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Malaria vaccines indicators

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Burden & epidemiology

Number of new cases per year (last 3-5 years)

There were an estimated 282 million malaria cases in 2024, an increase of 19 million cases compared to 2023. Approximately 95% of malaria cases occur in sub-Saharan Africa and mostly among African children under five years of age. 1 Case incidence has remained largely unchanged since 2015.

In many endemic areas, malaria parasite transmission occurs throughout the year, often with seasonal variation; in areas of highly seasonal malaria, transmission is influenced largely by rainfall patterns and limited primarily to several months per year. Intensity is usually heterogeneous within a country: there may be areas with very high transmission, areas with variable transmission where sporadic epidemics affect all age groups, and areas with little or no malaria transmission. In areas of high malaria transmission, young children often experience multiple episodes of clinical malaria each year, even while utilizing available malaria control tools. [2]

Proportion of the population affected by the disease or infected with the antigen

Malaria disproportionately affects children under five years of age. In many countries with high perennial transmission, the age of highest risk is under three years of age, while in areas of highly seasonal malaria, the age of highest risk may be extended. [3, 4, 5]

Adults who have resided in areas with high transmission since childhood generally develop partial immunity through repeated infection from early months of age and are generally not at risk of severe malaria. Pregnant women and immunocompromised individuals remain at a higher risk for severe malaria and death. [2] Malaria in pregnancy is an important cause of maternal morbidity, stillbirths, and low birthweight, which is in itself associated with infant mortality.

Serogroup or serotype distribution (for serogroup- or serotype-specific vaccines)

Five Plasmodium species are known to cause malaria in humans.

The vast majority of malaria deaths are caused by *Plasmodium falciparum*, and most occur in African children under five years of age. *P. vivax* is an important cause of malaria morbidity outside sub-Saharan Africa. The remaining human-infective species are *P. malariae*, *P. ovale*, and *P. knowlesi*. [1, 2]

Plasmodium parasites show genetic diversity and strain variation within species, as opposed to

classification by serogroups or serotypes, that are more relevant for viruses and bacteria. [6]

Number of deaths from the disease per year

In 2024, approximately 610 000 deaths were attributed to malaria, of which an estimated 440 000 occurred in children under five years of age, almost all caused by *P. falciparum*. [7]
While the global mortality rate has generally declined over the past two decades – the annual number of malaria deaths were higher in 2024 than 2023 (by 13 000). [7]

In 2024, one in six children aged 1-59 months died from malaria (17%) globally and one in four children died from malaria in sub-Saharan Africa (25%). [4] Malaria mortality rates begin to fall around 24 months of age in areas of moderate and high transmission, while in areas of highly seasonal malaria, acquired immunity may take longer to develop. [2]

Case Fatality ratio (number of deaths / number of new cases, in %)

The weighted mean CFR among children with uncomplicated *P. falciparum* malaria treated with artemisinin-based combination therapies was 0.068% (95% CI 0.024–0.112). Among studies that offered moderate to high quality care, the weighted mean CFR among hospitalized children with malaria diagnosis was 3.4% (95% CI 1.6–5.2) and among hospitalized children with severe disease was 13.6% (95%CI 8.4–18.8). [8]

Case fatality rates in severe malaria have been estimated at >90% if a child does not reach or receive adequate treatment, and 13-20% for hospitalized children. [9], [10] Those who survive malaria may have long-term sequalae, including neurocognitive and behavioral impairments. [10]

Non-specific signs and symptoms of malaria contribute to the CFR, as early presentation may be difficult to distinguish from other illnesses. Without treatment, malaria can progress rapidly, changing from an apparently mild condition to severe illness and death within 24 hours. [9]

Malaria also contributes substantially to child mortality indirectly by exacerbating other common childhood illness, such as pneumonia, diarrhoea, and malnutrition. [9] [11]

Outbreak, epidemic or pandemic risk

In most areas reporting malaria cases, the disease is endemic. Localized outbreaks or malaria epidemics can occur due to climate, flooding, population movement, and related factors, such as the spread of invasive vectors (*An. Stephensi*). Malaria epidemics have been reported in northern Nigeria, Senegal, Zanzibar, and Uganda. 12, 13, 14, 15, 16

The major malaria vector species and the parasite require specific climatic conditions and temperature ranges that are typically found in tropical regions; even though shifts in climate may alter the geographic areas suitable for transmission.

Contribution of the vaccine to achievement of the national, regional or global disease goals

WHO recommends the use of malaria vaccines (RTS,S/AS01 and R21/Matrix-M) for the prevention of *P. falciparum* malaria for children living in endemic areas, prioritizing areas of moderate and high transmission. 2 Currently available vaccines reduce disease burden (clinical and severe malaria and all-cause child deaths), but do not prevent infection or block transmission. The delivery of malaria vaccines should be part of a comprehensive malaria control strategy and integrated into primary health care service delivery.

Malaria vaccine is one of several WHO-recommended high-impact interventions (all only partially protective); higher impact can be achieved through a mix of tools determined by the country through subnational tailoring, and considering local context. 17, 5

The burden of malaria in Africa has been reduced substantially in recent decades as a result of scaled-up malaria control measures. However, since 2015, the rate of progress in reducing both malaria cases and deaths has stalled; in some countries with high malaria burden, the annual number of malaria cases has risen. Increased use of current control and prevention tools, which now include malaria vaccine, and the addition of new tools, strategies and enhanced problem-solving approaches are needed to further improve malaria control. 2

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Benefits of the intervention

Serogroup or serotype coverage by vaccines considered (for serogroup- or serotype-specific vaccines)

RTS,S/AS01 and R21/Matrix-M are pre-erythrocytic vaccines that target the central repeat amino acid sequence Asn-Ala-Asn-Pro (NANP) region of the *P. falciparum* circumsporozoite protein (CSP). [2]
Protection extends across diverse *P. falciparum* strains circulating in Africa. [18], [19]

Given the species-specific design of these vaccines and the substantial sequence divergence of CSP across malaria parasites, meaningful protection against non-*falciparum* species is not expected, although this has not been directly evaluated.

Efficacy and effectiveness estimates (e.g. against infection, disease, hospitalization, death), including in different populations

Clinical trials of age-based delivery of RTS,S and R21 vaccines showed more than 50% reduction in malaria cases over the first year of follow up, and prolonged protection with the fourth dose. [2], [20], [21], [22] WHO re-affirmed its recommendation for the 4-dose schedule after a case-control study showed the fourth dose provides 30% incremental effectiveness against severe malaria compared to three doses. [23]

An independent evaluation of RTS,S/AS01 pilot implementation in childhood immunization in three African countries during a 46-month period showed a 13% drop in mortality from all causes among children age-eligible for vaccination, and a substantial reduction (22%) in hospitalizations for severe malaria. [24]

About 75% reduction of malaria cases was achieved over the first year of follow up when malaria vaccines were given seasonally, just prior to the start of the high transmission season, and prolonged protection with annual seasonal doses. [25]

The WHO recommendation for R21/Matrix-M was based on the similar vaccine construct as RTS,S/AS01 and results from an ongoing trial that showed similar high vaccine efficacy across sites using age-based and seasonal vaccination approaches. There is no evidence to date showing that one vaccine performs better than the other. [21]

Duration of protection and waning of immunity in general and risk groups

Four doses of RTS,S/AS01 or R21/Matrix-M malaria vaccines provide added protection through early childhood, the period of highest risk of severe malaria in moderate-to-high-transmission settings.

Data show RTS,S/AS01 efficacy against clinical and severe malaria is highest in the first six months after the third dose, then wanes over time until a fourth dose is given 18 months later. [2, 20] The fourth dose extends protection but does not restore to highest efficacy. Protection against clinical malaria persists for up to seven years in children who received three or four doses, whereas sustained protection against severe malaria requires all four doses. [26] There is no evidence of severe malaria rebound in children who received only three doses. [27] When administered seasonally with Seasonal Malaria Chemoprevention (SMC), RTS,S/AS01 (up to seven doses) confers substantial and sustained protection against clinical and severe malaria for over five years. [28]

Data show R21/Matrix M demonstrates high efficacy against clinical malaria the first six months after the third dose, with minimal waning observed until the fourth dose was given 12 months later. Long term follow up of Phase-3 study sites using age-based and seasonal approaches is ongoing. [21]

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Safety of the intervention

Type, including severity, consequences and frequency of short- and long-term adverse events following vaccination

Both recommended vaccines (RTS,S/AS01 and R21/Matrix-M) have a good safety profile. There is a small risk of febrile seizures within seven days (mainly within 2-3 days) of vaccination. 2

Malaria vaccines should not be given to anyone who has experienced a severe allergic reaction after a previous hepatitis B vaccine dose, malaria vaccine dose or malaria vaccine component.

RTS,S/AS01 can be given to children with HIV infection. A trial of R21/Matrix-M in HIV-positive infants is ongoing and data are not yet available.

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Values and preferences

Perception of the target population on the risk of disease

General awareness of malaria risk is high in endemic settings, with many communities recognizing malaria as common, severe, and life-threatening, especially for young children and pregnant women. 29 Peer-reviewed articles demonstrate the perception of malaria among caregivers of young children in malaria endemic countries in sub-Saharan Africa. 30, 31, 32

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Acceptability to stakeholders

Acceptability of the vaccine and of vaccination against the disease

The introduction of malaria vaccines (RTS,S/AS01 and R21/Matrix-M) in 25 countries (as of January 2026) confirms its high demand and acceptability among key stakeholders. [33]

An independent evaluation of RTS,S/AS01 pilot implementation in childhood immunization in three African countries showed children's access to at least one malaria prevention measure increased to more than 90% with the introduction of a malaria vaccine. [24]

Peer reviewed articles demonstrating uptake and acceptability of malaria vaccines among caregivers and communities have been published from the RTS,S/AS01 pilot implementation [34], [35], [36], [37] and from other settings in Africa [38], [39], [40] , including on determinants of malaria vaccine acceptance. [41], [42], [43]

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Financing & funding

Estimated financial cost of materials per vaccine dose (syringes, needles, safety box) (in USD)

If procuring through UNICEF Supply Division (as of March 2026): a box of 100 AD syringes with needles (0.5 ml) is priced at US$ 4.20; a box of 25 safety boxes (each with a 5-liter capacity or around 100 AD syringes) is priced at US$ 21.50. [44], [45]

For RTS,S/AS01 reconstitution, a box of 100 syringes (2mL) is priced at US$ 5.40. [46]

Estimated vaccine financial cost per dose (in USD)

In the Gavi 6.0 strategic period (2026-2030), Gavi supported malaria vaccine doses are priced the same (US$ 2.99) regardless of product. [47]

Prices of malaria vaccines are expected to decline [48], [49] : RTS,S/AS01 from €9.30/dose to less than US$ 5/dose progressively by 2028 [50], and R21/Matrix-M (2-dose vial) from currently US$ 3.90/dose to US$ 2.99/dose should be expected from end-2026. [51]

The R21/Matrix-M one-dose vial presentation is only available for non-Gavi countries; as of November 2025, the price is US$ 4.20 per dose. [48]

UNICEF prices are subject to change. Access to the most up to date price can be found on UNICEF Supply Division vaccine price webpage. [48] Users are encouraged to confirm those prices by contacting UNICEF Supply Division.

Estimated financial cost per person vaccinated (in USD)

Resources required for malaria vaccine delivery are comparable to those needed for other new vaccine introductions. Malaria vaccine cost of delivery estimates suggest a cost range that varies both by country and delivery strategy. [52] [53] This range is indicative of the varied resource requirements for malaria vaccines across countries in sub-Saharan Africa.

Excluding the cost of vaccines and the initial setup costs, the estimated recurrent cost of delivery per dose ranged from US$0.29 to US$ 0.86 (financial), and from US$ 0.59 to US$ 2.29 (economic) based on a retrospective cost of delivery study of the phased pilot subnational introduction and delivery of a 4-dose schedule of RTS,S/AS01 [54]

Findings suggest that vaccine delivery using the seasonal schedule, with mass campaigns approach is the costliest option and the hybrid schedule without mass campaigns is the least costly option. [55]

Direct comparisons of the results across delivery costing studies should be made with caution, as the methods, delivery strategies and schedules, settings and context can

vary widely.

Cost-effectiveness ratio

Mathematical models estimate that introduction of RTS,S/AS01 and R21/Matrix-M into childhood immunization programmes could have a substantial impact on reducing malaria cases and deaths in endemic settings in Africa, with greater public health impact and cost effectiveness at higher levels of transmission. [2]

At assumed RTS,S/AS01 vaccine prices between US$5-10 per dose, incremental cost-effectiveness ratios (ICERs) were generally less than US$ 100 per disability adjusted life year (DALY) averted at moderate and high transmission intensities (>20% *P.falciparum* parasite rate among children 2-10 years of age (*Pf*PR2-10)) and across age-based, seasonal and hybrid delivery approaches [2, 56, 57] . At an assumed price of US$ 3 per dose and 20% *Pf*PR2-10, R21/Matrix-M ICERs ranged between US$ 30–48 per DALY averted depending on a range of delivery approaches, transmission settings, and intensities. [2, 58] Estimates were more uncertain in low or very low transmission intensities (<10% PfPR2-10). [2]

Cost–effectiveness varies considerably by several factors, including, the burden of disease, seasonality, malaria vaccine effectiveness, indirect effects, vaccination coverage, vaccine price, delivery costs, delivery approaches, and schedules. Caution is recommended when comparing estimates of cost-effectiveness for different interventions evaluated by different methods, with different outcome measures and time intervals, and in different contexts (e.g., with different concurrent health interventions and standards of care).

Is there a Gavi programme to support the introduction of this vaccine? If a Gavi programme is available, what support is available to countries?

Gavi opened funding windows for malaria vaccines in late 2022 to support the introduction and scale-up of the vaccines. Countries may request Gavi support to introduce the malaria vaccine using a 4- or 5-dose schedule, depending on local epidemiology, in areas with moderate or high *P. falciparum* malaria transmission. Requests for Gavi support for malaria vaccine in areas of low

transmission may be considered based on a strong programmatic justification and subnational tailoring of malaria control interventions [59].

In the 6.0 strategic cycle starting 2026, Gavi's scope of support is limited to the vaccine requirements for up to 70% of countries' areas of moderate and high *P. falciparum* malaria transmission [60]. WHO has developed guidance for countries considering where to introduce the malaria vaccine [61], according to national plans and priorities – as well as funding available.

Gavi supports WHO recommended and pre-qualified vaccines (RTS,S/AS01 and R21/Matrix-M). Countries approved to introduce malaria vaccines are matched with one of the two products. Switches from one product to another will be allowed on an exceptional basis with defined criteria, aligned with Gavi policy [62].

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Market (feasibility)

Available vaccines, licensing status, prequalification status, presentation, formulation, dosage and route of administration

Two malaria vaccines are recommended by WHO for programmatic use in children living in *P. falciparum* malaria–endemic areas: RTS,S/AS01 (Mosquirix) and R21/Matrix-M. [2] Both vaccines have WHO prequalification. [63], [64], [65]

Detailed information on the available products can be found in the vaccine comparison table, including licensing, presentation, formulation, dosage and route of administration. [66]

The malaria vaccination series for each child should be completed with the same product whenever feasible. However, if the product used for a prior dose is unavailable or unknown, the series should be completed with either of the available WHO-recommended malaria vaccines. Restarting the vaccine series is not recommended. [2]

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Service delivery (feasibility)

Number of doses and timing of administrations

Malaria vaccines are provided in a 4- or 5-dose schedule starting from around 5 months of age. The minimum interval between any dose is 4 weeks, however, to achieve prolonged protection, the fourth dose should be given 6-18 months after the third dose. 2, 67, 5

To reduce additional delivery burden, WHO recommends aligning the timing of the fourth dose with the timing of other vaccines and, where appropriate, other health interventions administered in the second year of life 2, 67, 5, 27. Alternately, the fourth dose may be given just prior to seasonal transmission peaks to optimize vaccine efficacy.

A fifth dose, given the year after the fourth dose, may be considered in areas of highly seasonal transmission where malaria risk remains high during the third year of life or beyond. 2, 67, 68

Three delivery approaches and schedules are recommended 5:
1) Age-based: year-round delivery of all four doses;
2) Seasonal: delivery of doses 1–3 just before the start of the high transmission season and a seasonal dose (the fourth and fifth doses) provided annually just before the start of the high transmission season;
3) Hybrid: age-based delivery of doses 1–3, year-round and, seasonal delivery of the fourth (and fifth) dose ideally just before the start of the high transmission season.

Although WHO prequalification issued for RTS,S/AS01 and R21/Matrix-M malaria vaccines permits children to receive the first dose from 5 months of age, the RTS,S/AS01 manufacturer's licensure specifies from 6 weeks to 17 months of age. Studies with RTS,S/AS01 have indicated lower efficacy when the first dose is given at 6 weeks; however, the efficacy is unlikely to be reduced substantially if the first dose is given at 4, rather than 5, months of age. 2, 69

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Logistics (feasibility)

Cold chain volume required per vaccine dose (in cm3)

RTS,S/AS01 carton of two-dose vial sets: 9.92 cm^3 per dose.

R21/Matrix-M carton of two-dose vial: 7.03 cm3 per dose.

R21/Matrix-M carton of one-dose vial : 14.06 cm^3 per dose. [70, 5]

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