



NATIONAL MALARIA CONTROL PROGRAM



Malaria Vaccine introduction and Scale up.

An overview of technical guidance to sub-national ,operational teams

Weekly NMED CME

Date:09th July , 2024





1: Introduction

2: R21Matrix-M characteristics

3. The Malaria Vaccine schedule.

**4. Data Management, communication
and AEFIS' surveillance**

**5. Malaria Vaccine Introduction
plan – Brief summary**





1

INTRODUCTION

Background.

Malaria Vaccine product information.

Malaria Vaccine mechanism of action.



Introduction:-Background



- ❑ In 2021(Oct) WHO recommended the vaccine for prevention of Falciparum in Children.
- ❑ Two(2) vaccines are so far WHO recommended and pre-qualified:
 - **RTS,SA01 (Recommended in Oct- 2021 & prequalified July 2022).**
 - **R21-Matrix M(recommended in Oct- 2023 & prequalified Dec- 2023).**
- ❑ No known cross protection for other Plasmodium species & are not designed for transmission interruption.
- ❑ Both are indicated for burden reduction, countries are guided to prioritize moderate to high transmission areas.
 - **Prevent infection, illness and death.**
- ❑ RTS,S-Phase 3 trials (2009-2014) in various transmissions including the vary highly seasonal at 11 sites with 4-7 years of follow up.
 - **Phase -3 trial for seasonal vaccination with/without chemoprevention at 2 sites in Africa with 5 years of follow-up.**
 - **Since 2019 16M doses have been given 2M children through a pilot implementation in Kenya, Ghana & Malawi.**
- ❑ R21-Matrix-M-Phase 3 trials on since 2021 and by Oct- 2022 the only available data was for :
 - **Follow up of 18 months for moderate –low transmission ,highly seasonal areas.**
- ❑ By early 2024 -8 countries were ready to introduce the Vaccine
 - **Uganda plans to introduce the R21-Matrix-M to 90-105 districts starting April 2025.**



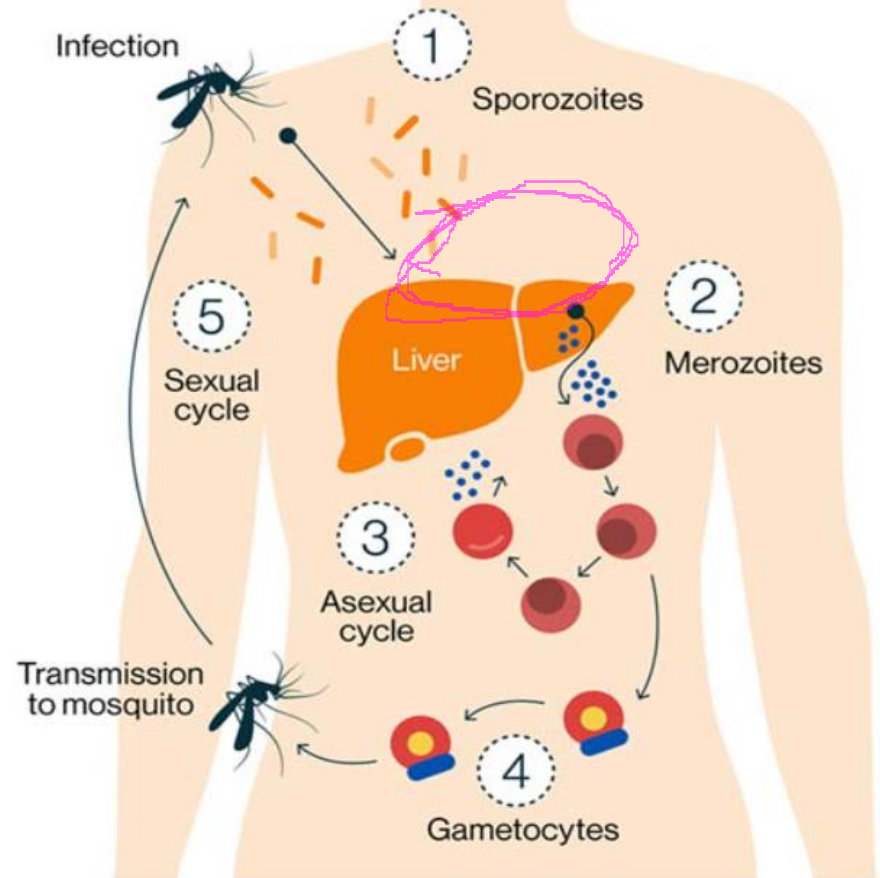
Vaccine product information

Information	RTS,SA01		R21-MATRIX-M
Schedule:	<ul style="list-style-type: none"> Four(4) doses given monthly from 5 months of age and a 4th dose provided to prolong protection. A fifth dose may be considered in cases of significant Malaria risk persisting 1 year after 4th dose. 		<ul style="list-style-type: none"> Four(4) doses given monthly from 5 months of age and a 4th dose provided to prolong protection. A fifth dose may be considered in cases of significant Malaria risk persisting 1 year after 4th dose
Presentation,cold chain:	<ul style="list-style-type: none"> Two vials clipped together, reconstituted for 2 doses. 2 to .8 degrees centigrade,36 months shelf life. 9.92 sq cms per dose in secondary packaging. 		<ul style="list-style-type: none"> Single dose vial(liquid)1-2 doses per vial. 2.8 degrees centigrade,24 months shelf life 7.03 sq cms per dose ,14.06sq cms in secondary packaging depending on the dose
Market price-2024:	<ul style="list-style-type: none"> US\$10.00 per dose 		<ul style="list-style-type: none"> US\$3.90 per dose
Manufacturer	<ul style="list-style-type: none"> GSK Belgium 		<ul style="list-style-type: none"> Serum Institute of India Pvt LTD
Safety:	<ul style="list-style-type: none"> Good safety profile, has a data base of 6M children. <ul style="list-style-type: none"> The only side effects include <ul style="list-style-type: none"> Pain at the site of injection . Fever Febrile convulsions are associated but rare 		<ul style="list-style-type: none"> Good safety profile, phase 3 trial on going among 4000 children. The only side effects include <ul style="list-style-type: none"> Pain at the site of injection . Fever Febrile convulsions are associated but rare
Administration	<ul style="list-style-type: none"> Intramuscular injection <ul style="list-style-type: none"> Thigh(6-12 months) Deltoid (>12months) 		<ul style="list-style-type: none"> Intramuscular injection <ul style="list-style-type: none"> Thigh(6-12 months) Deltoid (>12months)
Buffer & Wastage	<ul style="list-style-type: none"> Wastage:(7%) Buffer:(25%) 		<ul style="list-style-type: none"> Wastage(7%) Buffer(25%)
Availability:	<ul style="list-style-type: none"> 18 M doses available for the next 3 years;4 in 2024,6 in 2025 and 8 in 2026 for all eligible countries. 		<ul style="list-style-type: none"> To make available 100M -200m doses available per year for all eligible countries.

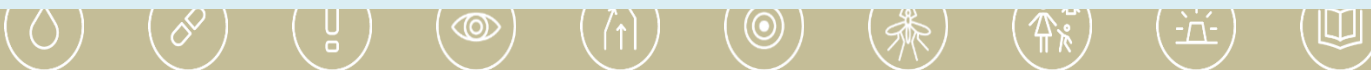


Life-cycle of the malaria parasite

- 1 The cycle begins when highly mobile 'sporozoites' are transferred from mosquito to human, when the mosquito bites.
- 2 The sporozoites travel to the liver, where they infect liver cells, multiply and mature into 'merozoites'. The current malaria vaccines are designed to block infection at this stage – before the parasites grow out of control.
- 3 The merozoites leave the liver and infect red blood cells, where they continue to grow and multiply, destroying the red blood cells and infecting others.
- 4 Some merozoites eventually develop into sexual forms of the parasite called 'gametocytes'. When another mosquito bites, they enter its gut and reproduce, producing new sporozoites.
- 5 These migrate to the mosquito's salivary glands, and the cycle begins again.



- The Malaria Vaccine through the Circumsporozoite protein, an antigen produced by Plasmodium Falciparum stimulates the production of antibodies.
- The antibodies prevent the infection of liver cells by the sporozoites and destroy liver cells that are already infected by sporozoites.
- This interrupts progression of disease to severe Malaria forms and prevents death.





2

R21MATRIX –M CHARACTERISTICS.

(preferred country option)

Vaccine composition

Storage Conditions

Administration

Contraindications





Two(2) dose vial

- R21 malaria vaccine (also known as R21/Matrix-M), is a subunit recombinant protein vaccine.
 - To prevent malaria, specifically *P. falciparum* malaria, which is the most common and dangerous form of malaria .
- 2-dose vial (1 mL of 0.5mL/dose) liquid
 - no reconstitution needed
 - no preservative – open vials to be discarded 6 hours after opening or at end of immunization session, whichever comes first.

- ❑ R21/Matrix- M is of the subunit type,pre-erythrocytic recombinant, protein based vaccine .
 - By subunit – comprise of an antigen from the disease causing agent(Circumsporozoite protein –CSP).
 - Recombinant –the CSP is combined with the Hepatitis –B surface antigen.
 - Vaccine is made up of the R21 and Matrix-M a Saponin derived adjuvant.
 - Pre-erythrocytic-acts at the liver stage of the Malaria cycle.
- ❑ It is an injectable vaccine given intramuscularly.
- ❑ The vaccine should be discarded 6 hours after opening OR at the end of a vaccination session .
- ❑ R21 malaria vaccine is freeze sensitive and light sensitive.
 - Vaccine vials should be stored in a refrigerator between +2°C and +8°C.
 - Do not open the refrigerator door often .
 - Regularly monitor the temperature of refrigerator.
 - When using coolant packs in cold boxes and vaccine carriers, they should be conditioned to reduce the risk of vaccine freezing.
- Those with VVMs & short expiry should be at the front of the refrigerator & should be used first.





Storage Conditions:

+ 2°C to + 8°C

- Keep vaccine away from all cold air vents. The vents blow in very cold air from the freezer which can damage vaccines.
- No food in refrigerator.
- No vaccine in doors.
- No vaccine in solid plastic trays or containers.
- No vaccine in drawers or on floor of refrigerator.

To reduce the risk of freezing, coolant packs are frozen or conditioned for use in the Vaccine carriers or cold boxes.

VVM for the MV is located on the cap of the Vial.

- Vaccine vial monitor indicates exposure to heat**

- Open Vial Policy- 2 dose vial without preservatives.
 - Should be discarded within 6 hours after opening or at the end of the vaccination session



Malaria Vaccine administration –critical steps

Before children arrive for Vaccination

- Take the vials out of the refrigerator.
- Check expiry date, status of VVM and colour of the liquid in the vial.
- Collect and arrange supplies, tools for that.
- Ensure that the AEFI is available

At the Immunization session.

- Great the care giver.
- Verify child's name and register them.
- Check the home based record for:
 - Vaccine,
 - Vitamin A supplementation,
 - Growth monitoring,
 - Other preventive services .
- Inform the care giver.
- Prepare the vaccine .
- Use the thigh(6-12months)& upper arm(> 12 months).
- Share date of next dose and remind caretaker to complete the 4 doses.
- Return Home Based Record & explain potential Side effects.

End of the session(after the children leave)

- Complete the tally sheet to document number of doses given.
- Return unopened vaccine vials to the refrigerator.
- Check the carriers for open vials with unutilised doses and discard them.
- Keep the safety box in a safe and dry place.





Contraindications to the Malaria Vaccine

- Malaria vaccine is **not recommended** for a child who has known severe hypersensitivity:
 - To a previous dose of malaria vaccines.
 - To a previous dose of Hepatitis B vaccines .
 - To any of these vaccine components.

- A minor illness – including respiratory tract infections , mild diarrhea and fever below 38.5°C – is not a contraindication.

- Malnourished or HIV – positive infants may be vaccinated with Malaria Vaccine using the recommended schedule.





3

The Malaria Vaccine Schedule

The adapted country schedule

Addressing late turn-ups





Malaria Vaccination –schedule adapted by Uganda

Child Age	Birth	6 wks	10 wks	14 wks	5 mos	6 mos	7 mos	8 mos	9 mos	12 mos	15 mo	18 mos	24 mos
BCG	1												
Oral polio	0	1	2	3									
Hep-B	0												
DTP-HepB-Hib (penta)		1	2	3									
Pneumococcal conj.		1	2	3									
Rotavirus		1	2										
Inactivated Polio		1		2									
Meningococcal A conj.												1	
Measles-Rubella									1			2	
Yellow Fever									1				
Malaria						1	2	3				4	
Vitamin A						1				2		3	4
Growth Monitoring	•	•	•	•	•	•	•	•	•	•	•	•	•
De-worming										1			2
ITN distribution		•											
PMC (formerly IPTi)			1	2					3				

- Explain if the visit is new/lone visit or combined with existing visits for either vaccination or other interventions.
- Additional visits that come along with the introduction of the vaccine provide an opportunity to track & address missed vaccinations, due health services.
- It is an additional chance for giving reminders on up-coming vaccination ,provide messages for net use and early treatment seeking.



Addressing late Vaccination turn -ups

- If the child misses the Malaria Vaccine for any reason, late vaccination should Happen.
- The interrupted Vaccination schedule should be resumed without necessarily repeating the previously given doses.
- A minimum of 4 weeks must be maintained between MV doses, no matter which MV dose.
- There is no upper age limit for malaria vaccine administration [country to update based on policy]
- Children aged 6- 12 months can receive the Malaria Vaccine dose 1.
- Once Vaccination starts ,children up to 5 years of age should complete their Malaria Vaccine 4 dose schedule.
- In cases of late Vaccination the next dose should be provided within the next 4 weeks





4

Data Management, communication & AEFIs' surveillance

Data management

Communication

AEFIs' surveillance





Communicating with care givers about the Malaria Vaccine

- Take time to interact with caregivers before, during, and after vaccination.
- Be respectful – Listen to caregivers' concerns and respond with empathy.
- “Triple A” communication (**Advise, Alert and Arrange**) helps to convey the correct messages on the vaccine as part of a malaria prevention strategy.
- Motivational interviewing can be used to understand reasons for delayed acceptance and to promote vaccine uptake. **Your recommendation matters!**
- The malaria vaccine is safe and reduces severe malaria
- 4 malaria vaccine doses provide the best protection
 - Specifically mention the 4th dose is given at [18] months of age
- Visit monthly to have their child
 - weighed and examined.
 - receive all needed vaccines and child health services
- Some common side effects include fever and injection site pain and swelling, but these are typically short in duration
 - Report to the nearest health facility should there be any concerns following vaccination
- Even after vaccination, a child can still become sick with malaria:
 - seek prompt diagnosis and treatment for a child with fever.
 - Continuous use of existing Malaria prevention services should be emphasized.
 - LLINs(every night,IRS,IPTp,LSM,SMC)



Recording and reporting Malaria Vaccine data.

- All existing routine immunization HMIS tools ,data sets and indicators are already updated to include the Malaria Vaccine;
 - The tools include:
 - The home based record.
 - Register.
 - Tally sheet monthly report
- In case of late vaccination tools to document children > 2 years will be catered for.
- Fill in the home-based record with the vaccines that have been administered .
- Children should begin vaccination/receive the 1st dose from 6 months of age and the 4th dose by 18 months.
- It is important that records utilized to:
 - Follow-up with children who have not returned for vaccinations: reminder cards, SMS/text, phone calls, community volunteers
 - Use enhanced methods to increase schedule awareness and coverage, such as announcements and linkages with other health services, particularly in the second year of life and beyond
- The DHIS-2 is already customized to capture Malaria Vaccine information/data.



Monitoring of adverse events following Immunization (AEFI):

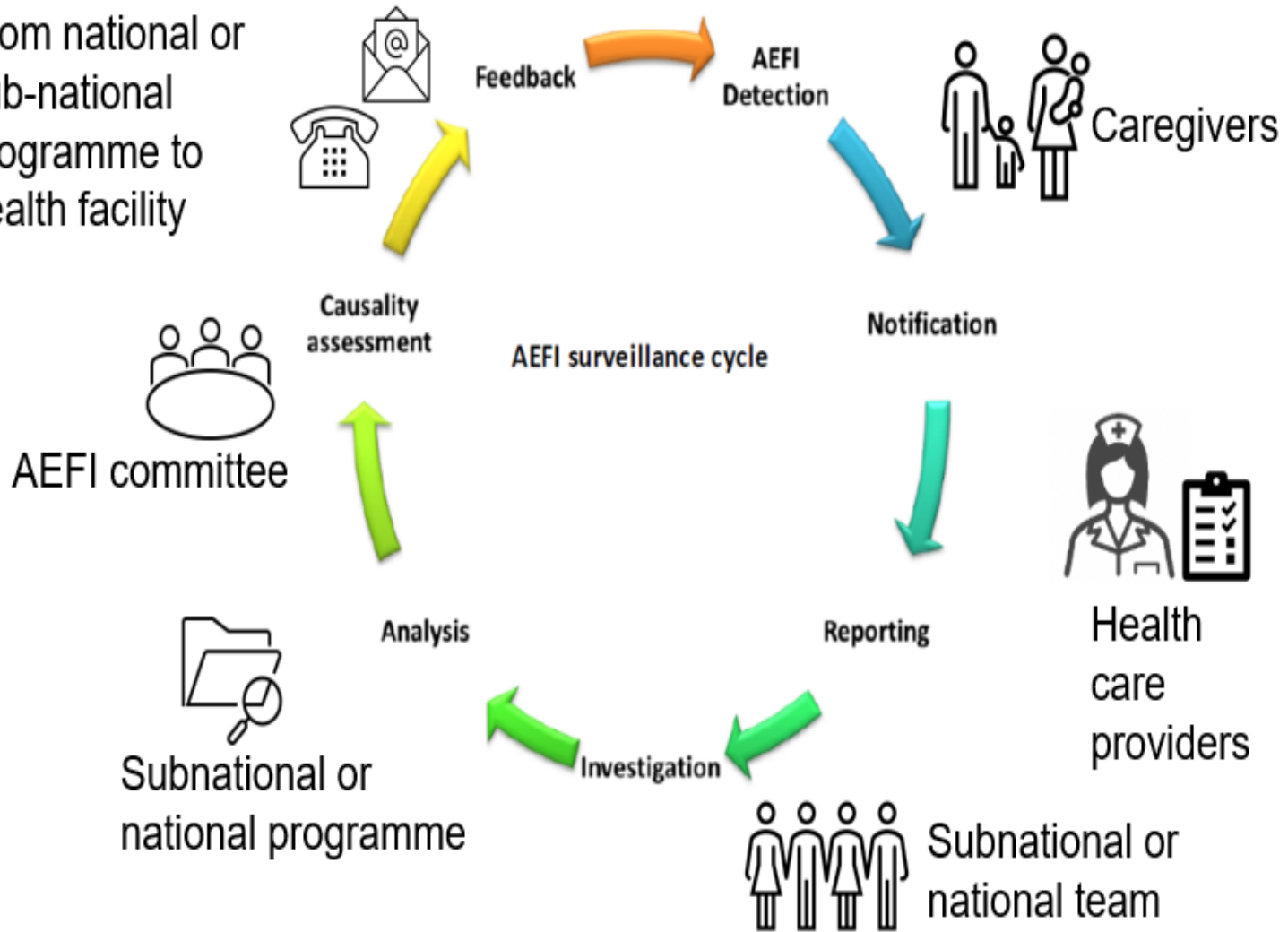
- ❑ **AEFI** : Untoward medical occurrence that follows immunization.
 - Does not necessarily have a causal relationship with the use of the vaccine or vaccine process
- ❑ **Note:** AEFIs (related to the vaccine or not) –
 - **Must be expected.**
 - Can happen independent of the health worker's action.
- ❑ They must be promptly & vigilantly investigated in order to maintain confidence in the immunization programme.
- ❑ The malaria vaccine is safe and well tolerated
 - **Commonly reported AEFI are:**
 - fever
 - irritability
 - pain and swelling at injection site**(these are typically short in duration)**
 - **An uncommon AEFI is febrile convulsions**
- ❑ Any adverse event should be reported immediately;
 - Reporter should only report and **NOT** assess causality
 - Complete the standard AEFI reporting form and send to supervisor immediately for information and decision making.
- ❑ Caregivers are to report to the nearest health facility should there be any concerns following vaccination.
 - **Even after vaccination, a child can still become sick with malaria: promptly seek diagnosis and treatment for a child with fever**
- ❑ As a vaccinator, do not speak to the media about an AEFI
 - **Refer to your supervisor who will know the identified spokespersons.**
 - **If you hear concerns or rumors – alert your supervisor .**





The AEFIs surveillance cycle and key players:

From national or sub-national programme to health facility





5

Malaria Vaccine Introduction plan-brief summary

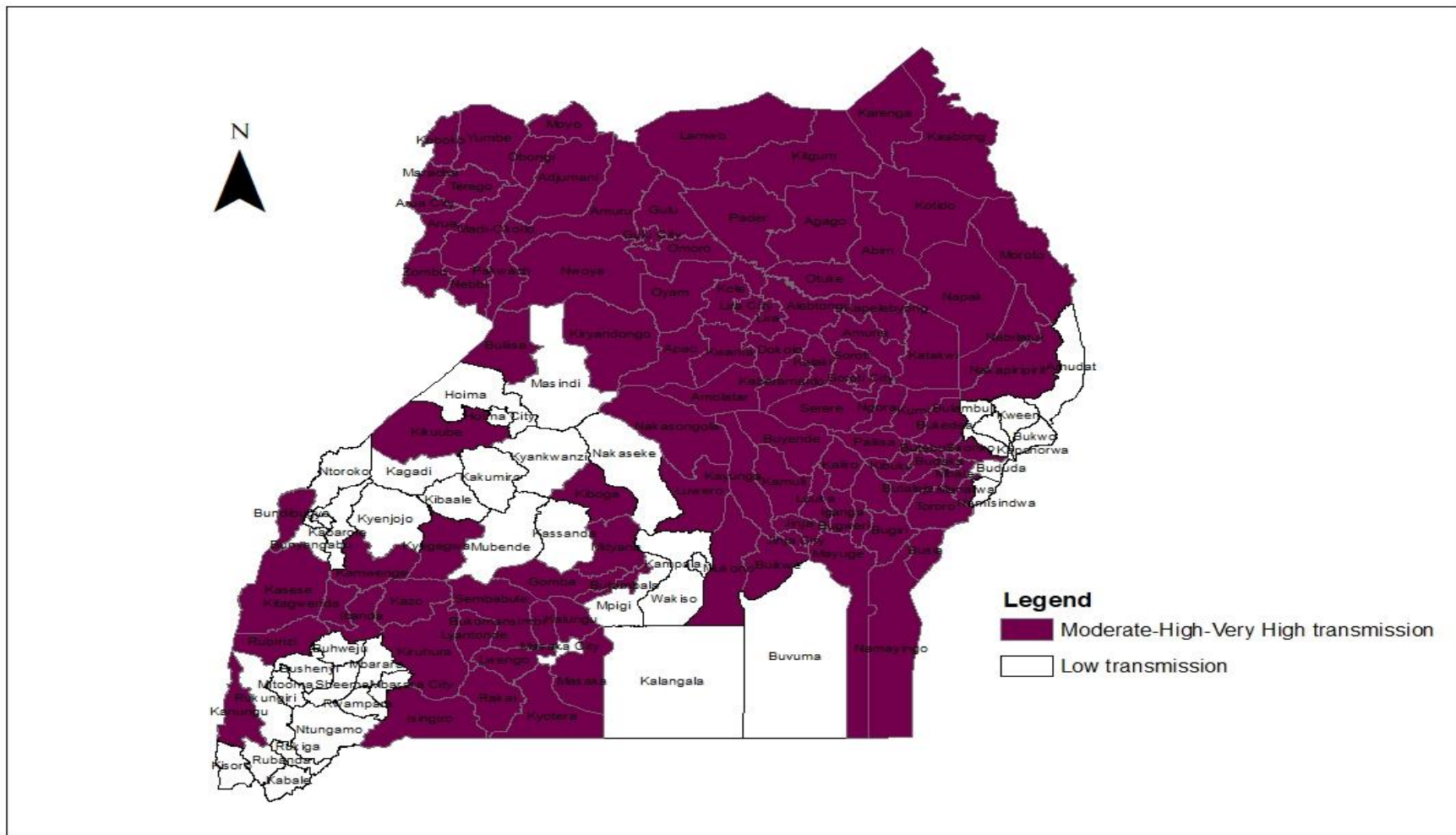
Malaria Vaccine Introduction Priority Districts

Country Vaccine need

Malaria Vaccine introduction plan timelines



Malaria Vaccine Introduction – subnational prioritization



As is the WHO guidance, vaccine introduction will prioritise the moderate to high transmission 105 districts based on 2022 DHIS2 Malaria Incidence data.





The targeted 14 regions and 105 Districts

Region	Number of Districts	Districts
West Nile	13	Arua, Arua City, Adjumani, Koboko, Madiokolo, Maracha, Moyo, Nebbi, Obongi, Pakwach Terego, Yumbe and Zombo
Acholi	09	Pader, Omoro, Nwoya, Lamwo, Kitgum, Gulu, Gulu City, Amuru and Agago
Lango	08	Oyam, Otuke, Lira City, Lira, Kwania, Kole, Amolatar and Alebtong
Karamoja	08	Moroto, Napak, Nakapiripiriti, Nabilatuk, Abim, Kotido, Karenga and Kaboongo
Teso	10	Soroti, Kumi, Bukedea, Ngora, Serere, Amuria, Kalaki, Katakwi, Kaberamaido and Kaperebyongo
Bugisu, Sebei and Bukedi	11	Tororo, Kibuku, Busia, Paliisa, Butebo, Butaleja, Budaka, Sironko, Mbale, Mbale-City, Manafwa,
Busoga	11	Jinja, Iganga, Kaliro Luuka, Mayuge, Bugiri, Bugweri, Namutumba, Kamuli, Buyende.
North central	06	Buikwe, Kayunga, Kiboga, Luwero, Mityana, Mukono and Nakasongola
South Central	09	Bukomansimbi, Butambala, Gomba, Kalungu, Lwengo, Lyantonde, Masaka, Rakai and Ssembabule
Bunyoro	03	Kiryandongo, Kikuube and Buliisa
Rwenzori	05	Kyegegwa, Kitagwenda, Kasese, Kamwenge and Bundibugyo
Ankole-Kigezi	06	Ibanda, Isingiro, Kazo, Kiruhura, Rubirizi and Kanungu





Vaccine needs at 100%

Year	Category	Total target population	Doses in Schedule	Vaccines Need
2024	Moderate to Very High*	1,327,091	4	3,640,407
2025	Moderate to Very High*	1,362,393	4	5,011,031
2026	Moderate to Very High*	1,397,814	4	6,124,830



Vaccine needs adjusted to the recommended 85%

Adjustment Percentage(%)	85%	85%
Year	2024	2025
Population in the target age cohort (#)	1,327,091	1,362,393
Population in scope(adjusted to the set percentage(85%)#	1,128,027	1,158,034
Final Vaccine allocation(with wastage and buffer)	3,002,008	4,122,799



MALARIA VACCINE INTRODUCTION PLAN -TIMELINES

Activity	Dec	Jan	Feb	Mar	April	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	April	May	Jun	
1 National Level Coordination meetings	On Track																			
2 Approval of scale up application									Started but not yet on track											
3 Develop & pretesting IEC materials							Started but not yet on track													
4 Communication, advocacy on media, social media, talk shows, press briefs							Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started	Not started
5 Orientation of CBOs, CSOs, journalists, FBOs, private sector and professional bodies to create demand, improve access and reduce missed opportunities								Not started												
6 Print and distribute training materials, IEC materials, HMIS tools, AEFI case investigation forms etc) by NMS									Started but not yet on track											
7 Develop training material, flip charts, and review of tools														Not started						
8 Funds receipt in the country													Not started							
9 Readiness assessment and verification of the cold chain inventory								Started but not yet on track												
10 Funds disbursement to district															Not started					
11 Distribution of vaccines and related logistics																Not started				
12 Conduct a cascade training of service providers and at national, regional and district level																Not started				
13 Distribution of logistics and cold chain maintenance to health facilities																Not started				
14 Mentorship and supervision by MOH and partners																	Not started			
15 National Launch																		Not started		
16 Implementation																			Not started	
17 Post introduction supportive supervision																				Not started
18 National stakeholders feedback meeting																				Not started

Colour code	Status
On Track	On Track
Started but not yet on track	Started but not yet on track
Not started	Not started





Key take home messages

- ❑ The vaccine is to complement other Malaria control interventions.
 - Consistent ,correct use of the following preventive measures should be maintained.
 - Use of Insecticide treated nets every night.
 - Seasonal Malaria Chemoprevention
 - Intermittent Preventive treatment in Pregnancy.
 - Indoor Residual Spraying
 - **Prompt diagnosis and treatment remains a must even among children that have received the vaccine,**
- ❑ The vaccine will be provided through routine immunization.
 - **Static clinics at the Health Facility & community outreaches.**
- ❑ **The vaccine is safe and effective**
 - **Already being Used in countries like Kenya, Malawi ,Ghana , Cameroon ,Burkina Faso etc**





End ,thank you and questions

