

Status Report: R21 and RTS,S Malaria Vaccine Rollout

Rolling Public Comment Version

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Executive Summary

The Goal: Vaccinate 50 million children against malaria over the next two years.

Background

- **New malaria vaccine could save many lives:** A new malaria vaccine (R21/Matrix-M) has been recommended by the WHO and can be produced in enough volume to save the lives of hundreds of thousands of children in Africa. Two studies estimate around 6,000 lives saved per million children vaccinated.
- **Current rollout plans do not fit available supply:** Up to 200 million R21 doses could be produced and delivered over the next two years, but the latest reports indicate just 25 million doses of R21 are expected to be distributed by the end of 2025 in at least seven countries: Chad, Central African Republic, Democratic Republic of the Congo, Mozambique, South Sudan, Uganda, and Nigeria.
- **We must commit to using every dose that can be made:** 200 million doses at \$3.90 per dose would cost \$780 million, with distribution costs adding several hundred million dollars more. At this price, the average cost of saving a child's life is projected to be less than \$4,000. Global institutions are obligated to set the shared expectation that all doses available will be distributed over the next two years.

Immediate Priorities

- **Funding:** Western governments and philanthropies must raise the funds necessary for vaccine distribution.
- **African logistical planning** needs to take place on a nation-by-nation basis, including national dose projections for Gavi applications for R21.
- **Gavi application review windows** were changed from a quarterly review process to a rolling process during COVID-19, which should be repeated for R21.
- **Updated Gavi forecast:** Gavi should update its malaria vaccine demand forecast and transparently indicate what steps are needed to vaccinate 50 million children over the next two years.

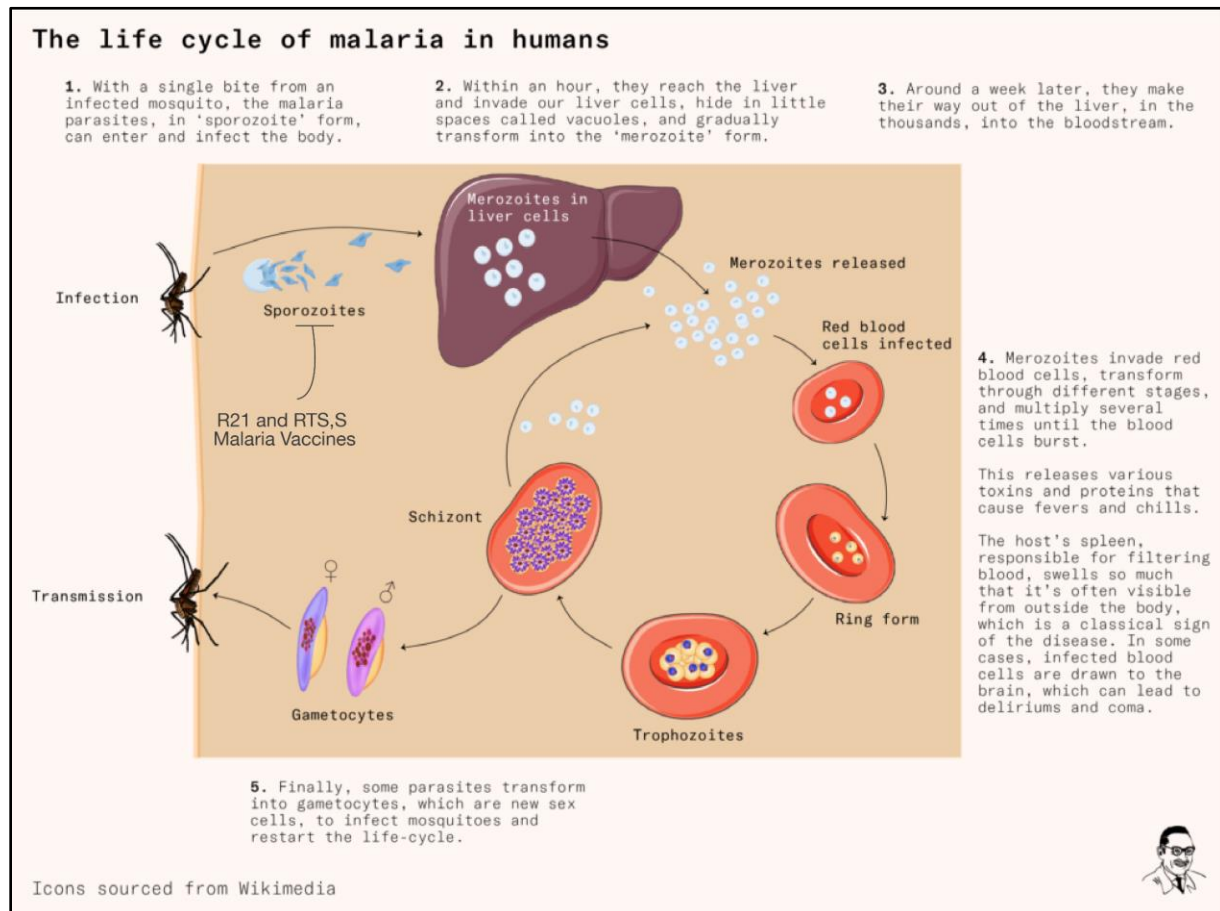
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Background on malaria and estimates of R21 vaccine impact

What is malaria?

Malaria is a disease caused by parasites of the *Plasmodium* genus carried by mosquitoes. Common symptoms include fatigue, fever, chills, and headaches. Severe cases can include impaired consciousness, convulsions, and abnormal bleeding.¹ Some cases are profoundly painful: one survivor likened it to “being stung repeatedly by an electric shock gun”.²



¹ [Malaria](#), WHO, March 29, 2023.

² Coumba Makalou, “[What it feels like to have Malaria](#),” NothingButNets, June 5, 2007.

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Illustration of the malaria life cycle and vaccine mechanism. The R21 and RTS,S malaria vaccines both block the entry of malaria sporozoites into the liver after a bite from an infected mosquito. (© [Works in Progress](#) 2023, adapted with permission.)

In 2022, there were roughly 249 million malaria cases worldwide, which caused 608,000 deaths.³ 94% of malaria cases and 95% of deaths from malaria occur in Africa, almost entirely in Sub-Saharan Africa.⁴ About three quarters of people who die from malaria are children under the age of 5.

The species *Plasmodium falciparum* is responsible for the vast majority of malaria deaths. *P. falciparum* needs to infect both a human and a mosquito to complete the four stages of its life cycle. As an infected mosquito bites a human, it releases parasites into the blood. Within minutes, they travel to the liver, where they further mature for about 5-7 days. The parasite re-enters the bloodstream and invades red blood cells, reproducing and breaking out of infected cells cyclically every two days, leading to characteristic “waves” of fever. Some reproductive forms of the parasite are then transmitted to mosquitoes that bite the infected person, beginning the life cycle once again.⁵

Existing methods of prevention include chemoprevention, mosquito control, and bed nets. Diagnosis of malaria alone has a median estimated cost of \$6.06, more than the cost of a dose of the R21 vaccine but less than the cost of RTS,S.⁶ Vaccination combined with existing methods will further reduce the burden of malaria in Africa.

The two malaria vaccines: RTS,S and R21

After more than six decades of struggle to create a working malaria vaccine, two have been approved by the World Health Organization in the last three years. The vaccines are RTS,S/AS01 (brand name Mosquirix, by GSK, “RTS,S” below) and R21/Matrix-M (developed by Oxford and manufactured by the Serum Institute of India, “R21”). Both were developed using multiple human challenge studies and protect against *P. falciparum*, the deadliest species of malaria parasite.⁷

The two vaccines are closely related: the creators of R21 describe it as “a next-generation RTS,S-like vaccine.”⁸ Both target the parasite’s circumsporozoite protein (CSP) before it can enter the liver,⁹ employ

³ [World malaria report 2023](#), WHO, November 2023, p. 8.

⁴ [World malaria report 2023](#), WHO, November 2023., p. 11-12. Nearly half of malaria cases in 2022 occurred in four countries (Nigeria, the Democratic Republic of the Congo, Uganda, and Mozambique). Slightly more than half of all malaria deaths in 2022 occurred in four countries (Nigeria, the Democratic Republic of the Congo, the United Republic of Tanzania, and Niger). Note that the [WHO African Region](#) does not encompass all of Africa; it excludes Somalia and most countries in North Africa.

⁵ Stephen L. Hoffman, Carlos C. Campbell & Nicholas J. White, “[Malaria](#),” in *Tropical Infectious Disease: Principles, Pathogens and Practices* (3rd. Ed., 2011).

⁶ Conteh et al. (2021), [Costs and Cost-Effectiveness of Malaria Control Interventions: A Systematic Literature Review](#), *Value Health* 24:8.

⁷ Sekhar & Kang (2020), [Human challenge trials in vaccine development](#), *Seminars in Immunology*, 50:101429.

⁸ Collins et al. (2017), [Enhancing protective immunity to malaria with a highly immunogenic virus-like particle vaccine](#), *Scientific Reports* 2017;7:46621. See also Katharine Collins (2014), [R21, a novel particle based vaccine for a multi-component approach to malaria vaccination](#), PhD thesis, St Cross College, Oxford University.

⁹ Laurens (2020), [RTS,S/AS01 vaccine \(Mosquirix™\): an overview](#), *Human Vaccines and Immunotherapeutics* 16:3.

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virus-like particles built from scaffolding derived from the hepatitis B virus,¹⁰ and use similar adjuvants, which enhance the immune response to a vaccine.¹¹ The surface of the R21 particle is covered with a greater density of the malaria protein (CSP) antigen than RTS,S.¹² The WHO recommended RTS,S in October 2021 and completed prequalification in July 2022.¹³ R21 was recommended on October 2, 2023 and prequalified on December 21, 2023.^{14, 15} (Prequalification is required before global funders like Gavi and UNICEF can formally procure vaccines.) Burkina Faso, Ghana, and Nigeria have already licensed R21.¹⁶

Malaria Vaccines' Characteristics and Cost		
	RTS,S	R21
Price (not including distribution cost)¹⁷	\$10.20 per dose	\$3.90 per dose.
Doses deliverable from 2024- 2025	14 million ¹⁸	Approx. 150 million ¹⁹
Phase 3 perennial efficacy in children age 5-17 months	First 12 months: 56% efficacy First 48 months: 36% efficacy ²⁰	First 12 months: 68% efficacy ²¹ First 48 months: Unknown ²²
Doses for full vaccination	Schedule of 4 doses with at least 4 weeks between doses	
Recommended population	Children over five months old. ²³	
Vaccine storage	Stable for three years at 2°-8°C. ²⁴	Stable for two years at 2°-8°C, and up to two weeks between 25°–40°C. ²⁵

¹⁰ For details on manufacturing standards related to production of R21, see Mukhopadhyay et al. (2022), [Production of a high purity, C-tagged hepatitis B surface antigen fusion protein VLP vaccine for malaria expressed in Pichia pastoris under cGMP conditions](#), *Biotechnology & Bioengineering* 119:10. See also Collins (2014), [R21, a novel particle based vaccine for a multi-component approach to malaria vaccination](#), PhD thesis, St Cross College, Oxford University; and Collins et al. (2017), [Enhancing protective immunity to malaria with a highly immunogenic virus-like particle vaccine](#), *Scientific Reports* 7:46621.

¹¹ The adjuvants in these vaccines are saponins, a chemical derived from the soapwort plant. R21 uses a simpler saponin-based adjuvant, Matrix-M (a Novavax product), than RTS,S, which uses a saponin-based adjuvant mixed with the liposomal compound MPL.

¹² [Collins et al. \(2017\)](#).

¹³ Cassandra Willyard, [The slow roll-out of the world's first malaria vaccine](#), *Nature Outlook*, December 19, 2022.

¹⁴ [WHO prequalifies a second malaria vaccine, a significant milestone in prevention of the disease](#), WHO, December 21, 2023.

¹⁵ [Oxford R21/Matrix-M™ malaria vaccine receives WHO recommendation for use paving the way for global roll-out](#), Serum Institute of India, October 2, 2023.

¹⁷ [Malaria Vaccines: Questions and Answers on Supply, Price, and Market Shaping](#), UNICEF Supply Division, October 2023.

¹⁸ [Malaria Vaccines: Questions and Answers on Supply, Price, and Market Shaping](#), UNICEF Supply Division, October 2023.

¹⁹ [‘The West is complacent’: inside the world’s biggest vaccine factory](#), *The Sunday Times*, March 10, 2024. This article, quoting the Serum Institute CEO, indicates that the Serum Institute can increase production capacity of R21 up to 100 million doses per year. The Serum Institute [indicated](#) in October 2023 that they have “more than 20 million doses” on hand and [stated](#) that they have “already established production capacity for 100 million doses per annum, which will be doubled over the next two years,” for a total of 200 million doses per year by 2026. 150 million doses represent 200 million doses/year figure prorated to the remaining 17–18 months before 2026.

²⁰ RTS,S Clinical Trials Partnership (2015), [Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial](#), *The Lancet* 3867:9988.

²¹ [Datoo et al. \(2024\)](#).

²² Initial results from the phase 2b R21 study in Burkina Faso did not include a four-year follow-up, and only recently concluded; results have not yet been posted. The phase 3 study includes data from follow up at 18-months at seasonal sites, where VE was 74% for first-time malaria episodes and 72% for multiple episodes, including 18-36-month olds, in whom vaccine protection is notably less strong ([Datoo et al. \(2024\)](#)).

²³ [Malaria vaccines \(RTS,S and R21\)](#), WHO, October 17, 2023.

²⁴ [Mosquirix: Product Information](#), European Medicines Agency, October 2023, p. 12.

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RTS,S was first created by GSK in 1987. Phase 3 testing concluded in 2014 and the European Medical Association approved the vaccine in July 2015,²⁶ but concerns about a potential meningitis risk led to WHO requiring further testing.²⁷ This took place from 2019-2021 and confirmed the vaccine's safety.

R21 was first formulated in 2011 at the Jenner Institute at Oxford University by Katharine Collins.²⁸ The first clinical trials testing the vaccine began in 2015, including a phase I study evaluating R21 combined with Novavax's adjuvant Matrix-M.²⁹ A phase 2b study concluded in 2023,³⁰ and results of the phase 3 trial were published in February 2024.³¹

The comparatively greater efficacy found at 12 months and indications that R21 may exhibit greater durability suggest that R21 is potentially a more potent vaccine.³² It is possible, though not likely, that R21 proves less effective in the long term, as peer-reviewed, four-year follow-up data is not yet available. The WHO has stated that there is no sufficient evidence to conclude either vaccine is better than the other, as the two vaccines have not been tested in head-to-head trials.³³

Both RTS,S and R21 have been found to be more effective among infants 5-17 months old than among older children. Efficacy also differs by region based on the seasonality of malaria transmission. Malaria in some regions of Africa is seasonal, corresponding with rainy seasons that allow for mosquitos to proliferate. In other regions, it is a perennial threat. R21 trials in seasonal contexts were timed to coincide optimally with the malaria season, which could lead to greater efficacy than in real-world scenarios with less ideal timing. Yet the observed efficacy gap between R21 trials conducted in seasonal and standard sites is relatively small.

Beyond R21 and RTS,S, the WHO has compiled a database of 89 malaria vaccine candidates under clinical development and more effective vaccines should continue to be developed.³⁴ Implementing a strong distribution infrastructure today will serve to save lives now and enhance the utility of future vaccines.

²⁴ [Mosquirix: Product Information](#), European Medicines Agency, October 2023, p. 12.

²⁵ [Malaria Vaccines: Questions and Answers on Supply, Price, and Market Shaping](#), UNICEF Supply Division, October 2023.

²⁶ [The RTS,S malaria vaccine](#), PATH, September 17, 2019.

²⁷ Meredith Wadman, [First malaria vaccine slashes early childhood mortality](#), *Science*, October 24, 2023.

²⁸ [Collins \(2014\)](#).

²⁹ There were two phase I safety/immunogenicity studies conducted by the Jenner Institute beginning in late 2015, assessing AS01B ([NCT02600975](#)) and Matrix-M ([NCT02572388](#)) as adjuvants.

³⁰ [Safety, Immunogenicity and Efficacy of R21 Matrix-M in 5-17 Month Old Children in Nanoro, Burkina Faso](#) (NCT03896724)

³¹ [Datoo et al. \(2024\)](#).

³² For more, see our detailed discussion on our website of the [efficacy and durability](#), and [immunogenicity](#) of the two vaccines. Direct comparison between R21 and RTS,S titers is hampered by substantial methodological variables between the two studies: [Datoo et al. \(2024\)](#) and [RTS,S Clinical Trials Partnership \(2015\)](#).

³³ [Malaria vaccines \(RTS,S and R21\)](#), WHO, October 17, 2023.

³⁴ [WHO review of malaria vaccine clinical development](#), WHO, November 2022.

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How many children in Africa should be vaccinated, and how many vaccines are needed?

Eligible R21 and RTS,S vaccine recipients must live in areas where there is a risk of *P. falciparum* malaria and be at least five months old. Existing data on age and malaria risk from the WHO and other international sources enable a rough estimate of the number of children meeting these criteria in 2024: **about 80 million**. How we arrived at this estimate:

- Approximately 91.7% of the population in Sub-Saharan Africa — 1.01 billion people — are at risk of contracting malaria, according to WHO estimates for 2021.³⁵ Malaria cases in Sub-Saharan Africa in recent years are almost exclusively (>99%) caused by *Plasmodium falciparum*.³⁶
- U.S. Census International Database population projections for Sub-Saharan Africa indicate that approximately 178.6 million people are children under the age of five as of 2023; 91.7% of this is 163.78 million.³⁷
- Assuming half of these 163.78 million falls between 5 and 36 months old,³⁸ the ideal age range for vaccination, approximately 82 million should thus be suitable targets for a malaria vaccine in 2024. 2 to 4 million children are to be vaccinated with RTS,S in 2024,³⁹ so we round down to **about 80 million other children who should be eligible for R21 and fall within the ideal age window for vaccination in 2024**.

This calculation is an estimate based on publicly available information and is not intended to be highly precise.

Each child requires three R21 doses in the first calendar year followed by a booster a year later. Thus, covering the approximately 80 million eligible children who need a vaccine would require 240 million doses along with another 80 million doses the following year as boosters.

The Serum Institute of India (SII) has previously stated it can produce 100 million doses per year in initial years,⁴⁰ in addition to the 25 million it has on hand as of January 2024,⁴¹ so the goal should be to **use every single one of the vaccine doses that can be made available** — enough to cover 50 million children in two years.⁴²

³⁵ [World malaria report 2022](#), WHO, December 2022, Annex 4G. Sum of all countries in the WHO African Region (AFRO) in the spreadsheet (Algeria, which is in AFRO but is not Sub-Saharan, is not listed) plus Somalia.

³⁶ [World Malaria Report 2023](#), WHO, November 2023, pg. 12.

³⁷ [U.S. Census Bureau IDB](#), accessed November 27, 2023.

³⁸ R21 was tested and had high efficacy in children between 5 and 36 months old.

³⁹ 6 million doses of RTS,S are expected to be delivered in 2024. How many vaccinations occur will depend on how many of these doses are used as boosters and how many are used in the primary three-dose vaccination courses.

⁴⁰ [Oxford R21/Matrix-M™ malaria vaccine receives WHO recommendation for use paving the way for global roll-out](#), Serum Institute of India, October 2, 2023.

⁴¹ [New phase 3 trial data confirm the uniquely high efficacy and good safety profile of the R21/Matrix-M malaria vaccine in African children](#), Oxford, February 1, 2024.

⁴² The exact figures SII claims to be able to produce have varied somewhat over time. See “How many doses are planned for delivery in 2024?” later in this report.

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Beyond the 80 million children who currently need the vaccine, each year more than 25 million children are born in areas with moderate to high malaria transmission,⁴³ and as both the population of Sub-Saharan Africa and the fraction of the continent with malaria transmission grow, this number will likely continue to rise. This estimate is substantially larger than demand figures calculated by UNICEF, as discussed below (see “What are the deficiencies of the current plan to deploy malaria vaccines?”).

For more discussion of the number of vaccine doses needed in ongoing years, see 1Day Sooner’s blog post, [How many malaria vaccine doses are needed in Africa?](#)

How many lives will be saved through malaria vaccination?

Two different peer-reviewed studies suggest that it is realistic to expect about 6,000 lives saved per million children vaccinated with R21.

The first study, by researchers at Imperial College alongside members of the Oxford R21 team, projected that in malaria-endemic regions of Sub-Saharan Africa with rates of transmission between 3-65%, for every one million children aged 5-17 months vaccinated by R21, about 1.8-2 million cases of malaria and 6,300-6,500 deaths would be averted over the next 15 years.⁴⁴ The study’s conclusions are highly dependent on malaria prevalence and are based on average prevalence across large areas of sub-Saharan Africa. Children in these areas are often infected with malaria multiple times, and the study assumes that multiple infections can be prevented. Importantly, the 40-80 million children this campaign is prioritizing are primarily within areas where malaria has a transmission rate of at least 3%. If this study’s conclusions are accurate, **vaccinating 50 million children would save more than 300,000 lives.**⁴⁵

Second, a recent WHO study found that RTS,S vaccination reduced childhood mortality, excluding accidental causes, by 13% for every child vaccinated.^{46, 47} If R21 has a similar impact, we would thus expect it to save around 6,000 lives per million children vaccinated, similar to the estimates modeled in the Imperial and Oxford paper.⁴⁸ Because the data behind the 13% number has not been made public, the 6,000 lives-saved projection is necessarily a rough estimate. Contrariwise, R21 may be more effective

⁴³ Table 1, [Framework for the allocation of limited malaria vaccine supply](#), WHO, July 2022.

⁴⁴ Schmit et al. (2024), [The public health impact and cost-effectiveness of the R21/Matrix-M malaria vaccine: a mathematical modelling study](#), *The Lancet Infectious Diseases*. Modeled efficacy depended on the intensity and seasonality of malaria in given areas. In areas with seasonal malaria transmission, 653 deaths per 100,000 fully vaccinated children could be averted.

⁴⁵ Note that lives saved per million will be lower for children vaccinated at age 18-36 months because they have fewer years at peak risk of death (under 5 years of age).

⁴⁶ Meredith Wadman, [First malaria vaccine slashes early childhood mortality](#), *Science*, October 24, 2023.

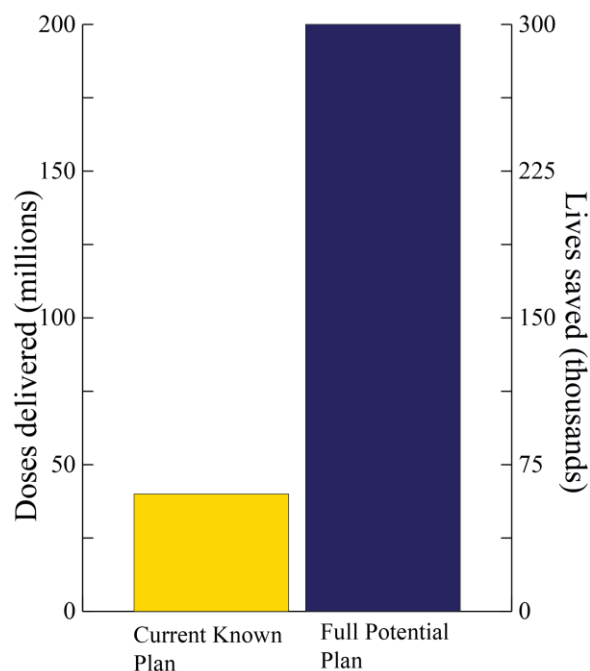
⁴⁷ The originally published [preprint](#) from July 2023 indicates a 9% reduction in mortality among eligible children (excluding injuries) and a 32% reduction in severe malaria. The [Science article](#) cited above as well as a [Gavi article](#), published in October and November 2023, respectively, are based on findings from the same study shared at the Annual Meeting of the American Society of Tropical Medicine and Hygiene, but with updated values of 13% mortality reduction and a 22% reduction of severe malaria. The authors of the study presumably altered or updated their analysis, but we do not currently have access to an updated preprint. We use 13% as the more relevant and recent figure.

⁴⁸ 74 out of 1,000 children born in Sub-Saharan Africa die before the age of 5, 27 of whom die in the first month of life and would not be protected by a malaria vaccine ([Levels and trends in child mortality](#), United Nations Inter-Agency Group for Child Mortality Estimation Report 2022). Subtracting 27 from 74 yields 47 deaths out of 1,000 children; reducing this by 13% would save about 6,110 children per million children vaccinated. This number is somewhat liberal given that children can die after the first month of life but before vaccination, and it does not account for accidental deaths, but that it is in the same range as the Imperial and Oxford estimate is encouraging.

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than RTS,S given its stronger efficacy and immune response in trials (see “The two malaria vaccines: RTS,S and R21” above).

For more discussion of the number of lives we expect malaria vaccines to save, see 1Day Sooner’s blog post, [How many lives could be saved through malaria vaccination?](#)



Lives saved if 200 million doses of R21 and RTS,S are delivered compared to the current rollout plan of 15 million RTS,S + 25 million R21 doses. Lives saved calculated in the text above, with ~6,000 lives saved per full vaccination course of four doses of RTS,S or R21.

What are the estimated costs of R21 vaccination?

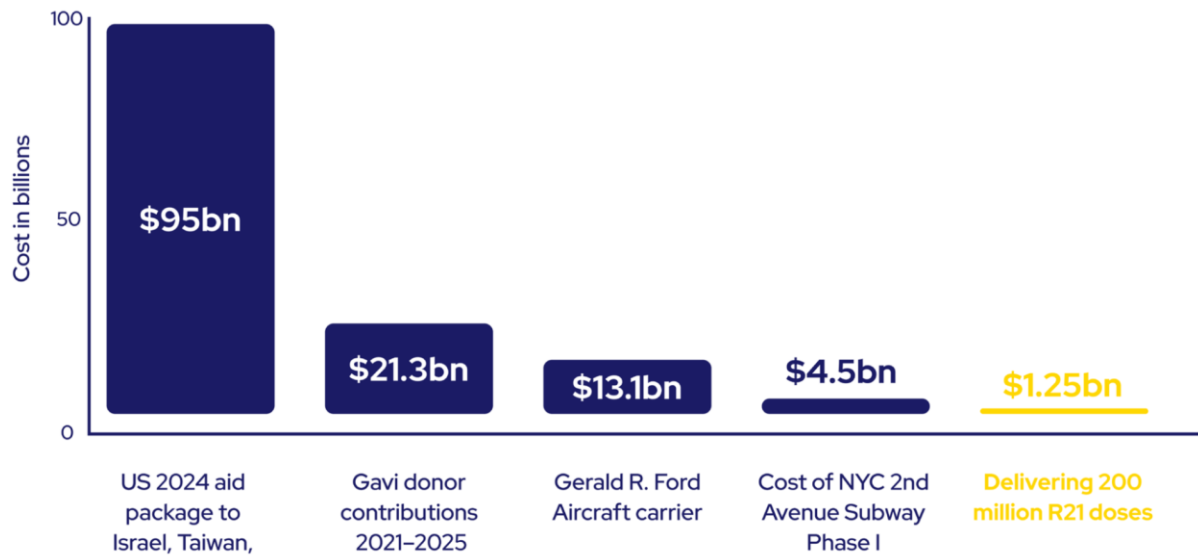
Based on analysis of RTS,S distribution costs and the current per-dose cost of R21, fully vaccinating children could cost as little as **\$25 per full course in early years**, and prices will decrease as vaccination campaigns scale. Based on studies suggesting around 600 lives saved per 100,000 fully vaccinated children, vaccination programs **will cost as little as \$4,000 per life saved initially, and less than \$3,000 in the long**

run.

Altogether, the total production and distribution costs of vaccinating 50 million children in Africa with 200 million doses of R21 would be around \$1.25 billion. This would cost around 6% of Gavi’s total donor contributions, and if funded by the governments of wealthy countries like the United States, would be significantly cheaper than other international spending packages.

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R21 costs in perspective



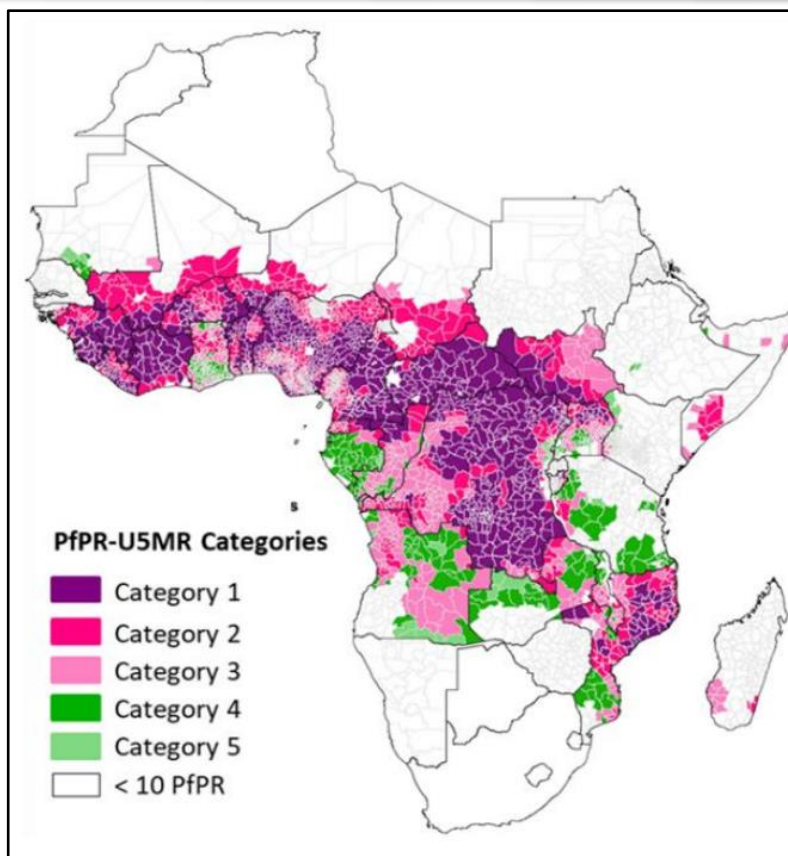
The net economic cost of RTS,S and R21 is likely to be lower than these estimates, which factor in the economic cost of using existing healthcare resources (such as staff time) to deliver vaccinations, but not the effect of a reduction in cases of clinical malaria in vaccinated children on resources used to diagnose and treat malaria.

The above are very rough estimates and should not be taken as precise predictions. Distribution costs are highly variable, and will likely be higher where states make concerted efforts to optimize vaccination schedules for peak malaria season. Nevertheless, it is clear that through R21, the deaths of many children can be prevented at a relatively low cost. Read more on 1Day Sooner's cost estimates [here](#).

The current plans for malaria vaccine rollout

Both the RTS,S and R21 malaria vaccines are expected to be delivered in line with a framework developed by the WHO that categorizes countries based on need, calculated by malaria prevalence and mortality rates in children under five.

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Composite classification of malaria prevalence and all-cause under-five mortality as proxy for need, WHO.

Category 1 is greatest need and category 5 is lowest need, and areas are prioritized by a combination of malaria prevalence and all-cause mortality in children under five. Areas with a PfPR <10% are excluded from the categorization and shown in white. Graphic adapted from the WHO [Framework for the allocation of limited malaria vaccine supply](#), page 18.

How many doses are currently planned for delivery in 2024?

RTS,S vaccine deployment is expected to continue, with GSK committed to delivering 6 million doses in 2024 and 8 million in 2025.⁴⁹

R21 rollout plans are unclear. The WHO has stated that it expects rollout to begin in mid-2024,⁵⁰ but details have been lacking. UNICEF announced a deal in October 2023 to secure supply of R21 with the Serum Institute of India from 2024–2028 but has not disclosed the number of doses covered by the deal.⁵¹ The Serum Institute also announced in October 2023 that it had already established production capacity for 100 million doses a year and would double that capacity over the next two years.⁵²

⁴⁹ [Malaria Vaccines: Questions and Answers on Supply, Price, and Market Shaping](#), UNICEF Supply Division, October 2023.

⁵⁰ Donato Paolo Mancini, [Oxford vaccine developer criticises WHO's mid-2024 target for malaria shot](#), *Financial Times*, October 6, 2023.

⁵¹ [UNICEF signs deal to deliver new malaria vaccine in breakthrough for child survival](#), UNICEF, October 11, 2023.

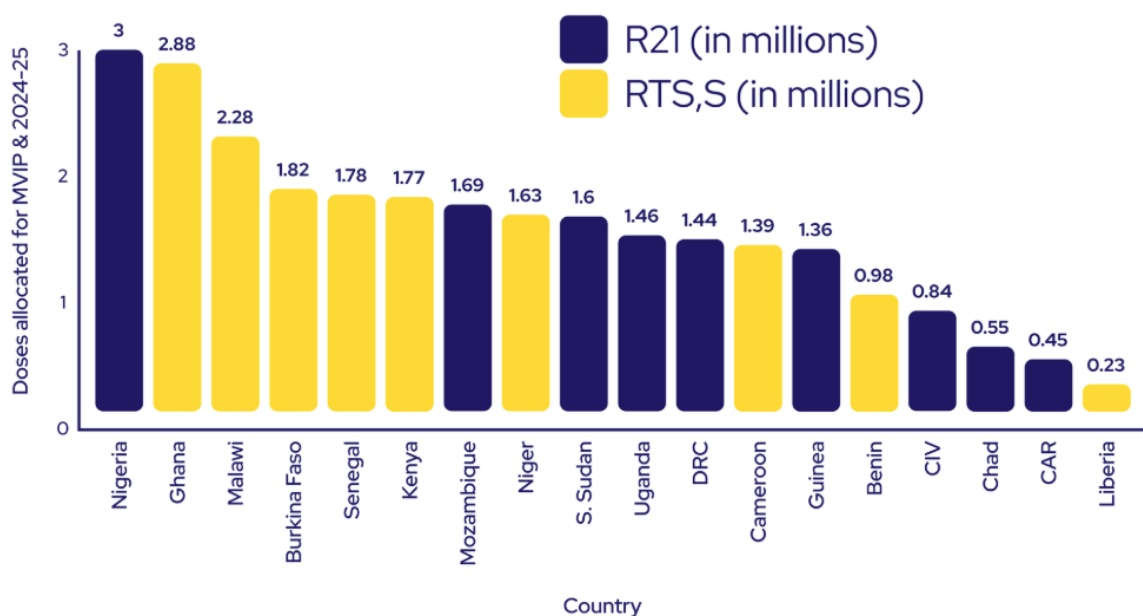
⁵² [Oxford R21/Matrix-M™ malaria vaccine receives WHO recommendation for use paving the way for global roll-out](#), Serum Institute of India, October 2, 2023.

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In March 2024, however, the CEO of SII told *The Times* that in “coming years we can scale up to 100 million doses a year,” suggesting that current anticipated capacity is less than previously stated.⁵³ *The Times* further reported that 25 million doses had already been manufactured and are being prepared for delivery, but we have been unable to confirm this information with UNICEF sources. Figures presented by representatives of the WHO at the Multilateral Initiative on Malaria (MIM) conference in Rwanda in April 2024 indicated that 10 million R21 doses will be distributed through 2025. Media reports in the following month, however, suggested 25 million R21 doses were planned.⁵⁴

Products choice and doses allocated for MVIP & 2024-25

Adapted from Gavi presentation given at the Multilateral Initiative on Malaria conference, April 2024



Doses allocated of R21 and RTS,S per country for 2024-2025. Figure adapted from WHO presentation given at the Multilateral Initiative on Malaria conference, April 2024.

For the purposes of this report, we continue to estimate that reaching a total of 200 million doses is possible over the next two years, including the 25 million the Serum Institute had already produced in early 2024.⁵⁵

How are vaccines distributed through Gavi?

Most African countries cannot afford to purchase vaccines without assistance, so they rely on Gavi, the Vaccine Alliance, to help buy them. Gavi procures vaccines through UNICEF, which pays the vaccine manufacturer, and then transfers the vaccines to individual countries, which manage distribution

⁵³ [‘The West is complacent’: inside the world’s biggest vaccine factory](#), *The Times*, March 10, 2024.

⁵⁴ *The Economist*, [New fronts are opening in the war against malaria](#), May 30, 2024.

⁵⁵ [New phase 3 trial data confirm the uniquely high efficacy and good safety profile of the R21/Matrix-M malaria vaccine in African children](#), Oxford, February 1, 2024.

(sometimes with the assistance of regional partners or other NGOs). Gavi has a cost-sharing formula so that poorer countries pay a smaller proportion of a vaccine's cost than Gavi-eligible countries with higher incomes. UNICEF and Gavi cannot purchase a vaccine unless it has been prequalified by the WHO.^{56, 57} For R21, now that prequalification is complete, "it is expected... that final steps to make doses available and ready for shipment will take a few months."⁵⁸

Gavi purchases vaccines and provides them to countries based on its forecast of their demand. That is, countries develop plans to distribute vaccines internally and then provide requests to Gavi to purchase doses on their behalf, which Gavi aggregates into a market shaping forecast.

What is the deployment pipeline for the R21 vaccine?

The Oxford developers of the R21 vaccine have a manufacturing deal in place with the Serum Institute of India, which reportedly has the production capacity for 100 million doses per year.⁵⁹ In addition to this, the Serum Institute of India will engage in a technology transfer deal to allow for the production of vaccines in other countries like Ghana, conditional upon the provision of manufacturing facilities in the capital.⁶⁰ As of February 1st 2024, 25 million doses had been produced and were ready for rollout within 3-4 months.⁶¹

One uncertainty in current rollout plans is whether available doses should be distributed on a seasonal schedule to align maximum immunity with the peak malaria season, or whether vaccines should be incorporated into existing national EPI programs to maximize distribution efficiency. Thus far, RTS,S is only being distributed through existing EPI programs and we have not seen any evidence of plans to treat R21 differently, though some experts are calling for this.



⁵⁶ UNICEF has stated that its purchase of R21 doses is conditional on prequalification ([UNICEF signs deal to deliver new malaria vaccine in breakthrough for child survival](#), UNICEF, October 11, 2023). COVID vaccines were an exception, but they went through a more rapid WHO emergency use listing process that was a substitute for prequalification. See the WHO's [Regulation and Prequalification of COVID-19 vaccines](#) web page.

⁵⁷ [WHO RECOMMENDATION OF WORLD'S SECOND MALARIA VACCINE – SEPTEMBER 2023](#), Gavi, October 2, 2023. "Once a vaccine is prequalified it can then be offered through Gavi programmes."

⁵⁸ [1st MALARIA VACCINE SHIPMENTS: Frequently Asked Questions \(FAQs\)](#), Gavi, 2023.

⁵⁹ [Five things you need to know about the new R21 malaria vaccine](#), Gavi, April 13, 2023.

⁶⁰ [Five things you need to know about the new R21 malaria vaccine](#), Gavi, April 13, 2023.

⁶¹ [New phase 3 trial data confirm the uniquely high efficacy and good safety profile of the R21/Matrix-M malaria vaccine in African children](#), Oxford, February 1, 2024.

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An additional uncertainty surrounds which age groups should be vaccinated. While 5-month-olds are the current target that will enable simple distribution of vaccines in existing EPI infrastructure, this will leave many children currently in the ~7-36-month age range with multiple years left at high risk of death from malaria.

The current status of the R21 and RTS,S rollouts in Africa

1Day Sooner has put together a [country tracker](#) to follow the rollout of both vaccines in specific countries.

Gavi has approved 22 total African countries⁶² for RTS,S or R21 rollout, 20 of which have been publicly announced: Ghana, Kenya, Malawi, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Côte d'Ivoire, the Democratic Republic of the Congo, Guinea, Liberia, Mozambique, Niger, Nigeria, Sierra Leone, South Sudan, Sudan, and Uganda,^{63, 64} following the WHO's prioritization framework.⁶⁵

What is the current status of the RTS,S rollout?

Ghana, Kenya, and Malawi have been administering RTS,S since 2019 as part of the Malaria Vaccine Implementation Programme (MVIP).⁶⁶ These three countries are expanding their RTS,S programs moving forward and have been guaranteed some number of doses with continued support from Gavi.⁶⁷

⁶² [Gavi Board approves next five-year strategy; outlines plans to support access to new vaccines, global health security, and sustainability](#), Gavi, June 7, 2024

⁶³ [Update on malaria vaccines](#), WHO Malaria Policy Advisory Group Meeting, Yaoundé, Cameroon, March 4-5, 2024;

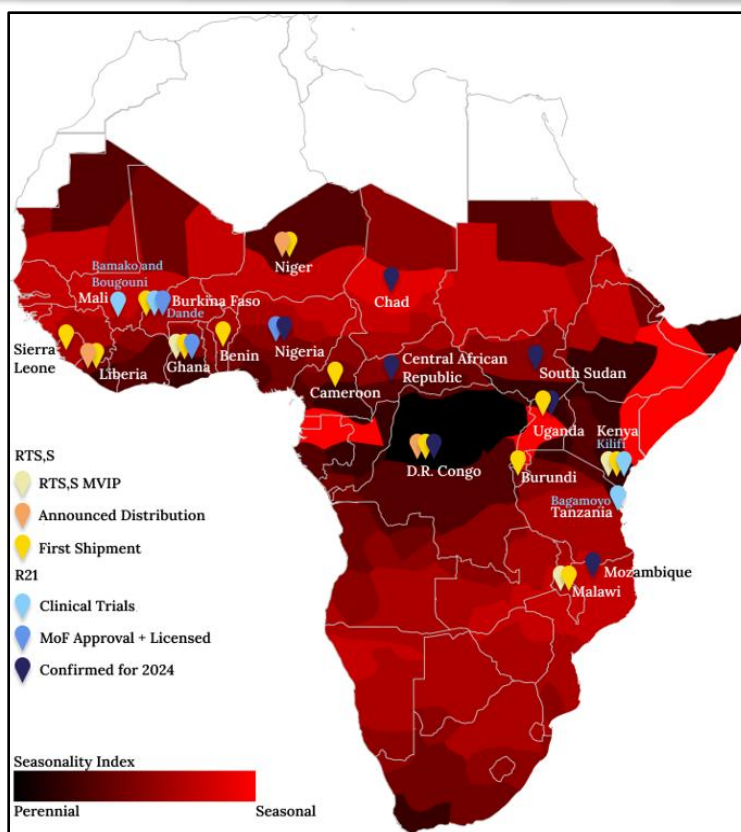
⁶⁴ [18 million doses of first-ever malaria vaccine allocated to 12 African countries for 2023–2025: Gavi, WHO and UNICEF](#), UNICEF, July 5, 2023.

⁶⁵ [Framework for the allocation of limited malaria vaccine supply](#), WHO, July 2022.

⁶⁶ Malaria: The malaria vaccine implementation programme (MVIP), WHO, March 2, 2020.

⁶⁷ Malaria vaccines (RTS,S and R21), WHO, January 17, 2024.

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Malaria Transmission Seasonality. Map of sub-Saharan Africa depicting the Markham Seasonality Index (MSI), which reflects the degree of seasonality in malaria transmission. Red regions denote highly seasonal transmission and black regions denote perennial transmission. The map is overlaid with pins representing the status of R21 and RTS,S rollout as of March 2024. Data are adapted from model simulations which align closely with observed malaria incidence, demonstrating MSI's robustness in capturing seasonal variations in transmission.^{68, 69} Figure adapted from [Cairns et al., 2015](#).

RTS,S is currently in the initial stages of a broad rollout, which began in November 2023 in Cameroon, December in Sierra Leone, and February 2024 in Burkina Faso, with additional expansion into other countries (including Liberia and Niger) in the coming months.^{70, 71} At least 3 million doses are set to be delivered across those five countries and others in the next two years, with additional African countries set to receive doses later this year as well. The rollouts in Cameroon and Burkina Faso are presented as case studies below.

⁶⁸ Seasonality in malaria transmission: implications for case-management with long-acting artemisinin combination therapy in sub-Saharan Africa, Cairns et al., August 19, 2015.

⁶⁹ Modelling the impact of vector control interventions on *Anopheles gambiae* population dynamics, White et al., July 28, 2011.

⁷⁰ [Shipments to African countries, including Sierra Leone, herald final steps toward broader vaccination against malaria](#), UNICEF, December 15, 2023.

⁷¹ [“Relief” as RTS,S malaria vaccine rollout set to begin in Burkina Faso](#), Gavi, February 1, 2024

What lessons can be drawn from the rollout of RTS,S?

- **Regulatory speed matters:** In 2015, the European Medicines Agency approved the RTS,S vaccine.⁷² In 2016, the WHO recommended pilot program implementation, and in 2019 RTS,S launched in Ghana, Kenya, and Malawi.⁷³ RTS,S was first recommended for widespread use by the WHO in October 2021.⁷⁴ The six-year delay between the EMA's approval and the WHO greatly slowed the rollout of RTS,S and shows how regulatory uncertainty and delays can be massively consequential.
- **Advance financing affects rollout:** In 2019, Gavi reduced the risk of investment in RTS,S vaccine, allowing production to begin while evidence was collected to support implementation plans and policies.⁷⁵ A similar effort to reduce financial risk by providing funding and transparency for R21 could accelerate deployment.
- **Community engagement is important:** Interviews with health service managers and frontline health workers in Ghana in 2019 aimed to understand lessons learned during RTS,S vaccine implementation, which was the first malaria vaccine deployment. Community engagement early in RTS,S deployment was important to the success of the vaccine.⁷⁶
- **MVIP sets a strong path to follow:** During the Malaria Vaccine Implementation Programme pilot programs, vaccine coverage was improved through supportive supervision visits to sites initially with low uptake. When children did not receive doses on schedule, updated guidance through communications materials for healthcare workers was also important. Lessons learned from the MVIP distribution program will enable proactive planning for R21 distribution to reduce the barriers encountered with RTS,S.⁷⁷ Because R21 is expected to be available in larger volumes, it may be used by larger countries to avoid the need to switch products.⁷⁸
 - Many challenges encountered during MVIP were related to infrastructure issues in Sub-Saharan Africa; however, others were specific to the MVIP: the term “pilot program” and unclear eligibility criteria led to distrust on social media⁷⁹ and the multiple dosing made it hard for full coverage, especially for the fourth dose.
 - Given that R21 will have less strict cold chain requirements and will not be a pilot program, there is reason to expect lower administrative costs and greater uptake of the R21 vaccine than the MVIP program achieved for RTS,S.
- **Four-dose distribution works:** While there were challenges, RTS,S deployment showed that implementation of a four-dose vaccine works with careful planning and that scaling up distribution is possible.

⁷² [Mosquirix](#). European Medicines Agency, 2015.

⁷³ [UNICEF Procurement: Comprehensive supply for impactful and cost-efficient health programmes](#), WHO, December 2022.

⁷⁴ [Malaria vaccines \(RTS,S and R21\)](#), WHO, October 2023.

⁷⁵ [1st Malaria Vaccine Shipments: Frequently Asked Questions \(FAQs\)](#), Gavi, 2023.

⁷⁶ Grant et al. (2022), [Challenges and lessons learned during the planning and early implementation of the RTS,S/AS01E malaria vaccine in three regions of Ghana: a qualitative study](#), *Malaria Journal* 21:147.

⁷⁷ [Learning lessons from the pilots: overcoming knowledge gaps around the malaria vaccine schedule in support of vaccine uptake](#), WHO, October 2022.

⁷⁸ [1st Malaria Vaccine Shipments: Frequently Asked Questions \(FAQs\)](#), Gavi, 2023.

⁷⁹ [Grant et al. \(2022\); Adjei et al. \(2023\), Post introduction evaluation of the malaria vaccine implementation programme in Ghana, 2021](#), *BMC Public Health* 23:586.

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What is the current status of the R21 rollout?

The R21 rollout began in late May, with 43,000 doses delivered to the Central African Republic out of 163,000 so far allocated to the country.⁸⁰ The latest sources indicate a total of 25 million doses are set to be delivered by the end of 2025 across at least seven countries: Chad, Central African Republic, Democratic Republic of the Congo, Mozambique, South Sudan, Uganda, and Nigeria.⁸¹

Problems with current plans for R21 distribution

What are the deficiencies of the current plan to deploy malaria vaccines?

The latest plan of 25 million R21 doses to be delivered in 2024-2025 is sufficient to vaccinate only around 8 million children with the first three doses.⁸² This is about 175 million fewer doses than what previous information from the Serum Institute indicated would be possible (100 million producible per year; 25 million on hand as of January 2024⁸³). 100 million doses, for comparison, would be enough to vaccinate over 30 million more children with the primary course (the first three doses of the four dose vaccine series). Based on the modeling published in *The Lancet Infectious Diseases* (see “How many lives will be saved through malaria vaccination?” above), vaccinating 30 million more children in 2024 would avert over 200,000 deaths.⁸⁴

This deficit is not just a problem for 2024. 2022 projections by UNICEF estimated vaccine demand in 2025 to reach 60 million doses and 75 million doses in 2026 (see Slide 12 in [this 2022 UNICEF presentation](#); this applies to only 19 countries).

Challenges to vaccinating more children in 2024

- **Vaccination campaigns are normally slow:** Vaccines typically take about ten years from starting human testing to regulatory approval and another 10-15 years to achieve broad distribution.⁸⁵ Malaria vaccine development has taken decades. Thus there is institutional and psychological inertia weighing against an immediate sprint to deploy vaccines, especially when sprinting is far outside the norm.
- **There’s not much money:** African countries have a very limited pool of resources to fight a variety of diseases. Philanthropic funding for global health is similarly overburdened. We estimate that about \$1 billion will be needed to purchase and distribute R21 vaccine doses. These budgets cannot be shifted at a moment’s notice, and without new sources of funding spending on one priority means shorting another.
- **Four doses are tough:** Many vaccines require fewer than four doses, and the timing for the current malaria vaccines does not fit well with the existing schedule for vaccinating children. This is not

⁸⁰ [Shipment of newest malaria vaccine, R21, to Central African Republic marks latest milestone for child survival](#), WHO, May 24, 2024.

⁸¹ [Cut-price Malaria Vaccine To Begin Africa Rollout From May](#), Barron’s, March 9, 2024.

⁸² [Cut-price Malaria Vaccine To Begin Africa Rollout From May](#), Barron’s, March 9, 2024.

⁸³ [The West is complacent: inside the world’s biggest vaccine factory](#), *The Times*, March 10, 2024.

⁸⁴ Roughly 630 deaths averted per 100,000 children vaccinated multiplied by 370 is 230,000. (The actual number of deaths averted varies slightly in [Schmit et al. \(2024\)](#) based on various factors, such as timing of vaccination campaigns.)

⁸⁵ See [SAVAC Stakeholders Meeting video](#) at 1:20:30. See also Plotkin’s *Vaccines*, 7th ed., Chapter 4 (“The Vaccine Industry”), table 4.3.

impossible: vaccination rates for RTS,S have been high in communities where it has been introduced,⁸⁶ and parents are very experienced with malaria and motivated to protect their children. But a four-dose vaccine is not as easy as most new vaccines to distribute.

- **The process is very complicated:** Institutionally, vaccination in poor countries requires a series of interlocking steps (described above) between the manufacturer, regulator, payor, facilitator, and nation-state distributors (including national and sub-national agencies and political bodies). Each of those institutions in turn may have multiple departments who share responsibility for a decision. This creates significant friction and delay, particularly if each step must be completed sequentially before the next can begin. Practically, giving out hundreds of millions of doses of a vaccine across dozens of countries requires educating and enabling tens of thousands of providers located across many poor and inaccessible areas, as well as coordinating with many country's public institutions such as Ministries of Health, Finance, Interior, and others that may have relevant authorities.
- **Vaccinologists are human:** While the many heroes who spent decades developing malaria vaccines are motivated primarily by saving lives, there are human factors that inhibit rapid and seamless cooperation. Tremendous effort was spent advancing RTS,S over many years, which can make it hard to immediately shift towards driving forward a different vaccine (even if that vaccine is based almost entirely on RTS,S).

What lessons can be drawn from the African COVID vaccine experience?

The response to Covid-19 showed that a fast and large-scale vaccine roll-out was feasible in low-to-middle-income countries. The COVAX mechanism was an initiative of Gavi, WHO, CEPI, and UNICEF that played a key role in making the vaccine available in 92⁸⁷ eligible countries. From 2021 to 2022, 1 billion doses were delivered through COVAX⁸⁸. However, the effectiveness of distribution varied significantly among these countries, as evidenced by a large comparative study that found that, over the first year of COVAX, vaccination rates ranged from 0.13% in the Democratic Republic of the Congo to 44% in Botswana.⁸⁹ Notably, integrating COVID vaccination with routine medical services improved distribution and uptake. All 22 African countries in the study recommended better integration with routine services, and many highlighted Zambia's success integrating COVID vaccination with routine tuberculosis vaccination, antiretroviral therapy clinics, and family planning services.

Conversely, less successful aspects of the COVID-19 vaccine rollout highlighted critical areas for improvement relevant for R21 distribution. While COVAX provided vaccine doses, many countries encountered significant challenges due to inadequate funding for essential operational aspects. These included preplanning, community outreach, post-vaccination monitoring, and training additional

⁸⁶ Mumtaz et al. (2023), [Acceptance, availability, and feasibility of RTS,S/AS01 malaria vaccine: A review](#), *Immunity, Inflammation & Disease*, 11:6; Schmit et al. (2024), [The public health impact and cost-effectiveness of the R21/Matrix-M malaria vaccine: a mathematical modelling study](#), *The Lancet Infectious Diseases*. "Pilot implementation of this regimen through the Malaria Vaccine Implementation Programme (MVIP) in Ghana, Kenya and Malawi has subsequently demonstrated the feasibility of delivery. To date, high demand has been demonstrated with 89%, 76% and 83% uptake of the 1st dose, 76%, 73% and 72% uptake of the 3rd dose and 50%, 52% and 36% uptake of the first booster dose in Malawi, Ghana and Kenya respectively in 2022."

⁸⁷ [92 low- and middle-income economies eligible to get access to COVID-19 vaccines through COVAX](#), Gavi, July 31, 2020.

⁸⁸ [COVAX: 1 billion vaccines delivered](#), UNICEF, January 19, 2022.

⁸⁹ Masresha, Ruiz, Atuhebe & Mihigo (2022), [The first year of COVID-19 vaccine roll-out in Africa: challenges and lessons learned](#), *Pan Afr Med J* 29:41(Suppl 2):2.

healthcare workers.⁹⁰ Together, these lessons underscore the value of integrating with existing healthcare frameworks and the importance of thorough pre-planning and operational support to ensure successful vaccination campaigns.⁹¹

The Goal: Vaccinate 50 million children against malaria within the next two years

Vaccinating 50 million children

R21 vaccination purchases about a year of a child's healthy life for every \$40 spent.^{92,93} At that price, **no dose that can be produced should go unused**. If the Serum Institute can produce 200 million doses in two years, then the expectation must be that 50 million children will be vaccinated.

Because there are many different institutions that will need to work together to achieve this and none can force the issue on their own, it is critical that all commit to a common expectation of distributing all possible doses and identifying the obstacles to achieving that outcome. Even if the target cannot be hit in 2024, sharing information about the critical path and causes of failure will save lives in 2025 and beyond. The bar must be set high.

Steps to catalyze more rapid mass rollout of R21

From 2021-2023 more than a billion COVID vaccine doses were distributed in Africa,⁹⁴ showing that rapid rollout can be achieved. The following are some of the policy steps that could enable optimal malaria vaccination in 2024.

Using the Collaborative Procedure for Accelerated Registration (CPAR),⁹⁵ which can shorten the time-to-national-approval for new pharmaceutical products by months. The WHO has initiated CPAR meetings with 37 countries that will result in authorization of the R21/Matrix-M malaria vaccine in these countries by the end of May. However, there remains a need to allow overlap with ongoing RTS,S rollout. This will increase vaccine access and widen coverage beyond the narrow age range and beyond the highest transmission areas.

Gavi application review windows should be converted to a rolling system. During the COVID-19 pandemic, Gavi changed its typical window-based application review process to a rolling process. Gavi

⁹⁰ [Masresha et al. \(2022\)](#); Afolabi et al (2021), [Tracking the uptake and trajectory of COVID-19 vaccination coverage in 15 West African countries: an interim analysis](#), *BMJ Glob Health* 6(12):e007518.

⁹¹ Collins et al. (2021), [‘Learn from the lessons and don’t forget them’: identifying transferable lessons for COVID-19 from meningitis A, yellow fever and Ebola virus disease vaccination campaigns](#), *BMJ Global Health* 6(9):e006951.

⁹² Current life expectancy in Sub Saharan Africa is 61 years, or about 3,200 weeks. [United Nations: World Mortality in 2019](#).

⁹³ [How cost-effective is the new R21 vaccine compared to existing malaria interventions?](#), 1Day Sooner, June 24, 2024

⁹⁴ [Africa CDC COVID-19 Vaccine Dashboard](#), accessed November 21, 2023.

⁹⁵ [Collaborative Procedure for Accelerated Registration](#), WHO.

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should do so for R21 as well to ensure no African countries must wait months after missing an application deadline.

Public WHO commitment to ensuring all doses produced are distributed over the next two years including a commitment to achieve the 200 million doses target and identify obstacles and enablers for this goal.

A new Gavi forecast for malaria vaccine demand that articulates what would be needed to achieve a 200 million dose target. Additionally, a transparent process is needed for regular public updating of the forecast in response to African government requests, which should be allowed on a rolling basis similar to that used for COVID-19 vaccines.

Demonstration rollout programs in select African countries: Nigeria, Burkina Faso, and Ghana approved R21 prior to the WHO's recommendation, and Burkina Faso both conducted clinical trials of RTS,S and R21 and have led early rollout of RTS,S. Making Burkina Faso (or another African country) the first one with a clear and funded plan to vaccinate all its eligible population would set a valuable precedent for other countries and global institutions to follow.

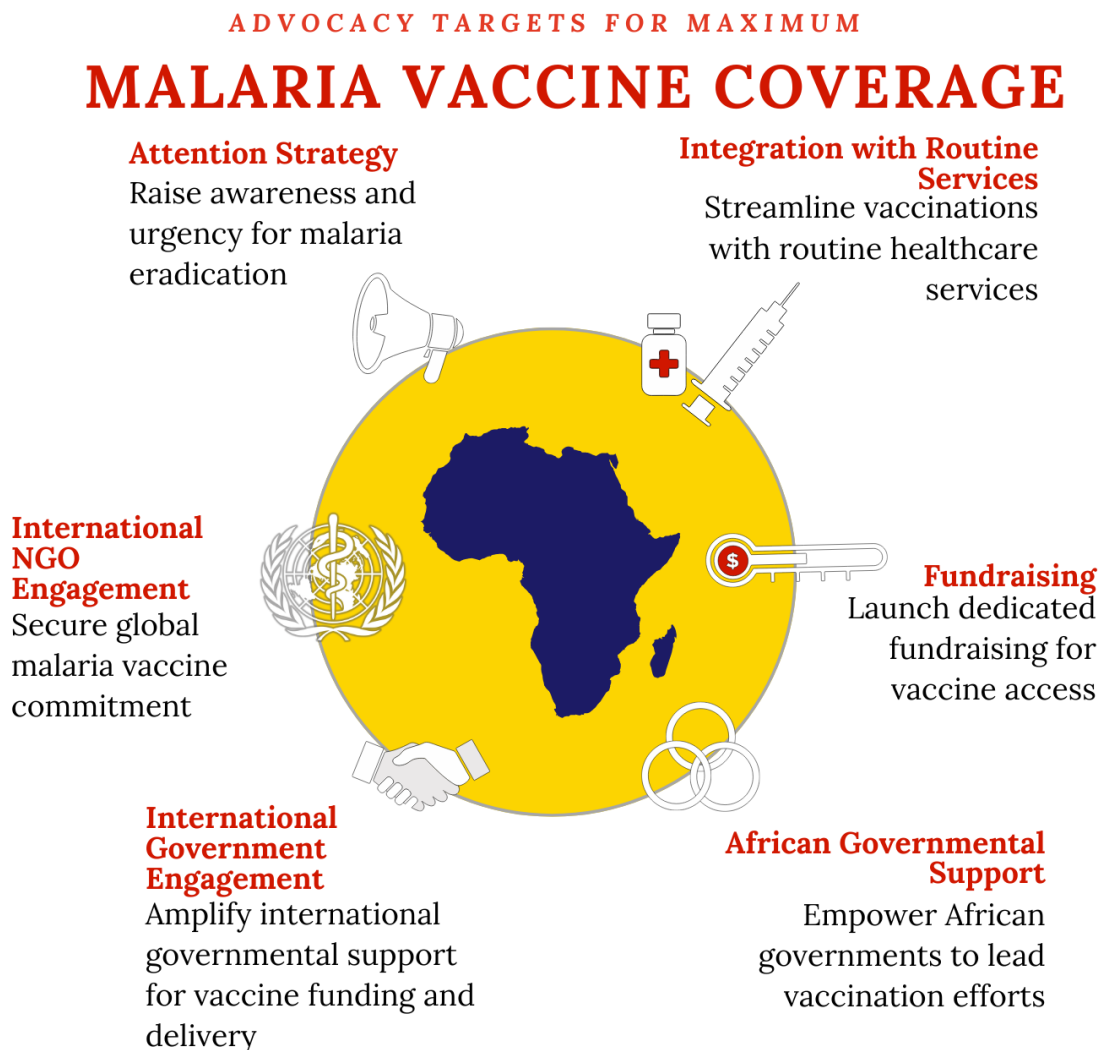
Advanced Market Commitments (AMCs) to subsidize distribution: Because the costs of distribution may be unpredictable and funds may be scarce, one potential way to help countries provide vaccination would be to create a fund that pays countries for each vaccine dose that is distributed in 2024 (possibly with a diminishing subsidy in later years).

Western technical assistance: The U.S. government help was important to the rollout of COVID vaccines over the last two years. USAID and the CDC can play a role in providing technical assistance to help African countries plan their R21 vaccination campaigns, as can European Union institutions. This would be especially useful as a public-private partnership in tandem with new philanthropic funding to support distribution efforts or other technical assistance from groups like PATH.⁹⁶

Confirm the resources needed for purchase and distribution of doses: Western funders must commit to provide the financial resources needed to enable the vaccination of 50 million children in 2024.

⁹⁶ [PATH — RTS,S Malaria Vaccines in Pilot Comparison Areas \(January 2022\)](#), GiveWell, January 2022.

Intermediate advocacy targets to help achieve maximum vaccine coverage



Intermediate Advocacy Targets. An infographic delineating six pivotal advocacy approaches to bolster malaria vaccine dissemination in Africa, emphasizing African governmental leadership, global resolutions, and international support, complemented by strategic public messaging and fundraising.

African governmental support and planning: Malaria vaccination cannot succeed without African governments leading the way. Therefore, it is critical to build expert networks and advocacy campaigns within each affected nation to ensure that the countries are motivated and enabled to (a) plan for and implement vaccination campaigns and (b) make the case to Western governments, international institutions, and the global public to treat this issue with urgency.⁹⁷

⁹⁷ Because 50% of malaria deaths occur in Nigeria, the Congo, Tanzania, and Niger, these countries are especially important to mobilize. Uganda and Mozambique are other countries with a major malaria disease burden.

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U.S. government inquiry: As a member of the WHO Executive Board and major funder, U.S. government inquiries (possibly via the President’s Malaria Initiative or HHS’s Office of Global Affairs) can drive global attention and engagement on the issue.

Fundraising: An extraordinary vaccine deployment process will require additional resources. Drawing funding from existing sources runs the risk of pulling funding from current priorities and robbing Peter to pay Paul. A fundraising campaign that brings in new sources of funding to global health would help mitigate this risk.

Attention: Setting a broad expectation of using all available vaccines will require persistent and pervasive public messaging across Europe, the Americas, and Africa. This will require a range of strategies for a range of audiences but promoting African experts and public health officials is one promising tactic.

Integration with routine services: All 22 countries that participated in COVAX recommended better integration of vaccine delivery with routine services to minimize required infrastructure and improve vaccine uptake. R21 rollout should be conducted as quickly as possible while also paying attention to opportunities to integrate it with existing services that may increase uptake.

What are 1Day Africa and 1Day Sooner doing?

1Day Africa and 1Day Sooner publicly launched our campaign to accelerate R21 vaccine deployment in December 2023. Our campaign aims to make progress on three different fronts:

1. Persuade international institutions — primarily the WHO, UNICEF, and Gavi – to set a public expectation that at least 40 million children will be vaccinated in 2024.
2. Collaborate with and support civil society groups within African countries to advocate for and enable comprehensive R21 malaria vaccination on a country-by-country basis.
3. Recruit resources (funding and technical assistance) from the West — including governments, NGOs, and philanthropies — to give African countries and global institutions what they need to make these plans work.

About 1Day Africa and 1Day Sooner

[1Day Sooner](#) is a US-based nonprofit that aims to accelerate the development and deployment of life-saving medical research and policy interventions. A core focus of 1Day Sooner is human challenge studies, a form of clinical research where adult volunteers are deliberately exposed to a pathogen, often to test a vaccine (as was done with R21 and RTS,S during their early stages of development).

[1Day Africa](#) is the African chapter of 1Day Sooner. 1Day Africa focuses on global vaccine equity and building scientific capacity for medical research and production on the continent.