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

Tedros Adhanom Ghebreyesus
@DrTedros

I started my career as a #malaria researcher, and I longed for the day that we would have an effective vaccine against this ancient and terrible disease. Today is that day: @WHO is recommending the broad use of the world’s first malaria vaccine. #EndMalaria

@UNITAID welcomes @WHO’s recommendation for wider routine use of the RTS,S #MalariaVaccine. With the #COVID19 pandemic threatening progress against diseases like malaria, this vaccine comes at a crucial moment.

Gavi, the Vaccine Alliance
@gavi

We welcome the @WHO recommendation for wider routine use of the RTS,S #malaria vaccine! We joined @GlobalFund and @UNITAID to fund the pilots of the world’s first malaria vaccine: this is a historic milestone: bit.ly/3DgJXEX #EndMalaria
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 **age-eligible for vaccination**
   - Confirms vaccine can have substantial added benefit to reduce child illness and death from malaria
30 April
Pilot Evaluation data lock for 24-month primary analysis

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

1 July
RITAG update

5 & 11 May
Technical briefings for SAGE & MPAG

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

24-26 August
Full evidence review by RTS,S SAGE/MPAG Working Group

6 October:
Joint SAGE & MPAG review
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
The RTS,S malaria vaccine development: 30-years and counting...

Discovery
1984
1987

Pre-clinical
1995
First clinical tests in adults begin in US, followed by trials in adults in Africa

Phase 1
2004
Proof of concept demonstrated in African children, then in infants

Phase 2
2009
Phase 3 trial in 11 sites in seven African countries

Phase 3
2015
Phase 3 final results published

2016
WHO recommendation for pilot implementation

2019
National Regulatory Approval; Vaccine launch in routine programme in Ghana, Kenya, Malawi

Malaria Vaccine Implementation Programme

Oct 2015
Joint SAGE & MPAC review

EMA positive scientific opinion granted
Four components of the MVIP

1. **RTS,S/AS01 Implementation through EPI Programme**
   - In selected areas of Ghana, Kenya & Malawi

2. **Pilot evaluation commissioned by WHO**
   - Incl. sentinel hospitals surveillance; community-based mortality surveillance; 3 household surveys

3. **Qualitative assessment (HUS) & economic analyses**
   - commissioned by PATH

4. **GSK Phase IV study**
   - Safety, effectiveness and impact
   - Part of GSK’s EMA Risk Management Plan
MVIP areas

Malawi | Ghana

11 districts | 81 districts in 7 regions | 51 sub-counties in 8 counties

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

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

Malawi 23 April

Kenya 13 Sept

Ghana 30 April

As of October 2021

>2.4 million vaccine doses administered

>830,000 children received at least one dose

Estimates as of 29 Oct 2021 - based on monthly MOH/EPI administrative data reports until August 2021 and MVIP team projections for September & October 2021
Immunization coverage: administrative data reports in MVIP areas

**Malawi**
- Penta-3: 95% in 2020, 97% in Jul-Sep
- RTS,S-1: 88% in 2020, 92% in Jul-Sep
- RTS,S-3: 73% in 2020, 76% in Jul-Sep

Dose 3 to 4 drop-out: ~23% (after 13 months)

**Ghana**
- Penta-3: 92% in 2020, 97% in Jul-Sep
- RTS,S-1: 71% in 2020, 75% in Jul-Sep
- RTS,S-3: 66% in 2020, 77% in Jul-Sep

Dose 3 to 4 drop-out: ~27% (after 12 months)

**Kenya**
- Penta-3: 72% in 2020, 93% in Jul-Sep
- RTS,S-1: 69% in 2020, 82% in Jul-Sep
- RTS,S-3: 60% in 2020, 71% in Jul-Sep

Dose 3 to 4 drop-out: ~52% (after 7 months)

Stock outs due to delayed shipment (COVID-19 related)

Health worker strikes

WHO Malaria Vaccine Implementation Program Briefing - 20 Nov 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, 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
     - 2/3 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
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 **age-eligible for vaccination**, when introduced in the real-world 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)
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

- Market dynamics: Level of supply availability
- Learning from experience
- Scientific & public health considerations: How to maximize benefit?
  - Based on principles on the use of the vaccine within the current mix of malaria interventions
- Implementation considerations
  - Readiness
  - Acceptance / Political feasibility
- Social values
  - Fairness / reciprocity
  - Equity / Access

Outputs:
1. Define objectives, principles & required inputs
2. Consensus on allocation framework
MVIP is a collaboration across many partners

Evaluation partners
Commissioned by WHO

Ghana

Kenya

Malawi

Funders

External monitor

Reference laboratories

Partners qualitative study
Commissioned by PATH
Thank you