190 Million Missing Doses:
How the West is Failing Africa on Malaria Vaccines

May 2024
Executive Summary

Every day, more than 1,000 children under the age of five die as a result of malaria, overwhelmingly in Sub-Saharan Africa. Fortunately, by the end of 2025, up to 200 million doses of R21, the newest malaria vaccine, can be produced. That is enough to vaccinate 50 million children for as little as US$1.25 billion.

What scarce information that can be assembled from public sources, however, suggests that just 10 million doses of R21 are planned for use by the end of 2025 out of the possible 200 million, despite enormous demand. The “missing” 190 million doses of R21 are enough to prevent tens of millions of infections and save approximately 300,000 children’s lives.

R21 vaccination procurement is coordinated by Gavi, the Vaccine Alliance. Gavi has thus far failed to adequately prioritize the purchase of R21 doses or communicate to its supporters and the public what obstacles prevent further purchases. Absent political pressure and resources from Western countries, which provide the overwhelming majority of Gavi’s funding, change will likely be hard to come by.

Notably, 25 million R21 doses have already been produced by the Serum Institute of India, raising further questions as to why just 10 million have been ordered by Gavi.

This is particularly frustrating for countries like Burkina Faso, which suffers from an extremely high malaria death rate and is already receiving doses of the other malaria vaccine — but is not allowed by Gavi to use R21 as well.

Vaccine production and rollout is no easy task, and procurement of more R21 is just one step of many required to ensure the vaccines are used to maximum effect. Funding must be raised, and African governments must prepare for distribution. Even so, over 1 billion doses of COVID-19 vaccines were delivered to Africa in less than three years, showing that expansive vaccination campaigns are possible with sufficient political will and resources.

While vaccine hesitancy, waste, and inevitable logistical complications certainly mean that not every single dose manufactured will be used, with 300,000 children’s lives on the line in under two years, it is imperative to set the bar as high as possible.

This report is based on research conducted by the 1Day Sooner malaria team. A more comprehensive analysis of issues raised in this report can be found in our regularly updated, long-form Status Report.
“I LOOK FORWARD TO A TIME WHEN PEDIATRIC BEDS WILL BE EMPTY WHILE PLAYGROUNDS WILL BE FULL OF HEALTHY CHILDREN. THE AVAILABILITY OF MORE MALARIA VACCINES CAN MAKE THIS POSSIBLE.”

Professor Halidou Tinto
founder of the Clinical Research Unit of Nanoro

“R21 CAN PUT US IN A MUCH BETTER POSITION TO CONTROL AND POSSIBLY ERADICATE MALARIA SOME DAY. THIS IS A HUGE STEP IN THE MANAGEMENT OF A DISEASE, BUT ENOUGH DOSES OF THE VACCINE MUST BE SECURED FOR AFRICA, WHERE MALARIA CONTINUES TO CLAIM MANY LIVES.”

Thandiwe Ngoma
1Day Africa malaria advocacy lead (Zambia)
The Problem: 190 Million Missing Doses

R21, the new malaria vaccine, is similarly effective to the existing vaccine, RTS,S, but cheaper and easier to produce. A total of 200 million doses of R21 could be produced by the end of 2025, including 25 million that have already been made. The most recent public evidence suggests just 10 million will be used by then — less than half of what is already prepared today and just 5% of the 200-million dose potential.

R21 and RTS,S
Recommended by the WHO in October 2023, R21 is the second of only two existing malaria vaccines. The first vaccine, RTS,S, was recommended by the WHO in October 2021. RTS,S and R21 are similarly effective.
against *Plasmodium falciparum*, the species of malaria parasite responsible for the overwhelming majority of deaths.\(^1\) Notably, R21 can withstand very hot ambient conditions for up to two weeks, which is particularly useful for distribution in tropical climates. Arguably the most important difference between the two vaccines relates to their manufacturing. RTS,S is manufactured by GSK and supply is extremely limited, with an estimated 18 million doses available through 2025\(^2\), enough for up to 4.5 million children. R21, in contrast, is much easier to produce.

### Total producible doses of R21

R21 is manufactured by the Serum Institute of India, a biotechnology and pharmaceuticals firm with very high production capacity; in 2021, the Serum Institute made over 1.5 billion doses of the Oxford-AstraZeneca COVID-19 vaccine.\(^4\) R21 doses had already been made and were ready for rollout over the next several months.\(^6\) This 25 million figure was repeated in a March 2024 *Times* article, but Serum CEO Adar Poonawalla stated that “[t]he coming years we can scale up to 100 million doses a year.”\(^7\)

The Serum Institute’s stated capacity for R21 production has varied somewhat over time, but its statements generally point to the ability to provide 100 million doses per year. In October 2023, Serum stated that it had a production capacity of 100 million doses per year, which would be doubled over the next two years.\(^5\) In February 2024, Serum further stated that 25 million

<table>
<thead>
<tr>
<th>Malaria Vaccine Characteristics(^3)</th>
<th>RTS,S</th>
<th>R21</th>
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<tbody>
<tr>
<td>Per-dose price</td>
<td>$10.20 per dose</td>
<td>$3.90 per dose</td>
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<tr>
<td>Doses deliverable by the end of 2025</td>
<td>18 million</td>
<td>Up to 200 million</td>
</tr>
<tr>
<td>Doses for full vaccination</td>
<td>Four; three in an initial course, one a year later</td>
<td></td>
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<tr>
<td>Recommended population</td>
<td>Children five months old and up</td>
<td></td>
</tr>
<tr>
<td>Vaccine storage</td>
<td>Stable for three years at 2 °-8 °C</td>
<td>Stable for two years at 2°-8 °C and up to two weeks between 25 °-40 °C</td>
</tr>
</tbody>
</table>

Serum’s previous figures are likely based on rough calculations of their internal capacity and may fluctuate as orders materialize, or do not materialize, from customers. **We assume that with sufficient funding, Serum could indeed produce a cumulative 200 million doses by 2025.** This would be enough to vaccinate up to 50 million children.
Total R21 doses planned and ordered
For low-income countries, vaccine procurement is generally managed through a system involving the respective recipient governments, UNICEF, and Gavi, among others. In the case of R21, Gavi procures the vaccines from the Serum Institute through UNICEF, and they are transferred to individual countries in Africa to manage distribution. These vaccines are co-financed by Gavi in conjunction with the recipient nation based on an application process determining which countries have the greatest need for the vaccines and the capacity to distribute them effectively.

There is no clear public record of how many doses of R21 have been purchased or will be distributed. UNICEF announced a deal in October 2023 to secure supply of R21 with the Serum Institute from 2024–2028, but did not disclose the volume purchased. Gavi has also not publicly indicated the number of doses it intends to release to African nations by the end of 2025.

Figures presented by representatives of the WHO at the Multilateral Initiative on Malaria (MIM) Conference in Rwanda in April 2024 indicated that 25 million doses of malaria vaccines in total will be distributed by 2025; of this, 10 million will be R21. This represents just 5% of the production capacity through 2025, and is particularly concerning given that 25 million R21 doses have already been manufactured.

Products choice and doses allocated for MVIP & 2024-25
Adapted from Gavi presentation given at the Multilateral Initiative on Malaria conference, April 2024

The case of Burkina Faso demonstrates how other policy decisions by Gavi, in combination with the artificial shortage of R21, inhibit more widespread immunization against malaria. Burkina Faso has maintained one of the highest rates of death from malaria throughout the 21st century. It was also the site of several large-scale vaccine studies for both RTS,S and R21, confirming the vaccines’ safety and efficacy.
The country began receiving shipments of RTS,S for general use in February 2024, but as discussed previously, supply is limited. Burkina Faso has the capacity and desire to expand the rollout of the vaccine, but current Gavi policy prevents it from using R21 to help fill the gap because it is already using RTS,S. This is especially confounding given that the Serum Institute of India has produced 25 million R21 doses already, more than double what Gavi has ordered.

During the COVID-19 pandemic, Gavi changed its typical window-based application review process to a rolling process. Gavi should do so for R21 as well to ensure no African countries must wait months after missing an application deadline.

“CONSIDERING THE CASE OF BURKINA FASO ALONE, WHERE OVER 1.7 MILLION CHILDREN ARE ELIGIBLE FOR MALARIA VACCINATION IN 2024, IT IS CLEAR THE 10 MILLION DOSES OF R21 THAT GAVI AND UNICEF PLAN TO DISTRIBUTE TO AFRICA FALL FAR SHORT OF THE CONTINENT’S NEEDS.”
The Consequences of the Shortfall

The shortfall in R21 malaria vaccine doses translates into a difference of approximately 300,000 children’s lives through 2025. Beyond the impact on child mortality, malaria can also impose enormous economic burdens on afflicted individuals, their families, their communities, and their countries.

Deaths caused by the R21 shortfall
In 2022, malaria caused an estimated 580,000 deaths in the WHO African Region, 78% of which were children under the age of five — an average of well over 1,200 per day. Malaria vaccination will be critical to lowering this grim figure.

Modeling based on the R21 phase 2b and 3 studies illustrates the profound importance of an expansive, rapid vaccine rollout. Schmit et al. (2024) in The Lancet Infectious Diseases calculate that for every million children aged 5 to 17 months vaccinated with four doses of R21, over 6,300 will...

Malaria kills at a relentless pace.
An average of over 1,200 children die every day of malaria, enough to fill three Boeing 747-400s. Using all 200 million R21 doses could save up to 300,000 lives. That’s 750 jumbo jets of young children spared a horrible fate.
be saved from death by malaria and 1.8 million infections will be prevented.\textsuperscript{13}

A plan to use 200 million doses is thus a plan to save 315,000 children’s lives, and a plan for 10 million doses just 15,750 — a gap of nearly 300,000 children.

**Malaria and poverty**
The consequences of malaria extend far beyond the suffering and loss of life it inflicts on children in Sub-Saharan Africa.

The majority of children infected with malaria survive, but infection can still be highly disruptive for them, their families, and at the macroeconomic level, the communities they live in.

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**Malaria consequences**

The heterogeneous nature of malaria burden and the diverse economies of the countries affected mean complete statistics on economic impacts for every country remain elusive, but it is known that malaria substantially hinders community wellbeing and economic development. Some of the many downstream harms of malaria infection include: \textsuperscript{14,15}
• Catastrophic household spending on treatment for severe infections, even in countries with free public healthcare (where malaria often occupies a very large portion of public health spending to begin with).
• Days or weeks of lost productivity for infected adults or the caretakers of infected children (who may also miss schooling).
• Depletion of household savings and slowed economic mobility through repeated bouts of illness that reduce ability to invest in education and income-generating activities.
• Lower birth weight, developmental delays, and overall greater mortality among infants born of the nearly 13 million pregnant women infected with malaria each year.

In aggregate, these costs represent a continuous drain on economic growth and by extension, human well-being. Jeffrey Sachs and Pia Malaney’s influential 2002 paper in Nature succinctly summarized the problem: “Where malaria prospers most, human societies have prospered least.”

“AS A TANZANIAN, IT HAS BEEN INSPIRING TO WITNESS THE COMMITMENT AND ENTHUSIASM OF POLICYMAKERS, SCIENTISTS, AND OTHERS TO PREPARE FOR THE R21 MALARIA VACCINE. HOWEVER, THE PRIORITIES OF INTERNATIONAL PARTNERS DO NOT SEEM TO MATCH THIS ENTHUSIASM.”

Abdulrahman Banisheyba
1Day Africa malaria advocacy lead
(Tanzania)
Realizing All 200 Million Doses

R21 vaccination requires substantial financial and logistical support, but vaccination of 50 million children could cost only $1.25 billion. In just a few years, Africa saw over 1 billion doses of COVID-19 vaccines delivered; with sufficient political commitment, external fundraising, and preparation of African governments, a malaria vaccination campaign driven by abundant supply of R21 is similarly achievable.

Cost of R21 vaccinations

Preliminary estimates by 1Day Sooner suggest that the overall cost of vaccinating a child with R21 in Sub-Saharan Africa could be as little as $25 on average. For 50 million children, vaccinations would cost $1.25 billion — less than $4,000 for every life saved. (In contrast, governments in Western democracies typically use figures in the several millions of dollars to represent the statistical value of a life when assessing policies that affect their citizens.)

At that price, every dose that can be produced should be used in 2024 and 2025. If the Serum Institute can produce 200 million doses by the end of 2025, the goal should be to vaccinate 50 million children with those 200 million doses.

R21 costs in perspective

- $95bn: US 2024 aid package to Israel, Taiwan
- $21.3bn: Gavi donor contributions 2021–2025
- $13.1bn: Gerald R. Ford Aircraft carrier
- $4.5bn: Cost of NYC 2nd Avenue Subway Phase I
- $1.25bn: Delivering 200 million R21 doses
Steps to mass R21 distribution
Rolling out 200 million vaccine doses in a year and a half will be challenging, but the successful distribution of over a billion COVID-19 vaccine doses across Africa demonstrated that extensive, rapid vaccine rollouts are possible.19

In light of this experience, we are confident that these challenges can be overcome with proper communication, planning, and prioritization. The following factors will be critical in ensuring R21 is deployed with maximum efficiency and speed.

Commitment:
Gavi and relevant stakeholders must commit to the goal of distributing every available R21 dose out of the 200 million producible by 2025 while identifying and addressing barriers to rollout.

Fundraising:
Gavi will need further funding to purchase R21 doses. Western governments and civil society, the traditional backbone of Gavi funding, should make funds available for the expressed purpose of the R21 rollout.

National preparation:
African ministries of health must prioritize malaria vaccine access, apply to Gavi for approval for R21 and co-financing (if relevant), and prepare their domestic infrastructure to receive and distribute the vaccine.
Endnotes

1. Malaria vaccines (RTS,S and R21), WHO, January 17, 2024.
6. New Phase 3 Trial Data Confirm the Uniquely High Efficacy and Good Safety Profile of the R21/Matrix-M™ Malaria Vaccine in African Children, Serum Institute of India, February 1, 2024.
7. The West is complacent’: inside the world’s biggest vaccine factory, The Times, March 10, 2024.
9. 1Day Sooner contacted representatives from Gavi on multiple occasions regarding the number of R21 doses, but we received no response. Earlier inquiries to the UNICEF Supply Division also went unanswered.
11. Abdel Aziz Nabaloum, “Relief” as RTS,S malaria vaccine rollout set to begin in Burkina Faso, Gavi, February 1, 2024.
13. 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 24(5). These effects are dependent on a number of factors, including whether or not vaccines are administered in areas with perennial transmission of malaria or in areas where transmission is only seasonal.
17. David Tellet, R21 Vaccine Cost Estimates, February 2024. This figure is in the same range as other common childhood immunizations in developing countries; see Logan Brenzel, Common approach for the costing and financing analyses of routine immunization and new vaccine introduction costs, working paper prepared for the Bill & Melinda Gates Foundation, August 2014.
18. See, for example, the US Environmental Protection Agency’s Mortality Risk Valuation for its figures and related discussion.