Gavi Malaria Vaccine Support

Abbreviated form for countries participating in the Malaria Vaccine Implementation Programme (MVIP) to access continued malaria vaccine support through Gavi

1. The request to access Gavi support will need to be endorsed by the Minister of Health and Minister of Finance, or their delegated authority.
2. The completed request, together with any supporting documents must be submitted to Gavi by e-mail to proposals@gavi.org, copying the Senior Country Manager, by **13 September 2022**.
3. Following submission, the request will be tabled for review at the next meeting of the Independent Review Committee (IRC).

PART 1: COUNTRY REQUEST

Country	***Malawi***
Ministry	***Ministry of Health Malawi***
Contact details of the country focal point for this request	Name: Dr Charles Mwansambo Charles Mwansambo Email:cmwansambo@gmail.com Telephone:+265999826946
Is there confirmation of the country's decision to continue malaria immunisation in areas covered by MVIP beyond December 2023 (e.g. Minister of Health sign off, NITAG meeting minutes, Immunization Inter-agency Coordination Committee (ICC) minutes)?	Yes ✓ No ☐ If yes, please submit the confirmation together with this request form.
Will the country maintain the joint EPI/ National malaria control programme (NMCP) coordination mechanism (or other mechanism) that will continue to oversee the coordination of the malaria vaccine implementation beyond the life of the MVIP?	Yes ✓ No ☐ If no, please provide further explanation.

A. Continuation of malaria vaccination in geographic areas covered by the MVIP (implementation and comparator areas)

Provide information on the requested doses, with a detailed calculation of how the **anticipated dose requirement** was calculated.

Year	Vaccine / presentation	Wastage	Target age	Population in target age cohort	Target population to be vaccinated according to coverage target	Total number of doses requested
2024	2	10%	under 2 years	553,593	429,375	1,003,209
2025	2	10%	under 2 years of age	556,254	442,384	1,031,342

The above calculations are done only for the 11 MVIP districts.

The total number of doses requested for 2024 is 1,003,209. This is based on the following assumptions:

- A total population target of 553,593(A sum of 274,525 surviving infants from 2023 and 279,069 cohort for 2024)
- Malaria vaccine dose 1 to 3 target coverage of 85% based on MVIP performance
- Malaria vaccine dose 4 target coverage of 70%
- A total of 429,375 target population to be vaccinated that year based on the above coverage estimates
- A wastage factor of 10%

The total number of doses requested for 2025 is 1,031,342. This is based on the following assumptions:

- A total population target of 556,254 (A sum of 277045surviving infants from 2024 and 279209 cohort for 2025)
- Malaria vaccine dose 1 to 3 target coverage of 87% based on the assumption that there will be a 2% increase of the 2024 assumptions
- Malaria vaccine dose 4 target coverage of 72% based on the same assumption as above
- A total of 442,384 target population to be vaccinated that year based on the above coverage estimates
- A wastage factor of 10%

An excel sheet is provided as an addendum to clarify additional assumptions made with this calculation

Are there **plans to expand implementation** of the vaccine beyond the current areas covered under MVIP (implementation and comparator areas)?

Yes, but this application is made to expand to the MVIP-comparator areas. Please refer to the situation analysis and malaria stratification report for details of the additional districts that will be added to the MVIP districts. In summary 7 additional districts have been identified as priority districts to be added on top of the 11 MVIP districts.

B. Expansion of malaria vaccination into additional geographic areas and/or population groups not covered by MVIP (implementation and comparator areas)

Does the country want to include into this request an expansion of malaria vaccination beyond geographic areas / populations covered in MVIP, noting such expansion will be guided by the Framework for the allocation of limitedtmalaria vaccine.

If yes, please provide detailed information on the areas and requested doses.

Year	Vaccine / presentation	Wastage	Target age	Population in target age cohort	Target population to be vaccinated according to coverage target
	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA

PART 2: SUPPORTING INFORMATION

Below should heavily draw from available MVIP documentation. You may choose to refer to existing documentation or reports; please be as specific as possible in below responses where relevant information can be found (e.g. document name and page numbers); and attach the relevant documents.

1. Please describe strategies and plans that are in place to ensure the **use of the malaria vaccine** will continue, as was the case during the MVIP, **as a complementary intervention** that does not replace the package of existing malaria prevention and case management tools nor does it weaken routine immunisation systems.

Malawi has a National Malaria Strategic Plan whose strategic goals are aligned with the Global Technical Strategy (GTS) for malaria 2016–2030, developed to accelerate progress towards malaria elimination. The GTS targets a global reduction of at least 90% in malaria case incidence and mortality rates, and elimination in at least 35 countries by 2030. The country recognizes the fact that in malaria control and elimination, no single intervention would suffice, there is need for a mix of several interventions to achieve effective malaria control and elimination. This is why the National Malaria Control Program (NMCP) embraced the novel malaria vaccine as an additional tool in the fight against malaria amongst age eligible children across the country. During vaccine delivery, it has been repeatedly emphasized to caregivers of all malaria vaccine beneficiaries that despite being vaccinated against malaria, children should continue sleeping under mosquito nets, seek early care when they have any signs and symptoms of malaria and continue with other malaria preventive measures. To show commitment on this, in 2021 during MVIP implementation, the country procured and distributed 9.2 million nets across the country and conducted indoor residual spraying in 4 districts including in the MVIP districts. In addition, the country continued implementing other malaria control prevention prioritized in the 2017-2021 National Malaria Strategic Plan. As the MSP approaches its end in December 2022, plans are under way to develop a successor plan to continue implementation of the effective interventions and add the Malaria vaccine as an additional intervention to ensure uninterrupted provision of malaria vaccine in all MVIP districts with expansion to new districts at a later stage. In the successor plan, apart from including the malaria vaccine for the first time, the country intends to step up access to malaria interventions including vector control, chemoprevention in high-risk populations, and prompt access to diagnosis and treatment of malaria in health facilities and communities across the country, including the MVIP areas. This malaria vaccine inclusion and step up of currently effective malaria control interventions provides an assurance that the malaria vaccine is not coming in to replace other interventions but to contribute to the overall goal of malaria control and elimination in the country. Malawi having participated in the MVIP, it clearly demonstrated that the malaria vaccine did not weaken the uptake of other malaria interventions or other routine immunization services as demonstrated by high coverage of tracer antigens i.e. Pentavalent vaccine dose 3.

Malaria prevention and control activities include two broad strategies that are chemoprevention and vector control. Chemoprevention involves giving of malaria drugs to high risk individuals such as young children, pregnant women and non-immune travelers. Malaria vector control strategies include use of Long-Lasting Insecticide Treated Nets (LLINs), Indoor Residual spraying (IRS), with insecticides, larval source management and other control measures such as house structural improvement to bar mosquito entry into dwelling structures. Recently in the GTS, surveillance has been added as a core intervention to help target resources appropriately for efficiency and where needed most.

All these strategies and others will be implemented in the areas where the malaria vaccine is being implemented. The Malaria Strategic Plan attached to this application has priority interventions confirming that the malaria vaccine will not replace current interventions.

2. Please describe how this application for vaccine funding support will contribute to **increasing vaccine coverage**. Specifically, please describe strategies and plans (including the use of digital health innovations) put in place to **enhance the coverage of the 4th dose** and reduce the drop-off between the 3rd and 4th dose observed during the MVIP.

To enhance the coverage of the fourth dose, during the expansion, vaccine demand creation activities will be carried out as part of implementing the malaria vaccine communication plan/ strategy attached as an addendum to this application. The following are the key goals of the strategy are:

- To create awareness and generate champions among relevant stakeholders to support malaria vaccination in particular targeting the fourth dose.
- To increase knowledge among caretakers regarding malaria vaccine as a complementary malaria control intervention.
- To increase the proportion of targeted health workers that are able to communicate effectively with caregivers about the vaccine.
- To provide up-to-date information to health workers on malaria vaccination.
- To mobilise communities to seek all four doses of the malaria vaccine in designated sites and outreach clinics.
- To prepare for the proactive handling of reputational risks to the vaccination programme through crisis communications planning and activities.
- To address any misconceptions about the malaria vaccine as well as ensure confidence in the vaccination effort through, for example, the proactive handling of rumours and reporting of AEFIs.
- To promote trust in the EPI and malaria control programmes.

There are several activities that have been identified in the MVIP that will continue to be used to improve the coverage of the 4th dose.

- Use of mother care groups to promote and encourage fellow mothers bring their children for vaccination
- Use of defaulter tracing which is an established strategy to ensure children receive all their age eligible vaccines within routine immunization services and an embedded role and responsibility of vaccinators.
- Use of reminder cards by community volunteers to facilitate follow up of children who are due to receive a scheduled routine antigen including malaria vaccine. This approach has been piloted in several MVIP districts and improved access and utilization of routine immunization services including uptake of all malaria vaccine doses and reduction of drop-out rate retention for vaccination.
- Use of mobile SMS reminders to facilitate retention of mothers with their children come for subsequent doses.
- Periodic Intensified Routine Immunization Activities (PIRI) to be done target in areas with low 4th dose coverage estimates.
- Use of missed opportunity for vaccination and second year of life vaccination strategy to ensure no child misses an age eligible dose of any routine antigen including malaria vaccine and promote uptake of MR2 and MV4 provided during second year of life.

3. Please describe strategies and plans that are in place (or will be developed) to create/ **sustain strong community engagement** to ensure **vaccine acceptance** and **resilient demand**.

Refer to the Community Health Strategy attached to this application that outlines community engagement activities. The plan is currently being implemented to both create and sustain demand for the malaria vaccine.
The Malawi Immunization System works with communities at all levels to ensure a sustained community engagement. With support from Gavi through the HSS grant, the Malawi immunization established a Mother care group model for default tracing of children missing immunization. We are also exploring and expanding another model called vaccinate My village which is community led. This helps the communities to take responsibility for the health of all the children in their communities. The chiefs working with Health volunteers are key to these interventions. There is a fully fledged community health department within the ministry of health also receiving support from Gavi to oversee the linkages with communities for preventive health services uptake by the communities including routine immunization. involvement of Area Development Committees, District Councils and politicians in general to ensure demand creation.

4. Please describe steps the country has taken to strengthen the pharmacovigilance system to enable **continued pharmacovigilance** of the malaria vaccine.

Since the introduction of the malaria vaccine, the EPI program has been working with partners including WHO and CDC to strengthen vaccine safety surveillance. Before the vaccine was rolled out in the implementing districts, all the health care workers were trained on vaccine safety, vaccine safety surveillance tools were made available and community awareness on AEFI reporting was conducted. During malaria vaccine implementation, HCW refresher training and mentorships have been done and ongoing in all the districts in order to improve detection and reporting of all AEFI. All these improved vaccine safety surveillance in Malawi, with the country achieving the Global Vaccine Action Plan indicator of reporting at least 10 AEFI cases/100,000 surviving infants.

With support from WHO and CDC, the program has established active vaccine safety surveillance sites in five sites as one way of improving our AEFI/AESI reporting rate.

Through the MVIP, the programme managed to establish and build capacity of AEFI investigation teams in the implementing districts and support the Medicines Safety and Quality Committee (National Safety Committee) to conduct causality assessment of serious cases. The Introduction of Covid-19 vaccine extended the establishment of the investigation teams in all the remaining districts. The programme will continue to support these teams to ensure all serious and cluster of cases are investigated to facilitate causality assessments and guide the programme on safety concerns that may arise in communities (maintaining confidence in the routine immunization).

The EPI programme will continue to use and strengthen these existing structures to strengthen vaccine safety monitoring. The country is also being oriented to the regional and global vaccine safety online database including vigiflow and vigibase to meet Regional and Global reporting requirements..

5. Please describe **how the routine immunisation programme and health system will be strengthened** so as to accommodate the additional work the malaria vaccine will create, including the need to provide the malaria vaccine at touch points (time points) not currently used in routine immunisation.

The Malaria vaccine will be given at 5, 6, 7 and 22 months of age. There are three additional new points of contact for caregivers with the health system. These points will provide the opportunity of the health system to provide other essential services including growth monitoring, vitamin A supplementation, deworming and provision of catch up vaccination as per MOV/2YL i.e. provision of malaria vaccine dose 4 at 22 months will provide additional check point for the second dose of the measles rubella vaccine. Further, the supportive supervision and mentorship would be integrated to cover all the areas as a comprehensive primary health care package. Efforts to strengthen the monitoring of the adverse events

following immunization will apply across all antigens. Multiple players are playing crucial roles in this regard including WHO and CDC through AFENET. The programme will leverage their additional resources to strengthen the whole cycle of vaccine safety monitoring across all antigens and not only malaria vaccine.

6. Please describe strategies or plans that are in place to enhance **monitoring, evaluation and learning** (MEL) and leverage on the learnings from the MVIP, including as relevant to inform the broader scale up.

The Malaria vaccine Monitoring and evaluation indicators, vaccine doses, were already included in the routine immunization M&E tools. these tools include;

- Under 2 registers
- Tally books for both static and outreach clinics
- Monthly reporting books
- Monitoring charts
- Vaccine stock management books

The under 2 registers capture information that include name, physical address among others of the child so that it is also used to track defaulters. During the past implementation, these tools were revised to incorporate the malaria vaccine. Malaria vaccine monitoring charts were developed to monitor the uptake and trend of all four malaria vaccine doses. As we plan for the expansion of the malaria vaccine across the country, it will be prudent to include it in the definition of the fully vaccinated child. Furthermore, the vaccine is already included into the DHIS2 and will be added in all other electronic monitoring tools.

Health facilities in the rollout districts will have an opportunity to leverage on the existing Gavi HSS grant to conduct facility data review meetings and audits to strengthen data quality for this new vaccine and the traditional vaccines.

The vaccine stock book was not revised in the past implementation and will need to be revised to include the malaria vaccine section for proper stock management of the malaria vaccine.

The EPI already did set up platforms for monitoring the progress of immunisation activities including the malaria vaccine. The table below has the activities and the timelines

Type of Monitoring/Evaluation	**Activities**	**Timelines**
Process Monitoring	Zonal/District meetings to review progress on key indicators in each district	Quarterly
	EPI Sub TWG meetings to review progress on key vaccine indicators nationally	Six monthly
Impact evaluation	Review of malaria vaccine	Yearly (2022- 2025)

	coverage indicators at district level and nationally	
	Review of AEFI/AESI surveillance indicators per district and nationally	Yearly (2022 and 2025)

The NMCP also has already set surveillance, monitoring and evaluation activities to monitor key indicators that show the impact of the core malaria interventions including the malaria vaccine. These activities are included in the malaria strategic plan. Some of the activities include.

- District level quarterly data review meetings to review key malara indicators
- Integrated Malaria Supervision and Mentorship, which includes supporting subnational staff on data entry, reviews, reporting and use of the data for decision making
- National Malaria Indicator Surveys to monitor malaria prevalence and other national/ regional indicators. These surveys are performed nearly every two years, the latest survey was conducted in 2021. The next is likely to be done in 2023/2024
- Malaria Behaviour Survey, last conducted in 2021, and the next one in two to three years. This survey assesses the behaviour that people have in using malaria interventions including the malaria vaccine.

7. Please explain **how past implementation challenges and lessons learned are being taken into account** for this request e.g. how challenges and lessons learnt from the MVIP will be leveraged to inform the continuation of malaria immunisation in the MVIP areas and/or introduction of the malaria vaccine in areas outside of the MVIP areas.

A detailed malaria situation analysis(that includes details on MVIP lessons learnt)and the malaria vaccine post introduction evaluation that document lessons learnt, challenges are added as addendums to this submission. The following are the key highlights from these assessments

Key MVIP Achievements and successes.

- Great coordination amongst EPI, NMCP, Heath Education Unit in the MOH driving an agenda to deliver malaria vaccine
- Successfully integrated malaria vaccine within routine immunization without disruption of uptake for the other vaccines

- Continuous improvement of malaria vaccine uptake from slow start to 93% of age eligible children reached with dose 1 in 2021 reporting period
- Reduction in the dropout rate of malaria vaccine dose 1 – 3 to around 12% in the reporting year 2021 (compared to over 40% in 2019 and 2020)
- Improved acceptability of malaria vaccines amongst caregivers – acknowledging its benefits from their perspectives
- Improved supportive supervision of routine immunization in implementing facilities
- AEFI/AESI surveillance reporting rate sustained to over 10 cases per 100,000 population over the period of implementation

MVIP Challenges in Malawi

- Low uptake of MV 4 over the entire period of implementation
- Inadequate follow up/default tracing strategies to promote uptake of dose 4
- MV3 coverage (administered at 7 months) below MR1 coverage, despite the opportunities the MR1 provides to have the MV defaulters getting vaccinated at 9 Months
- Challenges with documentation of routine immunization data – leading to missing data in U/2 registers
- Pockets of refusals at the start of the vaccination program
- Health and natural emergencies affected uptake of routine immunization vaccines including malaria vaccine
- Covid-19 Pandemic in 2020 on wards
- Polio outbreak in 2021/2022
- Cholera outbreak affecting 6 of the 11 malaria vaccine implementing districts
- Tropical storm Ana and Gombe affecting 3 of the implementing districts with disruption to service delivery

MVIP Lessons learnt and best practices	**How these will be leveraged in the expansion to comparator areas.**
High commitment by MoH; Planning and coordination at national level involving all key stakeholders – including EPI and NMCP	Continued national coordination through the current EPI and MMCP structures and coordination systems
High demand creation activities were critical to increase uptake of the vaccine	Implementation of the vaccine demand creation activities in the community engagement strategy
Community engagement (caregivers, key opinion leaders, local and religious leaders) increased demand for malaria vaccine over time particularly with key messages	Targeting these key groups in the demand creation activities.
Need for enhanced social mobilization for 4th dose of malaria vaccine demand creation – this is ongoing	Implementing activities outlined in section 2 of this application to enhance the coverage of dose four

Use of reminder cards to track defaulters has proved useful in reducing dropout rate and increase coverage	Continued implementation of this approach to track malaria vaccine defaulters in the current vaccinating clusters and start of using this approach in the now comparator areas**.**
Peer educators have played a critical role in linking eligible children to vaccinators and community awareness	Continued use of peer educators to encourage caregiver bring eligible children in the current vaccinating clusters and start of use them in the now comparator areas**.**
Supportive supervision (technical support in communities) to identify challenges and provide timely solutions	Encourage district level manages of plan and implement supportive supervision activities to vaccinators within their districts
Stakeholder engagement at district level so that district level stakeholders learn from each other.	Use the national existing stakeholder relations to improve district level stakeholder supporting malaria vaccine activities

8. Please describe **technical assistance** (if any) that the country would need to enable continuation of malaria immunization in the MVIP areas (implementation and comparator areas) or expansion into additional areas, and whether sources for this TA have already been identified.

The program will leverage the Gavi Targeted Country Assistance (TCA) to identify technical assistance that will support malaria vaccine expansion. The technical assistance will be in the areas of social mobilization and demand creation, supply chain and logistics, data management as well as routine immunization. This assistance will also be expanded to support vaccine safety surveillance for malaria vaccine. To a minimum, this TA support will be required for 12 months. The TA will work in close collaboration with the National EPI and Malaria program technical officers to ensure continuous capacity building and program strengthening.

9. Other comments/recommendations (optional): Provide any additional contextual information relevant to this request (any explanations that further clarify any possible linkages, routine monitoring, any considerations or data that informed this request)

PART 3: GOVERNMENT SIGNATURE FORM

The Government of ..... would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for:

Continuation of malaria vaccine implementation in the MVIP areas (implementation and comparator areas) beyond December 2023

The Government of ..... commits itself to developing national immunisation services on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of both the Minister of Health and Minister of Finance or their delegated authority.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all activities, including domestic funds and any needed vaccine co-financing[1] will be included in the annual budget of the Ministry of Health.

We, the undersigned, further affirm that the requested funding for salaries, salary top-ups/allowances, per diems and incentives does not duplicate funding from other sources (e.g. from other donors).

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[2]

Minister of Health (or delegated authority)

Name: Dr. Charles Mwansambo

Date: 7th September, 2022

Signature: .....

Minister of Finance (or delegated authority)

Name: MacDonald Mwale, PhD

Date: 7th September, 2022

Signature: .....

PART 4: ATTACHMENTS & SUPPORTING DOCUMENTS

I. Mandatory supporting documents:

Please ensure the following documents are provided together with this form to support your request:

- Clear calculation supporting the number of malaria vaccine doses requested
- Confirmation of country decision to continue with malaria immunisation in the MVIP areas beyond December 2023 e.g., Minister of Health sign off, NITAG meeting minutes, Immunisation Inter-Agency Coordination Committee (ICC) minutes, or other documented evidence

[1] Applications will not need to be accompanied by a pre-determined co-financing commitment. Countries whose applications are recommended for approval by the IRC will have an opportunity to review the new co-financing policy in early 2023 and consider the co-financial implications of their application for Gavi support.

[2] In the event the country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

In the case that an expansion to areas not included in the MVIP is requested, you will need to also provide:

- Documentation of country decision to expand into additional areas
- Information on these additional areas and rational to include them, in line with the Framework for the allocation of limited malaria vaccine elements and a detailed calculation on the additional number of malaria vaccine doses requested
- A detailed plan for the introduction of the vaccine (new vaccine introduction plan)
- As applicable, a budget for a vaccine introduction grant (using the Gavi Budgeting & Reporting Template) for the introduction of the malaria vaccine in areas outside the MVIP areas.

II. Other supporting documents (not mandatory):

To support your request, you are encouraged to provide the following documents:

- If available, an updated **National Malaria Strategy** (or an addendum to it) that describes the country's plans to use the malaria vaccine within a comprehensive malaria control strategy as a complementary intervention that does not replace the package of existing malaria prevention and case management tools
- If available, an updated **National Immunisation Strategy** (or an addendum to it) that describes the country's plans to roll out the malaria vaccine within a comprehensive immunisation strategy such that the vaccine introduction or continuation of immunisation does not weaken routine immunisation systems