BRIEF

Country decision-making about malaria vaccine introduction





Vaccinator Kembo Bolula prepares to administer a dose of the malaria vaccine at the Kandu 1 health center in Kisanto health zone, Democratic Republic of the Congo. Credit: PATH/Gloddy Tabende.

The World Health Organization (WHO) recommends the programmatic use of two vaccines—RTS,S/AS01 and R21/Matrix-M—for the prevention of *Plasmodium falciparum* malaria in children living in endemic areas. Rollout of these lifesaving vaccines is well underway, with more than 20 countries in Africa now implementing malaria vaccines.

Collaboration between a country's national immunization program and the national malaria control program is pivotal in the systematic decision-making process for adopting malaria vaccines. This process includes reviewing local data on malaria burden and transmission, following established national decision-making procedures. There are also several aspects of malaria vaccines that should be considered, including vaccine supply, cost, delivery schedule, and use of the vaccines alongside other malaria interventions and preventive child health services. Leveraging PATH's extensive experience in malaria vaccine implementation, this brief provides guidance to countries that are thinking about malaria vaccine introduction on key issues to be considered as part of the decision-making process.

Using malaria vaccines with other interventions

Other WHO-recommended malaria prevention and control measures to be used in conjunction with malaria vaccination include vector control through insecticide-treated nets (ITNs), indoor residual spraying, and larviciding. Since all malaria interventions provide partial protection, the highest impact is achieved when interventions are strategically layered and used together. The appropriate mix of interventions is defined by national malaria control programs based on the local malaria epidemiology.

Each malaria immunization visit offers an opportunity to provide other preventive health services. These services may include catch-up of previously missed doses of other vaccines, reminding caregivers about the importance of continuing to use an ITN every night, and seeking prompt diagnosis and treatment for a child with fever. In addition, sharing resources and knowledge across health programs, as well as optimizing health worker training and service delivery costs and logistics, can integrate a variety of activities and services in a more efficient, effective, and sustainable way.

It is critical to ensure that health workers and community stakeholders are comfortable using messages about the added value of a malaria vaccine and the importance of continuing to use other recommended malaria prevention tools so they can communicate effectively and accurately with caregivers.

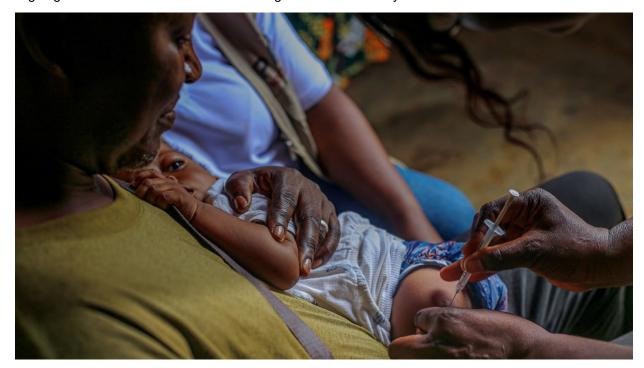
Determining a vaccine delivery schedule

To maximize impact, each country considers its local context when selecting the appropriate malaria vaccination delivery strategy and schedule, including the following: ensuring early protection with timely doses of malaria vaccine; supporting programmatic ease and achieving high coverage; and implementing an effective schedule to reduce disease burden. There are several delivery approaches that countries can consider for the introduction of a malaria vaccine.

Age-based introduction

The two currently available malaria vaccines are used for the prevention of *Plasmodium* falciparum malaria among children living in regions with moderate-to-high malaria transmission. WHO recommends that the first dose of malaria vaccine be administered from around five months of age with year-round delivery. Malaria vaccines may be administered simultaneously with other vaccines given in the childhood immunization program.

Both malaria vaccines are administered in a three-dose primary schedule, with a minimum of four weeks between doses. A fourth dose is provided a minimum of six months after the third dose to prolong the duration of protection. However, there can be flexibility in the schedule to optimize delivery; for example, aligning the fourth dose with other vaccines given in the second year of life.



Grenadi, aged six months, receives a dose of the malaria vaccine at the CBFC Banzangungu health center in Loma, Democratic Republic of the Congo, accompanied by his father, Alain Lakalanangu. Credit: PATH/Gloddy Tabende.

Seasonal introduction

Countries may consider providing malaria vaccines seasonally, using a five-dose strategy, in areas with highly seasonal malaria or with perennial malaria transmission with seasonal peaks. This strategy seeks to maximize vaccine impact by ensuring that the period of highest vaccine efficacy (just after vaccination) coincides with the period of highest malaria transmission. The primary series of three doses should be provided at monthly intervals, with additional doses provided annually, prior to peak transmission season.

Countries adopting the seasonal deployment of a malaria vaccine are strongly encouraged to document their experience comprehensively. This should include vaccine effectiveness, the feasibility of implementation, and the occurrence of any adverse events following immunization. This data collection is crucial in providing valuable insights for future updates to global guidance.

Phased introduction

Countries should begin planning malaria vaccine introduction activities at least 6 to 12 months in advance. Early activities include engagement with leaders at all levels of the political and health systems. Phased introduction strategies may vary throughout a country based on different subnational settings and assessment of the optimal resource use to achieve highest coverage and protection.

The successful introduction of a malaria vaccine relies heavily on a collaborative effort with the country's malaria control program, leveraging data for decision-making. This collaboration includes reviewing comprehensive data sets to prioritize regions with the highest malaria transmission rates.

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The main recording and reporting tools that are used for all immunizations need to be adapted to include malaria vaccines. In a subnational or phased introduction, countries decide how to incorporate malaria vaccines into existing monitoring tools and distribute them to the implementing areas.

Planning should account for the number of months prior to the peak transmission season to implement the primary vaccination series and a maximum age for children to receive their first dose. To optimize protection, countries should ensure that that the period of highest vaccine efficacy (just after vaccination) coincides with the period of highest malaria transmission (peak season). To ensure effective delivery of the fourth and fifth (if applicable) doses, countries can consider campaigns or PIRIs (periodic intensification of routine immunization) to try to achieve high coverage before the period of highest malaria transmission.

Vaccine supply considerations

Rollout of malaria vaccines is well underway in more than 20 countries as of November 2025. With two malaria vaccines recommended and available, vaccine supply is expected to be sufficient to meet the high demand. Funding from Gavi, the Vaccine Alliance is available for countries to introduce malaria vaccines in medium- and high-burden areas, but Gavi funding to countries will be limited to a proportion of the total population of those areas.

Countries can use the best available local data and contextual information to prioritize use of the nearterm vaccine supply/funding as part of a tailored mix of interventions to maximize the impact on malaria transmission and the burden of disease.

The national immunization program will determine the target population using up-to-date national or local census data by working together with the national statistics office. Estimates of the target population are

frequently derived from previous census data or similar surveys at the national level to determine surviving infants. It is appropriate to use the same target population used for other vaccines given to infants and children of similar age.

Cost of delivering vaccines

Country decision-making about adding a malaria vaccine to its national immunization program will include the same cost considerations used in any new vaccine introduction. This includes cost implications related to the delivery of vaccines, procurement of both the vaccine and injection supplies, and introduction costs. Countries can consider a budget impact analysis to help understand the funding needs, funding gaps, and implications to ensure sustainability of the malaria vaccination program.

County decision-making about adding a malaria vaccine to their national immunization program will include the same cost considerations used in any new vaccine introduction.

A 2023 retrospective costing study estimated the incremental costs of introducing and delivering RTS,S within routine immunization programs in the context of malaria vaccine pilot introduction to help inform country decision-making. The study found that the financial costs of introducing RTS,S are comparable to costs of introducing other new vaccines. Country resource requirements for malaria vaccine introduction are most influenced by vaccine price and potential donor funding for vaccine purchases and introduction support.

Another study prospectively estimated the cost of seasonal malaria vaccine delivery using RTS,S in Mali and Burkina Faso.² The study included three scenarios for seasonal vaccine delivery (mass campaign, routine immunization, and a mixed approach using both delivery methods). The study found that malaria vaccine delivery using the mass campaign approach is most costly, followed by mixed delivery and routine delivery approaches in both countries. These cost estimates may provide useful insights for countries considering seasonal malaria vaccine delivery.

Related resources

- Recommendations to mitigate barriers to uptake and delivery of a four-dose malaria vaccine schedule: insights from the MVIP's qualitative evidence
- TechNet-21: A curated package of technical resources for malaria vaccine introduction technical resources
- <u>United Nations Children's Fund (UNICEF): Malaria vaccine questions and answers on supply, price,</u> and market shaping
- UNICEF: Malaria vaccine price data
- WHO: Framework for the allocation of limited malaria vaccine supply

¹ Baral R, Levin A, Odero C, et al. Cost of introducing and delivering RTS,S/AS01 malaria vaccine within the malaria vaccine implementation program. *Vaccine*. 2023; 41(8): 1496-1502. https://doi.org/10.1016/j.vaccine.2023.01.043.

² Diawara H, Bocoum F, Dicko A, et al. Cost of introducing and delivering malaria vaccine (RTS,S/AS01E) in areas of seasonal malaria transmission, Mali and Burkina Faso. *BMJ Global Health*. 2023;8:e011316. https://doi.org/10.1136/bmjgh-2022-011316.