria vaccine for children is a breakthrough for science, child health and malaria control," said **WHO Director-General Dr Tedros Adhanom Ghebreyesus**. "Using this vaccine on top of existing tools to prevent malaria could save tens of thousands of young lives each year."

Malaria remains a primary cause of childhood illness and death in sub-Saharan Africa. More than 260 000 African children under the age of five die from malaria annually.

WHO Press release:
Oct 2021: https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk

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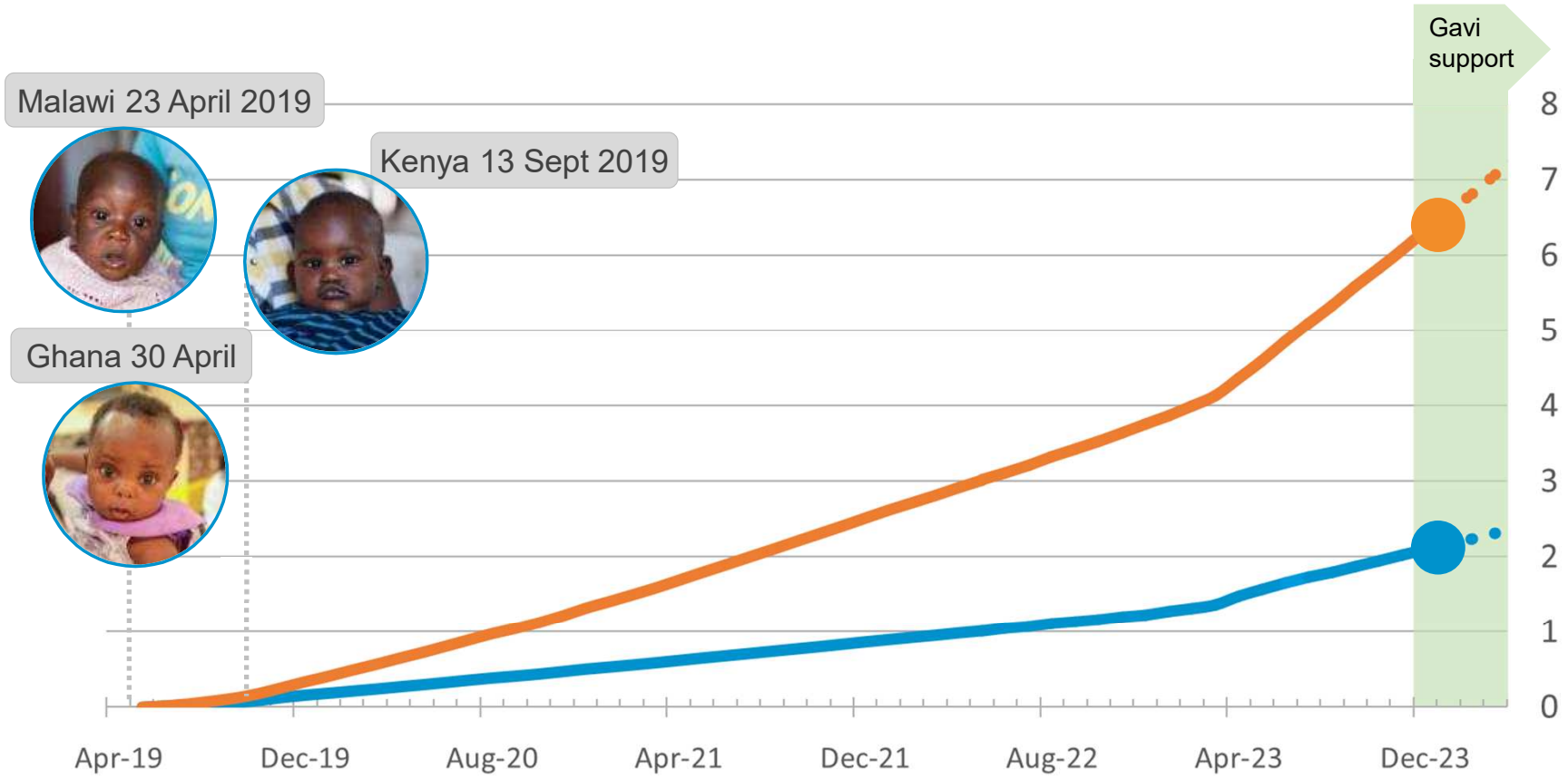
Malawi MVIP update

In 2024, MVIP countries successfully transitioned to Gavi-supported (and co-financed) vaccine doses



> 6 million vaccine doses **administered**

> 2 million children received **at least one dose**

As of December 2023

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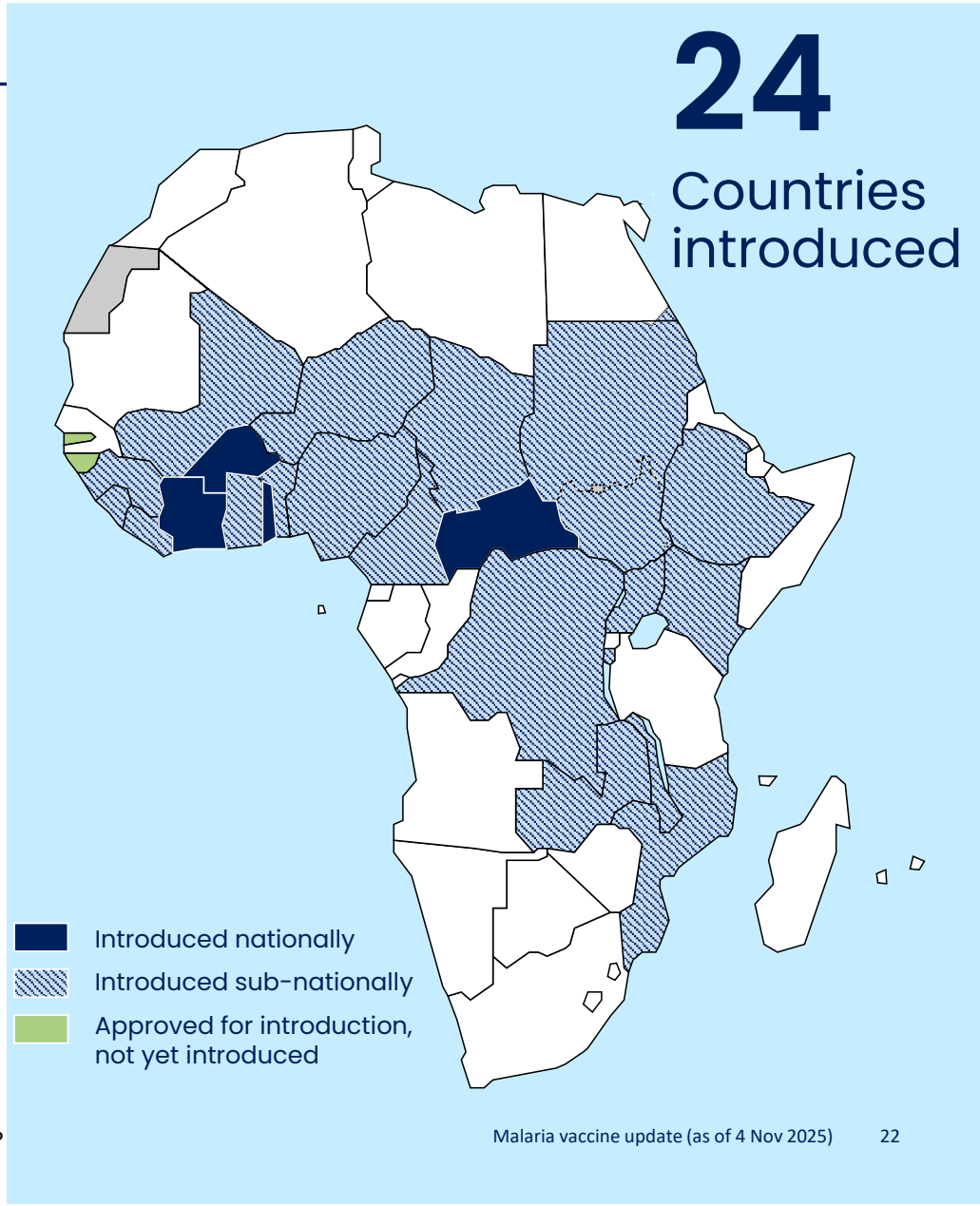
Estimates as of January 2024 - based on monthly MOH/EPI administrative data reports until December 2023, MVIP team projections for subsequent months.

Status of malaria vaccine roll-out

As of 4 November 2025

- **24 countries introduced**[1] (4 nationally, 19 sub-nationally)
  - Malawi, Ghana, Kenya, Cameroon, Burkina Faso, Liberia, Benin, Sierra Leone, Côte d'Ivoire, South Sudan, Mozambique, Central African Republic, Niger, Chad, Democratic Republic of the Congo, Sudan, Nigeria, Burundi, Uganda, Mali, Guinea, Togo, Ethiopia, Zambia
  - Additional introductions and scale-up in 2025 and 2026
- **More than 47 million doses delivered by UNICEF**[2] for a cumulative annual target population of **>10 million children** …rapidly increasing. **Supply sufficient to meet demand.**
- **But, limited geographic reach due to funding constraints:** Gavi support is limited to a maximum of 85% vaccine volume for the **target population** in moderate and high transmission areas. Risk of further cuts due to funding gap for 2026-2030 strategy period
- **Market shaping ongoing:** GSK and Bharat Biotech commit to progressive RTS,S/AS01 price reductions to < US$5/dose by 2028.[3] SII to reduce R21/Matrix-M price (depending on volumes procured)



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Sources:
1 WHO Malaria Vaccine Introduction Dashboard (24 Sep 2025)
2 UNICEF Immunization Market Dashboard + doses delivered during MVIP
3 GSK press release (25 Jun 2025)

WHO recommendation: malaria vaccines

WHO recommends the 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

- 4-dose schedule from around 5 months of age[1]
- A 5th dose, given one year after dose 4, may be provided where malaria risk remains high
- Malaria vaccines should be provided as part of a comprehensive malaria control strategy

Two malaria vaccines

RTS,S/AS01

Recommended: since October 2021
WHO PQ: since July 2022

R21/Matrix-M

Recommended: since October 2023
WHO PQ: since December 2023

Malaria WHO position paper (May 2024)

2024, 99, 225–248 No 19

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

10 MAY 2024, 99th YEAR / 10 MAI 2024, 99e ANNÉE
No 19, 2024, 99, 225–248
http://www.who.int/wer

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Malaria vaccines: WHO position paper

Introduction

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes. They summarize essential background information on diseases and vaccines and conclude with the current WHO position on the use of vaccines worldwide.

The position papers have been reviewed by external experts and WHO staff and have been reviewed and endorsed by the WHO Strategic Advisory Group of Experts (SAGE) on Immunization.[1] This paper has also been reviewed and endorsed by the WHO Malaria Policy Advisory Group (MPAG).[2] The Grading of Recommendations Assessment, Development and Evaluation (GRADE) method was used to assess systematically the quality of the available evidence. The SAGE and MPAG decision-making process is reflected in "evidence-to-recommendation" tables. The processes followed for the prepara-

Note de synthèse: position de l'OMS à propos des vaccins antipaludiques

Introduction

Conformément à son mandat, qui prévoit qu'elle conseille les États Membres en matière de politique sanitaire, l'OMS publie une série de notes de synthèse régulièrement mises à jour sur les vaccins et les associations vaccinales contre les maladies ayant une incidence sur la santé publique internationale. Ces notes portent principalement sur l'utilisation des vaccins dans le cadre de programmes de vaccination à grande échelle. Elles résument les informations essentielles sur les maladies et les vaccins concernés et présentent en conclusion la position actuelle de l'OMS à propos de l'utilisation de ces vaccins à l'échelle mondiale.

Examinées par des experts externes et des membres du personnel de l'OMS, ces notes sont également évaluées et approuvées par le Groupe stratégique consultatif d'experts sur la vaccination (SAGE) de l'OMS.[1] La présente note a par ailleurs été examinée et approuvée par le Groupe consultatif sur la politique de lutte contre le paludisme (MPAG) de l'OMS.[2] La qualité des données disponibles a été évaluée de manière systématique au moyen de la méthodologie GRADE (Grading of Recommendations Assessment, Development and Evaluation). Le processus de décision du SAGE et du MPAG est reflété dans les tableaux des données à l'appui des recommandations. La procédure suivie pour

Source: https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers/malaria

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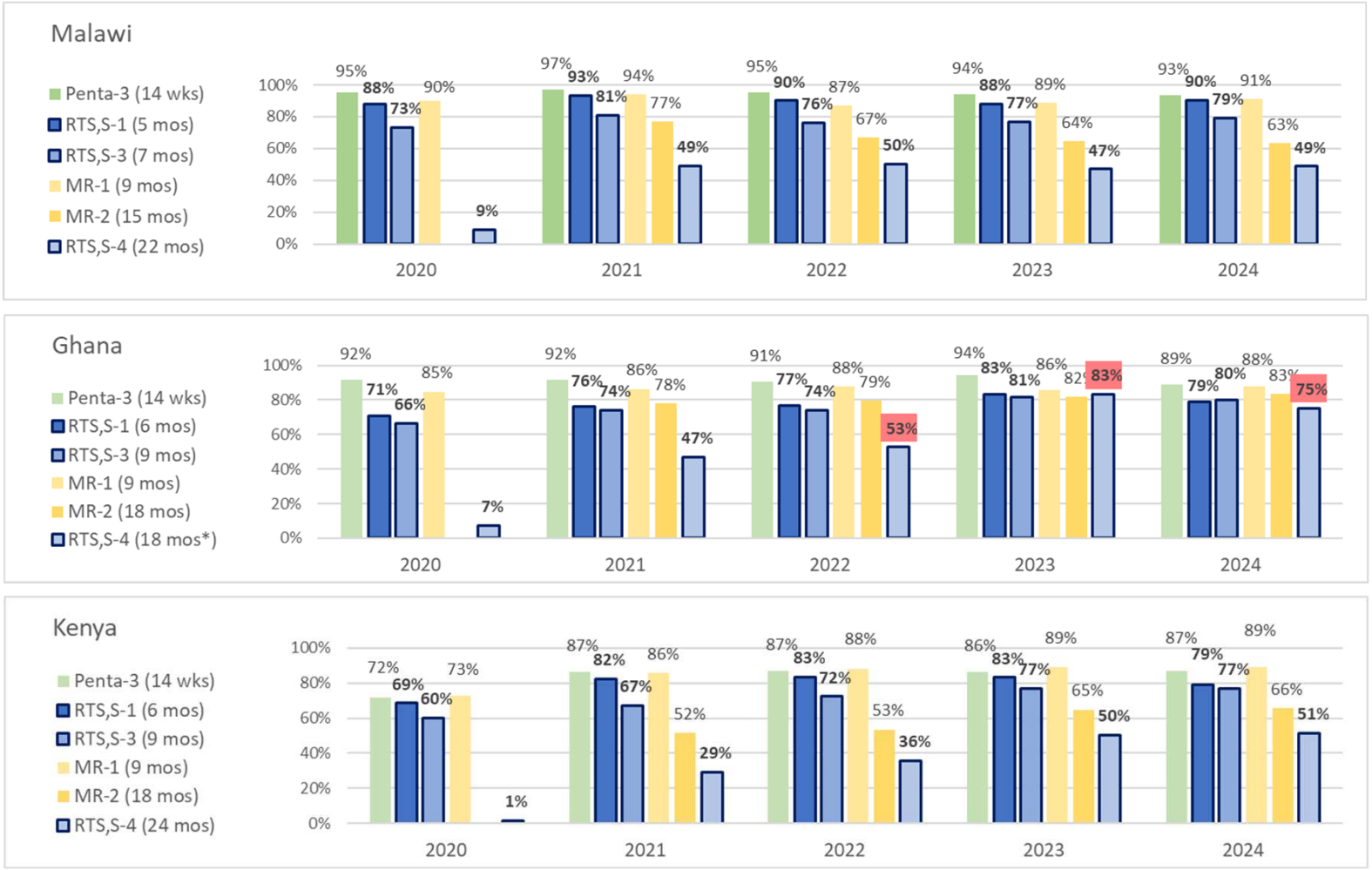
[1] Countries may choose to give the first vaccine dose earlier than 5 months of age on the basis of operational considerations, to increase coverage or impact.

Malaria Vaccine Implementation Programme (MVIP) coverage, 2020 – 2024

- The MVIP demonstrated that a 4-dose schedule is **feasible to implement** with generally **high demand and acceptance**
- By the end of 2024, all 3 countries reached approximately **80%** of the target populations with dose 1 and **>77%** with dose 3
- External factors (COVID-19, tropical storms, health worker strikes, etc.) disrupted access to vaccines at various time points; uptake in all countries returned to prior levels
- In Ghana, >80% coverage reached after dose 4 schedule changed from 24 months to 18 months in early 2023 to coincide with Men A, MR-2, and ITN provision

A 2020-2024



Penta-3 = Pentavalent (DTP-Hib-HepB) vaccine dose 3 ; RTS,S-1 = Malaria vaccine dose 1 ; RTS,S-3 = Malaria vaccine dose 3 ; RTS,S-4 = Malaria vaccine dose 4 ; MR-1 = Measles and rubella containing vaccine dose 1 ; MR-2 = Measles and rubella containing vaccine dose 2

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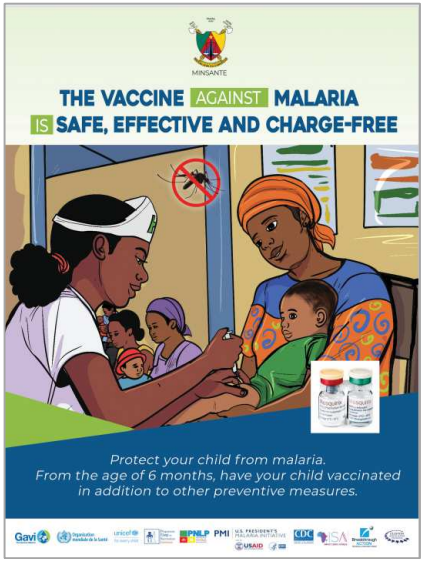
Ministry of Health

Countries launching have continued to emphasize malaria vaccine as part of a package of control measures



Examples of information, communication and education materials developed by Ministries of Health:
Top left: MoH Liberia
Bottom left: MoH Cameroon
Middle: MoH Burkina Faso
Right: MoH Niger

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Source: WHO Malaria Vaccine Introduction Dashboard

WHO guidance allows for flexibility in vaccine schedule

Schedules chosen among countries implementing malaria vaccines

Country	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Benin						1	2		3									4						
Burkina Faso					1	2	3								4									
Burundi						1	2		3									4						
Cameroon						1	2		3															4
CAR						1	2		3							4								
Chad						1	2		3						4									
Côte d'Ivoire						1		2	3						4									
DR Congo						1	2	3							4									
Ethiopia						1	2		3						4									
Ghana						1	2		3									4						
Guinea					1	2	3								4									
Kenya						1	2		3															4
Liberia					1	2	3								4									
Malawi					1	2	3															4		
Mali*					1	2	3																	
Mozambique						1	2		3									4						
Niger						1	2	3								4								
Nigeria					1	2	3								4									
Sierra Leone						1	2	3										4						
South Sudan					1	2	3											4						
Sudan					1	2	3											4						
Togo					1	2	3								4									
Uganda						1	2	3										4						
Zambia						1	2	3										4						

*In the **hybrid approach**, children return for a seasonal dose (**doses 4 and 5**) each year just before the high transmission season (and at least 6 months after dose 3)*

23/24 countries providing 4-dose age-based schedule, 1 country (Mali) providing 5-dose hybrid schedule

Dose 1-3: Between 5 and 9 months of age

Dose 4: mostly in second year of life (2YL) & aligned with existing visit (e.g. measles 2nd dose, MenA) at 15, 16 or 18 months of age.
Efforts in place to strengthen 2YL

Opportunities created to share experiences and learnings across countries and partners

4 malaria vaccine peer-learning workshops to share and discuss experiences and lessons learned, including through field visits

- Organized by WHO and partners in Cameroon, Ghana, Benin and Malawi
- Attended by representatives from ministries of health (EPI & NMCP) of 23 countries and their partners

WhatsApp group created by AMVIRA for informal exchanges among programme managers and partners

Continued exchange of experiences and learnings across countries is facilitated through weekly webinars organized by **AMVIRA** (WHO Regional Office for Africa's initiative to Accelerate Malaria Vaccine Introduction and Roll-out in Africa)

Regular Malaria Vaccine Coordination Team (MVCT) meetings in plenary and sub-teams on implementation and communications and advocacy

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Kenya’s Malaria Vaccine Expansion and Switch

- Kenya currently planning to expand the malaria vaccine to all areas in the lake endemic region
- Kenya plans to switch to R21 product formulation
- Trainings and sensitizations just concluded with country ready to expand and switch in 2025

Technical report: https://iris.who.int/handle/10665/380223 **Research Brief:** https://iris.who.int/handle/10665/380228

Thank you

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REPUBLIC OF KENYA

Ministry of Health