

Malaria Vaccine Implementation Programme (MVIP)
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Emergencies v



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 800 000 children since 2019.

This long-awaited vaccine, developed in Africa, by African scientists, is a breakthrough for science, child health and malaria control... This vaccine is a gift to the world, but its value will be felt most in Africa, because that's where the burden of malaria is greatest.

-WHO Director-General Dr Tedros Adhanom Ghebreyesus.

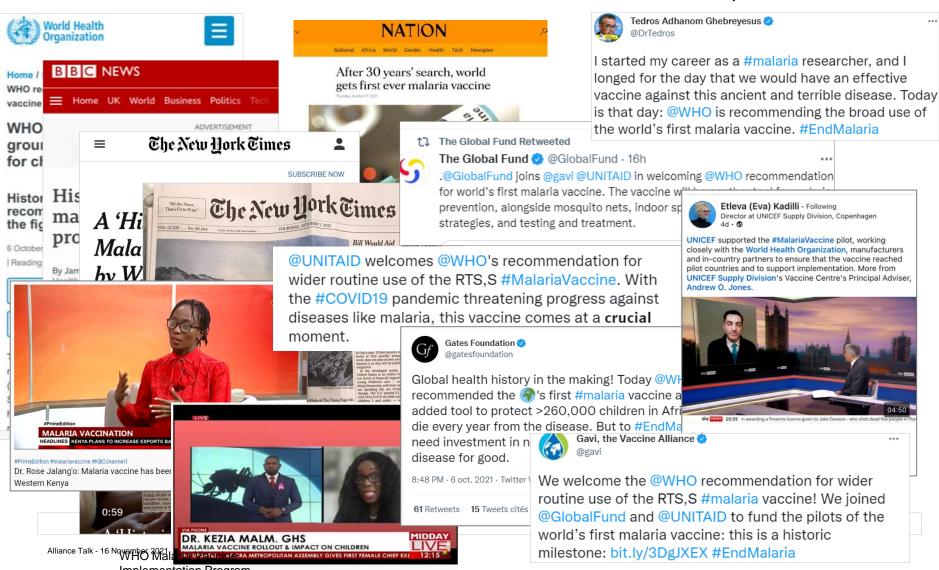




"This is a historic moment."



Within 24-hours, over 6 300 media mentions referenced RTS,S malaria vaccine, + hundreds of media stories and about 1 billion social media impressions



Oct 6 2021: SAGE & MPAG full evidence review of RTS,S/AS01, including 2 yr data from pilot evaluations



- 1. Feasible to deliver: Vaccine can reach children, with high coverage
 - During global pandemic high demand
 - Introduction did not negatively impact uptake of other vaccines, insecticide-treated bed nets (ITNs), care-seeking behavior
 - The vaccine was able to reach children not yet protected by ITNs, extending the reach of malaria preventive measures to vulnerable children
- 2. Safety: Vaccine has a favorable safety profile
 - No evidence in the pilot evaluations that the safety signals seen in the phase 3 trial were related to the RTS,S vaccine
 - No new safety concerns after over 1 million doses provided
- 3. Impact: Vaccine introduction resulted in a substantial and statistically significant reduction in hospitalized severe malaria and hospitalization with malaria infection
 - In the real-world setting, among children <u>age-eligible for vaccination</u>
 - Confirms vaccine can have substantial added benefit to reduce child illness and death from malaria

Review by expert advisory bodies, 2021



30 April

Pilot Evaluation data lock for 24-month primary analysis

27-28 July
Review by
MVIP DSMB
of safety and
impact analysis

9 Aug

Review by African Advisory Committee on Vaccine Safety (AACVS)

10 Aug

Review by Global Advisory Committee on Vaccine Safety (GACVS)

2 or 8 Sept Technical briefings for SAGE & MPAG 6 October: Joint SAGE & MPAG review

1 July RITAG update

5 & 11 May Technical briefings

for SAGE & MPAG

24-26 August

Full evidence review by RTS,S **SAGE/MPAG**Working Group

WHO recommendations on RTS,S/AS01 malaria vaccine



WHO recommends the RTS,S/AS01 malaria vaccine be used for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO



Background on RTS,S/AS01 and the Malaria Vaccine Implementation Programme

Credit: WHO/Neil Thomas.

The RTS,S malaria vaccine development: 30-years and counting...





Oct 2015
Joint SAGE &
MPAC review

2016
WHO
recommendation
for pilot
implementation

2015 EMA positive scientific opinion granted

Discovery

Preclinical Phase 1

Phase

Phase 3

Malaria Vaccine Implementation Programme

1984 1987

1995

First clinical tests in adults begin in US, followed by trials in adults in Africa 2004

Proof of concept demonstrated in African children, then in infants

2009

Phase 3 trial in 11 sites in seven African countries 2015

Phase 3 final results published

2019

National Regulatory Approval; Vaccine launch in routine programme in Ghana, Kenya, Malawi

Four components of the MVIP







RTS,S/AS01
Implementation
through EPI
Programme

In selected areas of Ghana, Kenya & Malawi Pilot evaluation commissioned by WHO

Incl. sentinel hospitals surveillance; community-based mortality surveillance; 3 household surveys

- Qualitative assessment (HUS) & economic analyses
 - commissioned by PATH
- GSK Phase IV study

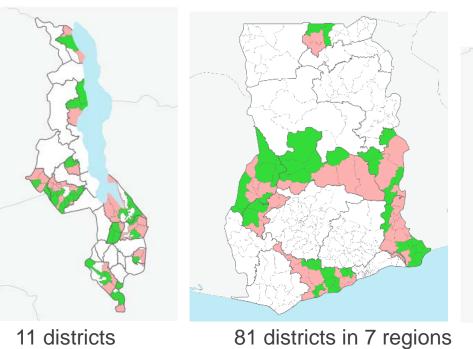
Safety, effectiveness and impact Part of GSK's EMA Risk Management Plan

MVIP areas



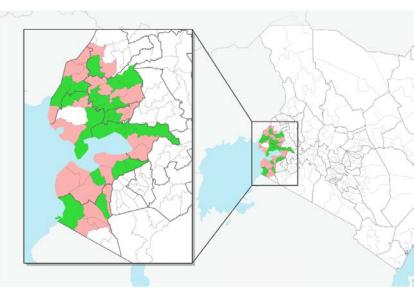
- Vaccinating (+ pilot evaluation)
- Non vaccinating (+ pilot evaluation)

Malawi



Ghana

Kenya



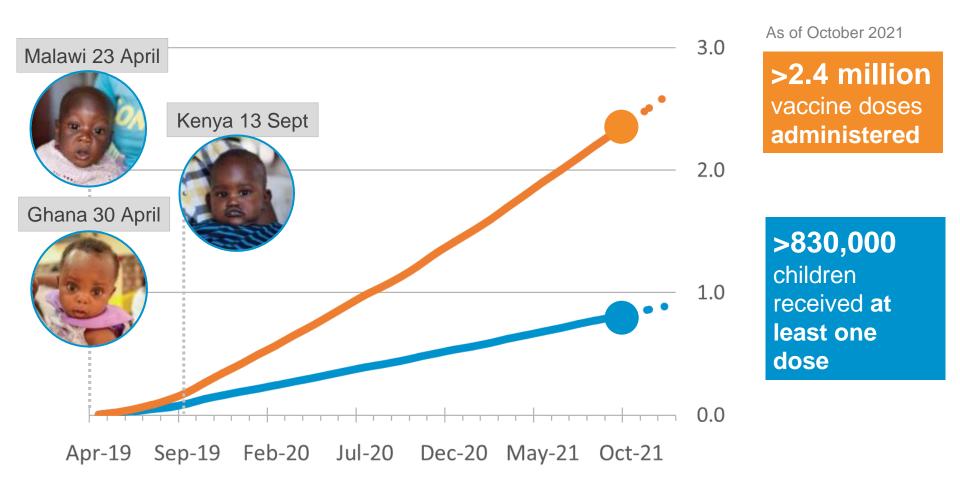
51 sub-counties in 8 counties

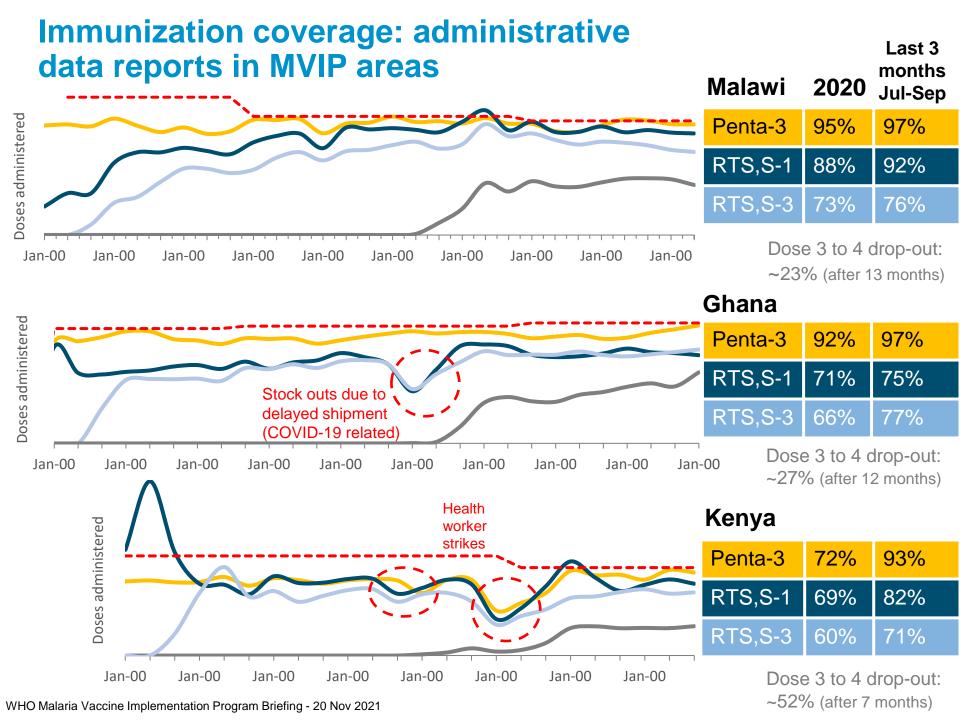
The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: MoH Kenya; MoH Malawi; MoH Ghana. Map Production: WHO GIS Centre for Health, DNA/DDI. © WHO 2021. All rights reserved.

Malaria vaccine implementation programme on track despite COVID-19







Recommendation is based on a full evidence review of RTS,S/AS01, including 2-year data from pilot Reviewed jointly by SAGE & MPAG on October 6 2021



Key findings:

- 1. Feasible to deliver: Vaccine can reach children, with high demand
 - Good coverage reached with first 3 doses through the routine systems
 - Introduction did not negatively impact uptake of other vaccines, insecticidetreated bed nets (ITNs), care-seeking behavior
 - The vaccine was able to reach children not yet protected by ITNs, extending the reach of malaria preventive measures to vulnerable children
 - 2/3 of children not sleeping under an ITN receiving the RTS,S vaccine
 - Overall, more than 90% of children benefitted from either sleeping under an ITN or RTS,S vaccination

Recommendation is based on a full evidence review of RTS,S/AS01, including 2-year data from pilot Reviewed jointly by SAGE & MPAG on October 6 2021



Key findings:

- 2. Safety: Vaccine has a favorable safety profile
 - No evidence in the pilot evaluations that the safety signals that were seen in the phase 3 trial were related to the RTS,S vaccine
 - No new safety concerns after over 1 million doses provided
- **3. Impact:** Vaccine introduction resulted in a substantial and statistically significant reduction in hospitalized severe malaria and hospitalization with malaria infection
 - Among children <u>age-eligible for vaccination</u>, when introduced in the realworld setting
 - Impact seen even in setting with good ITN use and access to ACTs
 - Confirms vaccine can have substantial added benefit to reduce child illness and death from malaria

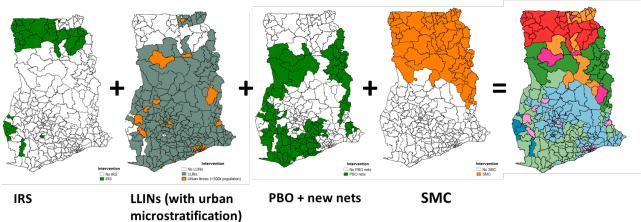


RTS,S/AS01 access & supply, and next steps

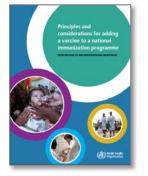
Next steps: WHO operational guidance on vaccine use



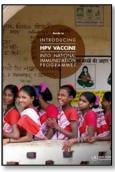
- New operational manual on sub-national tailoring of malaria interventions (in progress)
 - Expands on approaches for stratification, criteria for sub-national intervention targeting and the identification of the optimal mixes of interventions



 New vaccine implementation guidance (in progress)



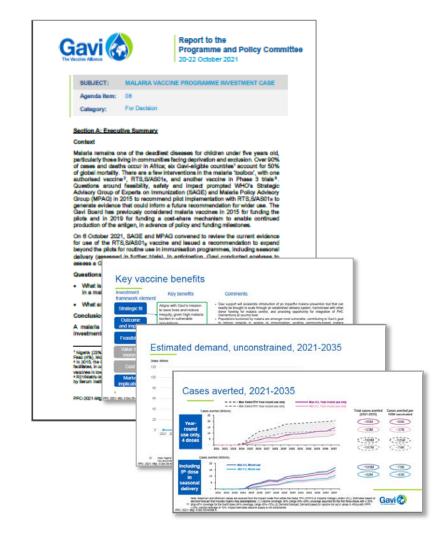
Intervention mixes



Next steps: Global funding decisions



- Malaria Vaccine Programme Investment Case, developed by Gavi Secretariat
- Review and decision by Gavi Board, 1-2 December
- If approved, development of Malaria
 Vaccine Programme and activation
 of market shaping team



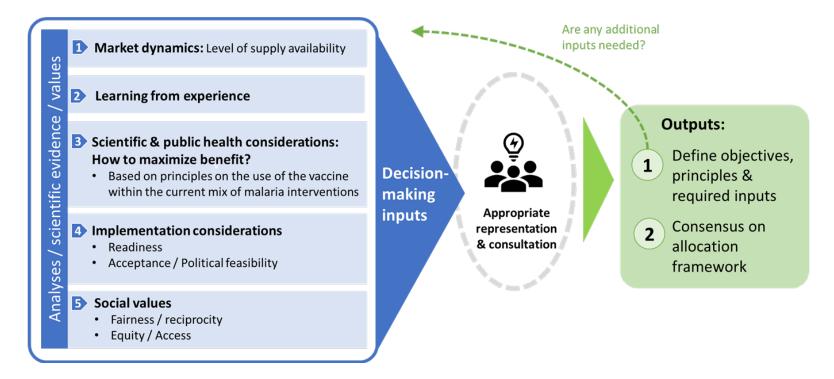
Next steps: Development of allocation framework for limited supply





Guiding principle: Legitimacy

Make global decisions about vaccine allocation through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by key parties



MVIP is a collaboration across many partners











Ministry of Health Ghana, Kenya Malawi

REPUBLIC OF KENYA







Evaluation partners

Commissioned by WHO

Ghana













Kenya











Malawi





Funders



The Global Fund



External monitor





Reference **laboratories**

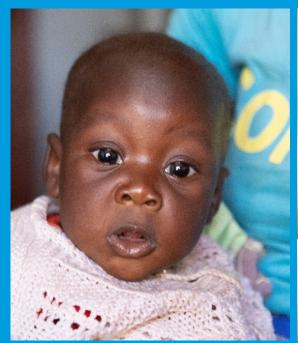






Partners qualitative Study Commissioned by PATH









Thank you