INTRODUCTION OF MALARIA VACCINE INTO NIGERIA's ROUTINE IMMUNIZATION SCHEDULE

TRAINING MANUAL FOR HEALTHCARE WORKERS

NOVEMBER 2024

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Acknowledgement

The development of this manual was a joint effort led by the National Primary Health Care Development Agency (NPHCDA) in collaboration with the National Malaria Elimination Program (NMEP) and partners. I want to congratulate the leadership of the Federal Ministry of Health, NPHCDA, and NMEP for their immense effort towards a successful introduction of the malaria vaccine into the routine immunization schedule. We acknowledge the contributions of the stakeholders at sub-national levels including the SPHCAs/Bs, SMoH, LGA teams, Health Care Workers, and the community.

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Dr Ahmed-Rufai Garba,

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Foreword

Malaria disease remains a significant public health issue globally, with Nigeria bearing the highest burden. In 2022, Nigeria accounted for 27% of global malaria cases and 31% of malaria deaths, primarily affecting vulnerable populations like children under five. Despite ongoing efforts using preventive tools such as insecticide-treated nets (ITNs) and indoor residual spraying (IRS), the disease continues to cause widespread morbidity and mortality.

The recent approval of the malaria vaccine marks a milestone in malaria control in Nigeria. This vaccine has shown high efficacy in reducing *Plasmodium falciparum* malaria in children, particularly in regions with moderate to high transmission. Integrating the malaria vaccine into Nigeria's routine immunization program will complement existing measures and is expected to significantly reduce malaria incidence and mortality.

The introduction of this vaccine will be carried out in phases, starting with two high-burden states; Bayelsa and Kebbi, before expanding nationwide. The phased approach ensures the vaccine reaches the most affected areas first while managing the supply effectively. Healthcare workers are key to the success of this roll-out and must be equipped with the knowledge and skills to implement the vaccination program efficiently.

This manual serves as a critical resource, offering comprehensive guidance on the malaria vaccine introduction in Nigeria. It is an essential tool for healthcare workers and stakeholders, providing instructions on vaccine administration, storage, and reporting. With their efforts, we can reduce malaria-related deaths and move closer to achieving global malaria elimination goals.

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XXII. Christian Health Association of Nigeria (CHAN)
XXIII. Africa Centres for Disease Control and Prevention

Acronyms and Abbreviations

ACSM	Advocacy, Communication, and Social Mobilization
AD	Auto Disable
AEFI	Adverse Events Following Immunization
CBO	Community Based Organization
CCE	Cold Chain Equipment
CCO	Cold Chain Officer
CHIPS	Community Health Influencers, Promoters, and Services
CPR	Cardiopulmonary Resuscitation
CSO	Civil Society Organization
DHIS	District Health Information System
DIP	Daily Implementation Plan
DRIMMAC	Detection, Reporting, Investigation, Monitoring, Management, Analysis, and Communication
DSNO	Disease Surveillance and Notification Officer
EPI	Expanded Programme on Immunization
FBO	Faith Based Organization
FCT	Federal Capital Territory
FP	Focal Person
GIS	Geographic Information System
HAPPI	HPV Vaccine Acceleration Program Partners Initiative
HCW	Health Care Worker
HF	Health Facility
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HW	Health Worker
IDP	Internally Displaced Person
IDSR	Integrated Disease Surveillance and Response
IEC	Information, Education, and Communication
IEV	Identify Enumerate and Vaccinate
iSC	Immunization Supply Chain
IV	Intravenous
LGA	Local Government Area
LIO	Local Immunization Officer
LMIS	Logistics Management Information System
MAC	Multi-Age Cohort
MDVP	Multi Dose Vial Policy
MPAG	Malaria Policy and Advisory Group
NRIWG	National Routine Immunization Working Group
NHMIS	National Health Management Information System

NPHCDA	National Primary Health Development Agency
NPSIA	Non-Polio Supplementary Immunization Activity
NSIPSS	Nigeria Strategy on Immunization and Primary Health Care System Strengthening
NTOT	National Training of Trainers
PHC	Primary Health Care
PM	Project Manager
PPM	Planned Preventive Maintenance
PQS	Performance, Quality, and Safety
REW	Reach Every Ward
RI	Routine Immunization
RIO	Routine Immunization Officer
SAGE	Strategic Advisory Group of Experts on Immunization
SBC	Social and Behavior Change
SC	Supply Chain
SDG	Sustainable Development Goal
SDSNO	State Disease Surveillance and Notification Officer
SERICC	State Emergency Routine Immunization Coordination Centre
SIA	Supplemental Immunization Activities
SIO	State Immunization Officer
STF	State Technical Facilitator
STI	Sexually Transmitted Infection
TD	Tetanus-Diphtheria
TFP	Temporary Fixed Post
TM	Trademark
TV	Television
TWG	Technical Working Group
UNICEF	United Nations Children Fund
VCM	Village Community Mobilizer
VIA	Visual Inspection with Acetic Acid
VLP	Virus-like Particles
VM	Vaccine Management
VMA	Vaccine Management Assessment
VVM	Vaccine Vial Monitor
VWR	Vaccine Wastage Rate
WFP	Ward Focal Person
WHO	World Health Organization

Introduction

Malaria disease remains a significant public health challenge globally, with countries in Sub-Saharan Africa bearing the highest toll. It is caused by *Plasmodium* parasites and transmitted through the bites of infected female *Anopheles* mosquitoes, malaria has a substantial impact on morbidity and mortality worldwide.

In 2022, WHO estimated that there were 249 million cases of malaria globally, with about 619,000 deaths. The vast majority of these cases (94%) and deaths (95%) occurred in the WHO African Region, underscoring the heavy burden of the disease on the continent. Nigeria alone accounted for approximately 27% of global malaria cases and 31% of malaria deaths, making it the country with the highest burden of malaria worldwide (WHO WMR ,2023).

In Nigeria, malaria disease is a major public health concern, with an estimated 67 million cases and 188 thousand deaths due to the disease in 2022 (WHO WMR 2023). Malaria is a complex disease with multiple causes rooted in the interaction between the *Plasmodium* parasite and its transmission vectors, primarily the *Anopheles* mosquitoes.

Malaria disease is transmitted through the bite of female *Anopheles* mosquitoes, which are most active during night-time. The risk of transmission is particularly high in areas where the mosquito population is dense, and where preventive measures like insecticide-treated nets (ITNs), intermittent preventive treatment, perennial malaria chemoprevention, seasonal malaria chemoprevention, post discharge malaria chemoprevention, and indoor residual spraying (IRS) are less accessible. Tropical and subtropical regions, particularly sub-Saharan Africa, are more prone to high malaria disease transmission due to favorable climatic conditions for the mosquitoes' breeding and survival.

Certain groups are more vulnerable to severe malaria and its complications, including young children, pregnant women, and people with compromised immunity, such as those living with HIV/AIDS. The incubation period of malaria typically ranges from 7 to 30 days, depending on the specie of *Plasmodium* involved. However, delayed onset can occur, especially in cases caused by *Plasmodium vivax* and *Plasmodium ovale*, which can remain dormant in the liver for months before becoming symptomatic (WHO ,2023)

Almost all malaria disease related deaths are caused by *Plasmodium falciparum (P.falciparum)* and most occur in African children under 5 years of age, with the highest burden concentrated in those under 3 years of age. Older children greater than five years and Adults who have lived in areas with high malaria transmission since childhood and remain resident in such areas are generally not at risk of death from malaria, as they usually have partial immunity acquired as a result of repeated infections in childhood (World malaria report 2023). However, in Nigeria, data from malaria survey and DHIS2 is demonstrating an

increasing burden of malaria in children under 5, despite the aggregate decline in malaria burden as a result of multiple interventions.

The recent approval for use of the malaria vaccine in Nigeria for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO represents a significant milestone in the fight against malaria disease. Furthermore, the NGITAG has reviewed the evidence for the malaria vaccine and has approved it for use in Nigeria. This vaccine, which has shown efficacy in reducing malaria cases among children in high-transmission settings, complements existing preventive measures such as ITNs, IRS, Larval Source Management (LSM) and antimalarial medications. Integrating the malaria vaccine into Nigeria's routine immunization schedule is expected to substantially reduce the malaria disease burden, especially among children under five, who account for the majority of malaria disease associated deaths (WHO Website).

At least 14 African countries have introduced the Malaria vaccines (RTS,S and R21), and the latest among these countries is Chad, which introduced it in October 2024, with safe and promising results. In view of this development, the New Vaccines Strategic Task Team (NVSTT), following the successful approval of the country's application, has been mandated to introduce this vaccine into the routine immunization system in a phased approach, starting with two states with the highest burden of the disease and compatibility with the programmatic needs in the North (Kebbi) and South (Bayelsa) of the country.

Rationale for Introducing the Malaria Vaccine in Nigeria

Given Nigeria's high malaria burden, the introduction of the malaria vaccine is a critical intervention. The vaccine's incorporation into the routine immunization program is expected to complement the country's other malaria control interventions in a scalable manner. The vaccine is particularly important in rural and under-served areas where access to other preventive measures may be limited and environmental factors are favorable for the vectors. By reducing the incidence of malaria, the vaccine will also alleviate the strain on the healthcare system and contribute to broader public health gains.

Objective for the Introduction of the Malaria Vaccine in Nigeria

- To complement existing Malaria control intervention
- To reduce malaria incidence and under 5 mortality and align the country to WHO global technical strategy target of reducing case incidence and mortality by at least 90% by 2030.

Introduction Strategy

The introduction of the malaria vaccine into Nigeria's routine immunization system is strategically planned to occur in three distinct phases. This phased approach is designed to address the malaria burden effectively and manage vaccine distribution based on availability.

Phase 1: Bayelsa and Kebbi States

The first phase targets all Local Government Areas (LGAs) in Bayelsa (8) and Kebbi (21) states with a combined target population of 231,949 children under the age of 2 years (84% of total eligible population). These states were selected based on specific criteria:

- ***High Malaria Prevalence:*** Both Bayelsa and Kebbi states have a significant malaria burden, with at least 40-50% of their LGAs affected. These states are located in high to moderate malaria transmission areas, with a Plasmodium falciparum parasite rate (PfPR) exceeding 10% in children under five years old.
- ***Geographic Representation:*** Bayelsa and Kebbi represent different geographic zones, providing a diverse range of settings for the vaccine rollout. This ensures the vaccine's effectiveness across varied environmental and demographic conditions.
- ***Vaccine Supply Alignment:*** The initial delivery tranche of 1 million doses of the vaccine to Nigeria is sufficient to cover the target population in these two states, ensuring that the limited vaccine supply is used efficiently.
- ***GAVI Support Eligibility:*** Both states meet the criteria for support under GAVI's guidelines, focusing on areas with moderate to high transmission.

During this phase and subsequent phases, the target population will be children aged 5-11 months as part of an expanded eligible age group for dose 1. These children will receive four doses of the vaccine: at 5, 6, 7, and 15 months. The timing of the fourth dose aligns with WHO recommendations which stipulate that there should be at least a 6-month duration between the 3rd and 4th dose to prolong the duration of protection. Unlike previous vaccine introductions that relied on campaign-style mass immunization, the vaccine will be administered at regular service delivery points within primary health care facilities, utilizing the fixed, outreach and mobile delivery strategies. A robust ACSM strategy would be deployed to foster caregivers' cooperation with health facility service providers, ensuring consistent access to the vaccine and reducing missed opportunities for immunization.

Phase 2: Expansion to 19 states + FCT

Following introduction in the two highest burden states, malaria vaccine introduction will focus on the next 19 malaria high burden states.

Phase 3: Nationwide Rollout involving remaining 15 States

Rationale for the Phased Introduction

The phased introduction strategy is designed to maximize the impact of the malaria vaccine. By focusing initially on states with the highest malaria burden and ensuring geographic representation, Nigeria can effectively address the most pressing public health needs while preparing for broader nationwide implementation.

Additionally, by integrating the vaccine into routine immunization systems at primary health care facilities, the strategy aims to achieve sustainable, long-term malaria control, with the potential for high coverage and reduced mortality in vulnerable populations. This phased approach will not only optimize the use of available funds but also enable the country to learn lessons in phase 1 that will be applied in the scale up to other states.

The strategic introduction of the malaria vaccine in Nigeria represents a significant advancement in the fight against malaria. By targeting high-burden areas first and ensuring that the vaccine is readily accessible through routine immunization systems, Nigeria is poised to make substantial progress towards reducing malaria incidence and mortality. This phased approach will not only optimize the use of available resources but also support the country's efforts to align with global malaria elimination goals.

1. MODULE 1: MALARIA DISEASE AND PREVENTION

Learning objectives

At the end of this section, participants will be able to:

- Understand the epidemiology of malaria in Nigeria
- Identify the causes and transmission of malaria
- Recognize symptoms and diagnostic methods for malaria
- Apply knowledge of malaria treatment and management
- Explore malaria prevention strategies

Nigeria has the highest burden of malaria globally, accounting for nearly 27% and 31% (WHO WMR ,2023) of the global cases and death. Prevalence of malaria in Nigeria declined from 27% (MIS 2015) to22% (MIS 2021). The risk of transmission exists throughout the country, all year round with seasonal variation. However, the prevalence of malaria is highest in the north-western region of the country.

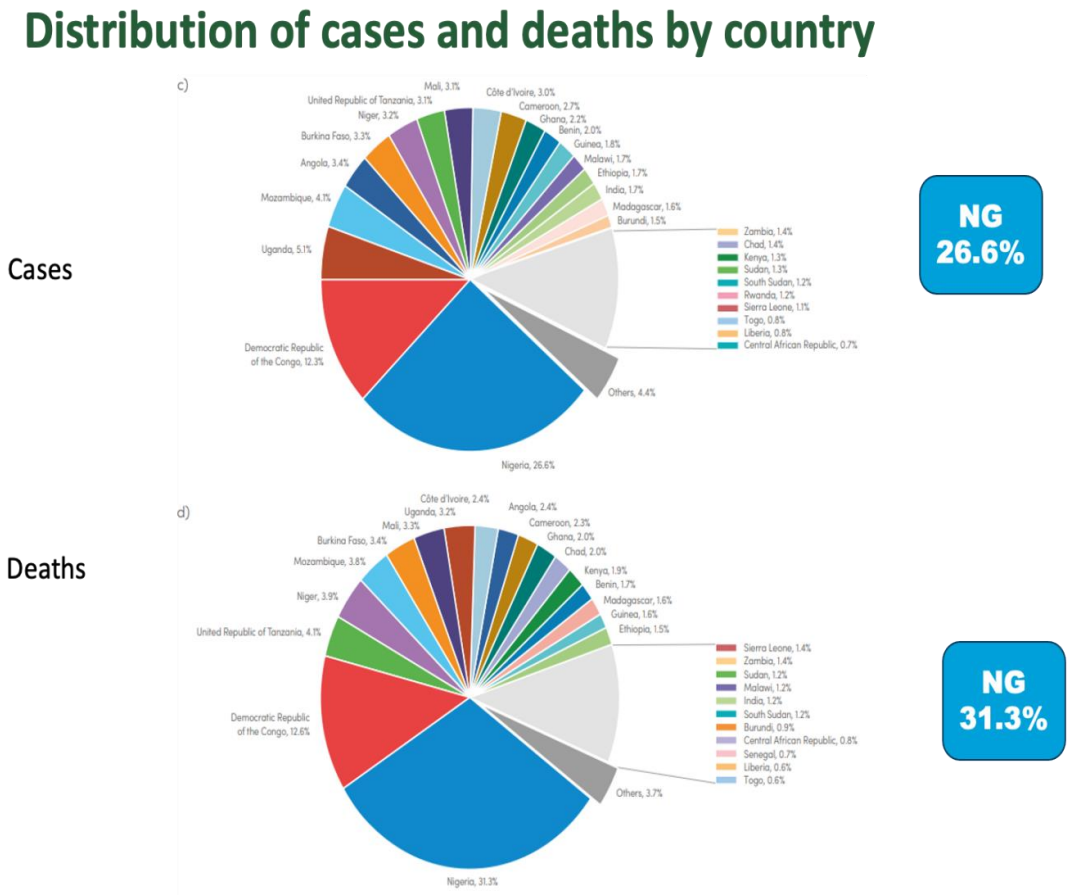


Figure 1: Distribution of Malaria Cases by Country in The Sub-Saharan Region

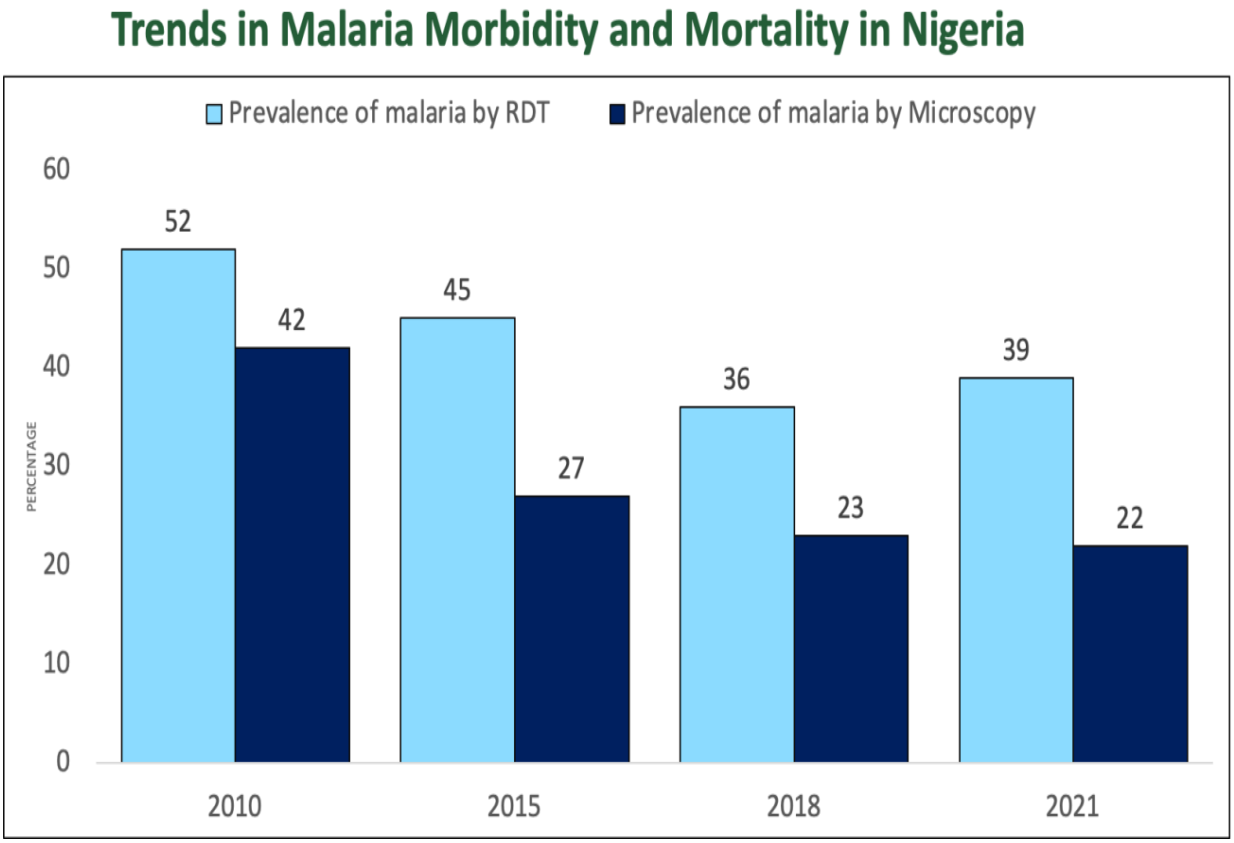


Figure 2: Malaria Morbidity and Mortality in Nigeria

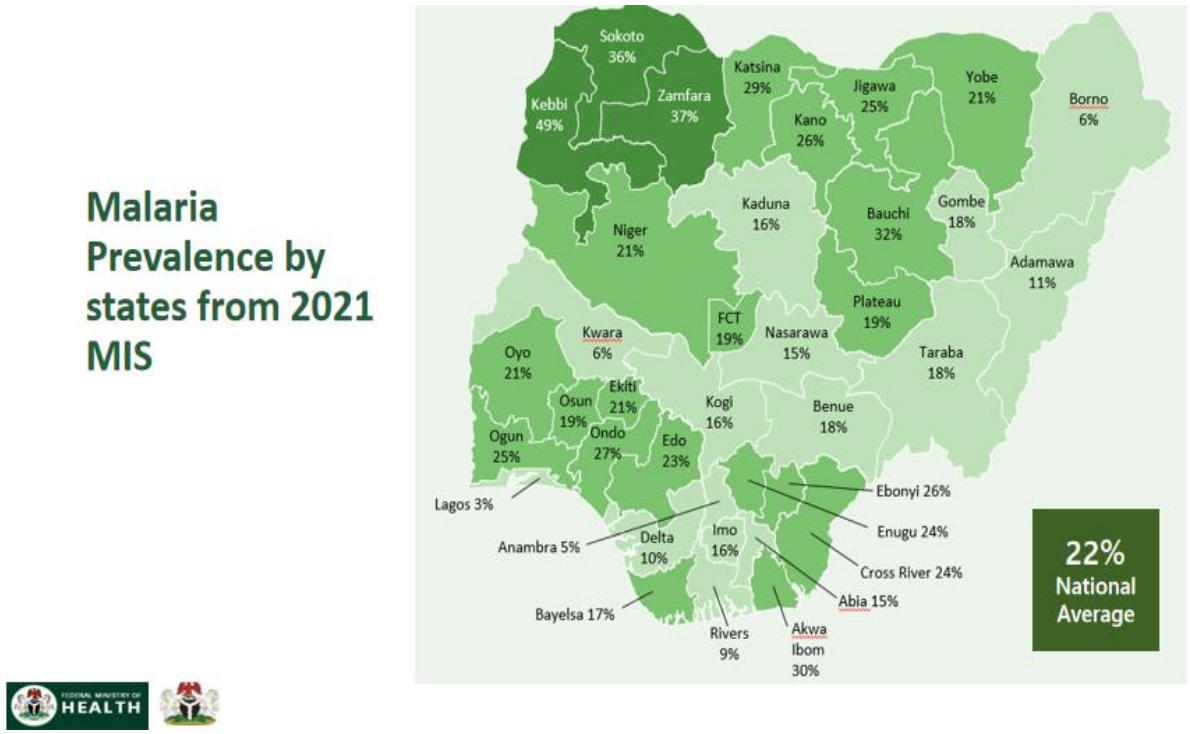


Figure 3: Malaria Prevalence by States from 2021 MIS

1.1 Causes of Malaria

Malaria is a parasitic infectious disease caused by parasites of the genus plasmodium and is transmitted mostly by the bite of an infected female *Anopheles* mosquito. It is characterized by recurrent symptoms of chills, fever and generalized body pain. The five Plasmodium species that infect humans are *P. falciparum, P. vivax, P. ovale, P. malariae* and *P. knowlesi*.

Plasmodium falciparum is found worldwide, mainly in tropical and subtropical areas. It accounts for about 97% of uncomplicated malaria in Nigeria and is the main species that causes severe, potentially fatal malaria.

1.2 The Life Cycle of Malaria Parasite

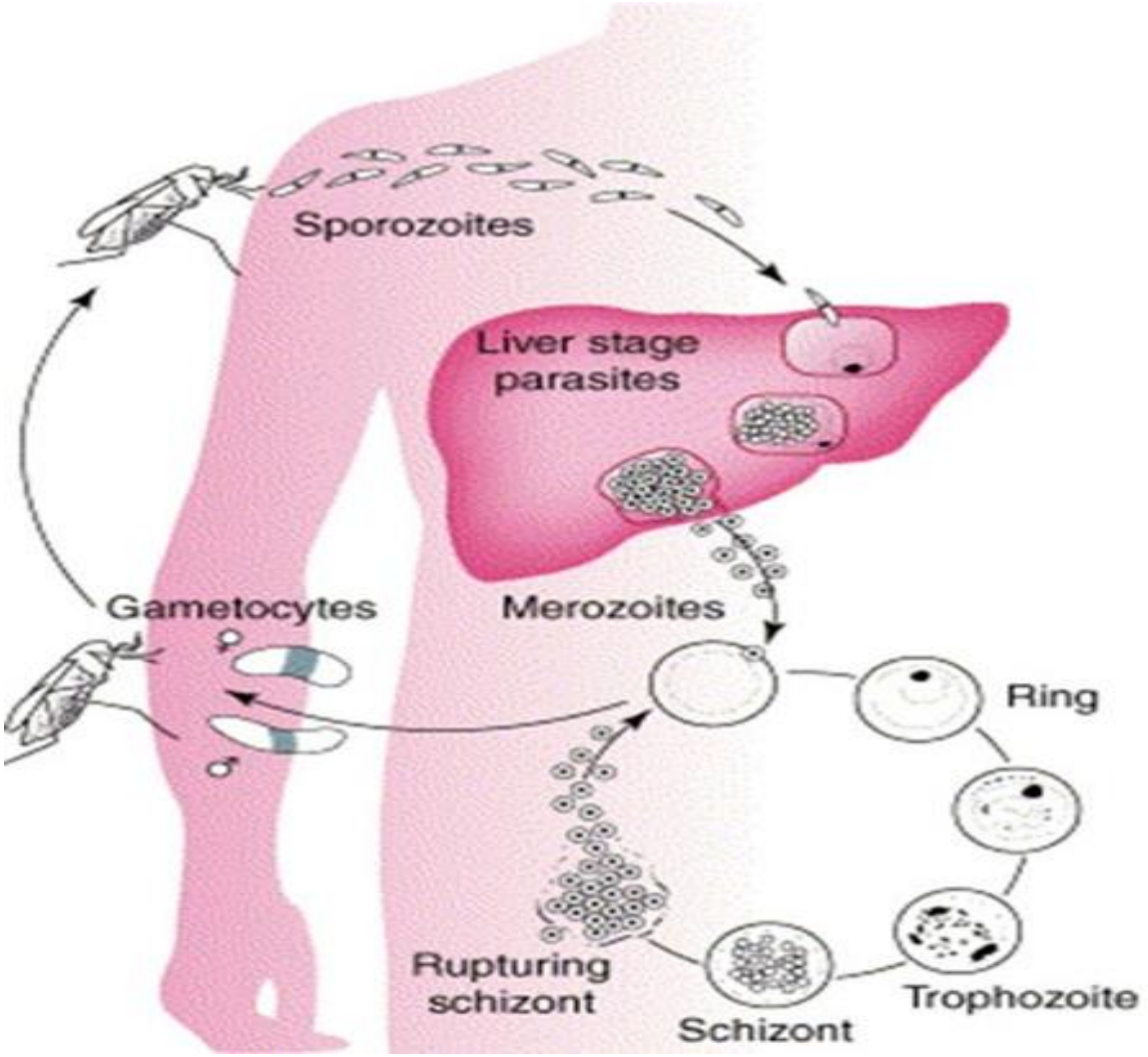


Figure 4: The life cycle of the malaria Plasmodium parasites illustrating the parts of the cycle that take place in the human body.

While taking a blood meal the female mosquito injects saliva into the person's blood vessels to stop the blood from clotting to make it easier to suck in. If she is infected with malaria parasites, she injects sporozoites into the person's blood. On the other hand, if the person is infected, when the mosquito draws up the blood it will also take up malaria parasites as gametocytes, the sexual forms of the malaria parasite. The malaria parasites which have been sucked up from the blood as gametocytes develop inside the mosquito to become sporozoites in the salivary glands. At this stage the female Anopheles mosquito becomes infective to the next person it feeds on.

Once the sporozoites get into a person, they undergo various stages of development to cause disease. Specifically, the sporozoites travel rapidly to the liver where they enter the liver cells and divide rapidly forming merozoites.

When a liver cell is full of merozoites it bursts and discharges the merozoites into the blood where they rapidly enter the red blood cells. In the red blood cells, the merozoites grow and rapidly divide again until the red blood cell bursts to release them into the blood stream to attack other red blood cells. This causes the person to experience symptoms such as fever, sweating and shivering.

Some merozoites however change into the male and female forms of the parasite called gametocytes which are taken in by the mosquito when she sucks the blood. The gametocytes enter the mosquito's stomach and mate to form eggs which then in turn become sporozoites and move to the mosquitoes' salivary glands where they are ready to be injected into another person. The transmission cycle is illustrated in Figure 4 above. A good knowledge of the life cycle helps to treat malaria effectively and implement appropriate strategies for control.

1.3 Mode of Transmission

There are 3 main modes of transmission:

1. Bite of an infected female Anopheles mosquito. This is the primary mode of transmission
2. Accidental inoculation through blood transfusions and needle stick injuries
3. Congenital transmission of malaria from mother to child

The female Anopheles mosquito is the vector of malaria parasites. The most efficient species which predominate in Nigeria are *A. gambiae, A. arabiensis, A. funestus* and *A. melas*. Other vectors common in Asian countries includes *A. Stephensi, A. minimus,* and *A. dirus.*

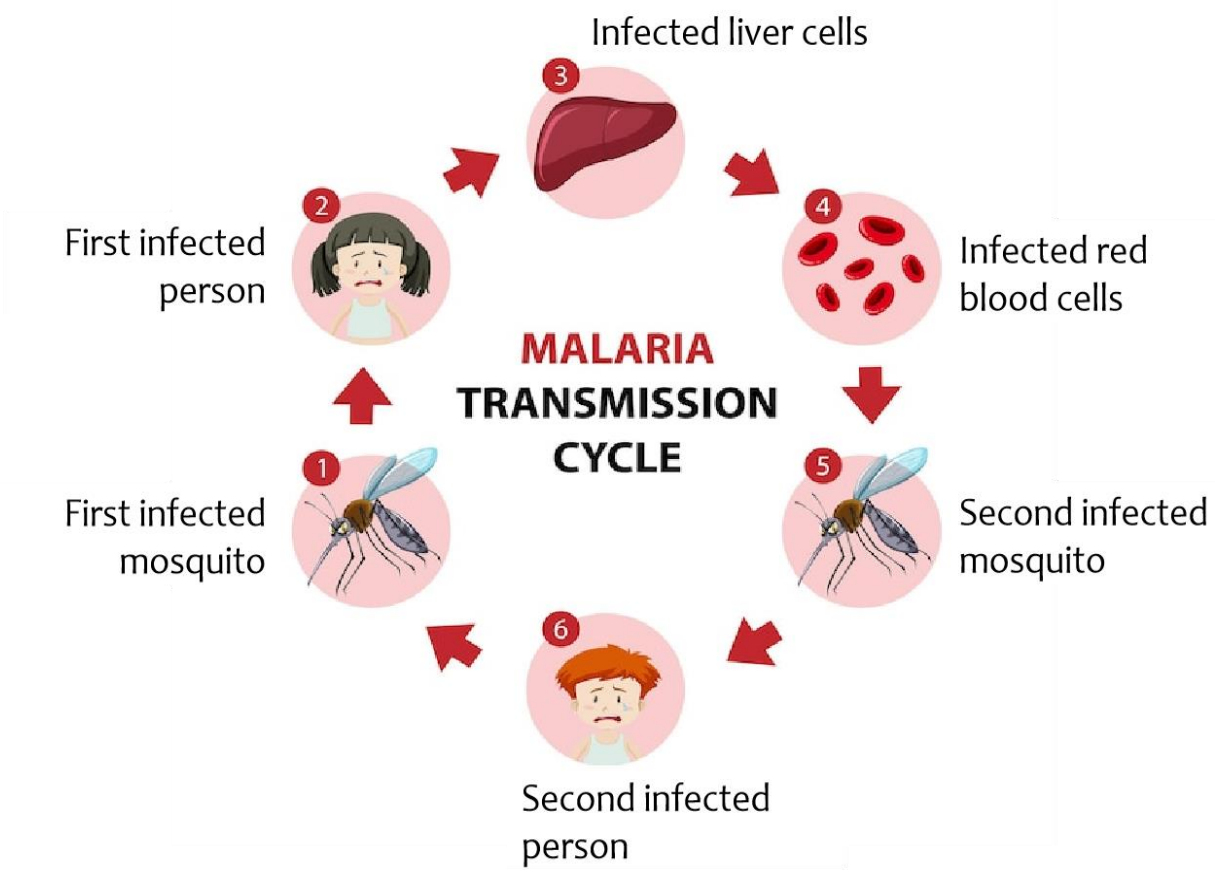


Figure 5: Malaria Transmission cycle

1.4 Classification of Malaria

Malaria manifests in two forms namely uncomplicated malaria and severe malaria.

- **Uncomplicated malaria:** A patient with a fever or history of fever in the last 24 hours who has a positive RDT or blood smear test and no symptoms of severe illness.
- **Severe malaria:** Severe falciparum malaria is defined as one or more of the following (refer to section 1.5.2), occurring in the absence of an identified alternative cause, and in the presence of *P. falciparum* asexual parasitemia.

1.5 Symptoms and Diagnosis of Malaria

Understanding the symptoms and accurate diagnosis of malaria is crucial for timely treatment and preventing severe complications.

Figure 6: Populations Susceptible to malaria complications

The symptoms of malaria are non-specific. Malaria can be suspected with the following features of uncomplicated and severe malaria listed below:

1.5.1 Specific Features of Uncomplicated Malaria Disease

- Fever
- Febrile paroxysms
- Chills: Subjective feeling of “being cold” despite normal environmental temperature
- Rigors: Shivering with involuntary muscle contractions causing shaking of the body
- Headaches and other body aches
- Other symptoms are Vomiting, Joint pains, Weakness, Cough, and nausea.

1.5.2 Features of Severe Malaria Disease

- Impaired consciousness
- Prostration
- Multiple convulsions
- Acidosis
- Hypoglycaemia
- Severe malarial anaemia

- Acute kidney injury
- Jaundice
- Pulmonary oedema
- Significant abnormal bleeding
- Circulatory collapse
- Hyperparasitaemia

Other infections can have similar presentation, in such situations the clinician should ask about other illnesses such as:

- Contact with someone in isolation, or someone from an area with an epidemic
- History of travel to or from an area with an epidemic
- Cough or respiratory distress
- Diarrhoea
- Ear pain
- Skin rashes in the last three months.

For Physical examination, the clinician should;

- Check for fever; body temperature ≥37.5°C
- Pallor – Especially in children and pregnant women
- Examine for hepatosplenomegaly
- Examine for features of possible severe disease

Prompt and accurate diagnosis of malaria is part of effective disease management and will, if implemented effectively, help to reduce unnecessary use of antimalarials. It is important to note that clinical diagnosis alone will result in over-diagnosis of malaria and inappropriate treatment of non-malarial febrile illnesses, hence, parasitological confirmation is required. Thus, clinical criteria may be applied for the empiric diagnosis of malaria, but a parasite-based test is the basis for confirming the diagnosis and instituting treatment.

1.5.2.1 Criteria for an initial Clinical diagnosis

The signs and symptoms of malaria are non-specific. Where the features described above are present, the health worker should make an initial clinical diagnosis of suspected malaria. A parasitological test should be conducted to confirm a diagnosis of uncomplicated malaria. **Based on the National Malaria Policy, all forms of malaria treatment that are not based on parasitological diagnosis are not accepted. In all situations, malaria treatment should be based on a positive parasitological diagnosis.**

There are two ways to confirm a clinical diagnosis of malaria: microscopy and RDTs. **Microscopy** done on a blood smear can be used to identify the presence of malaria parasites, the type of plasmodium species and the number of parasites present.

Malaria RDTs are single use tests, normally in a cassette format, that provides a simple and reliable method to test for the presence of malaria parasites in a blood sample.

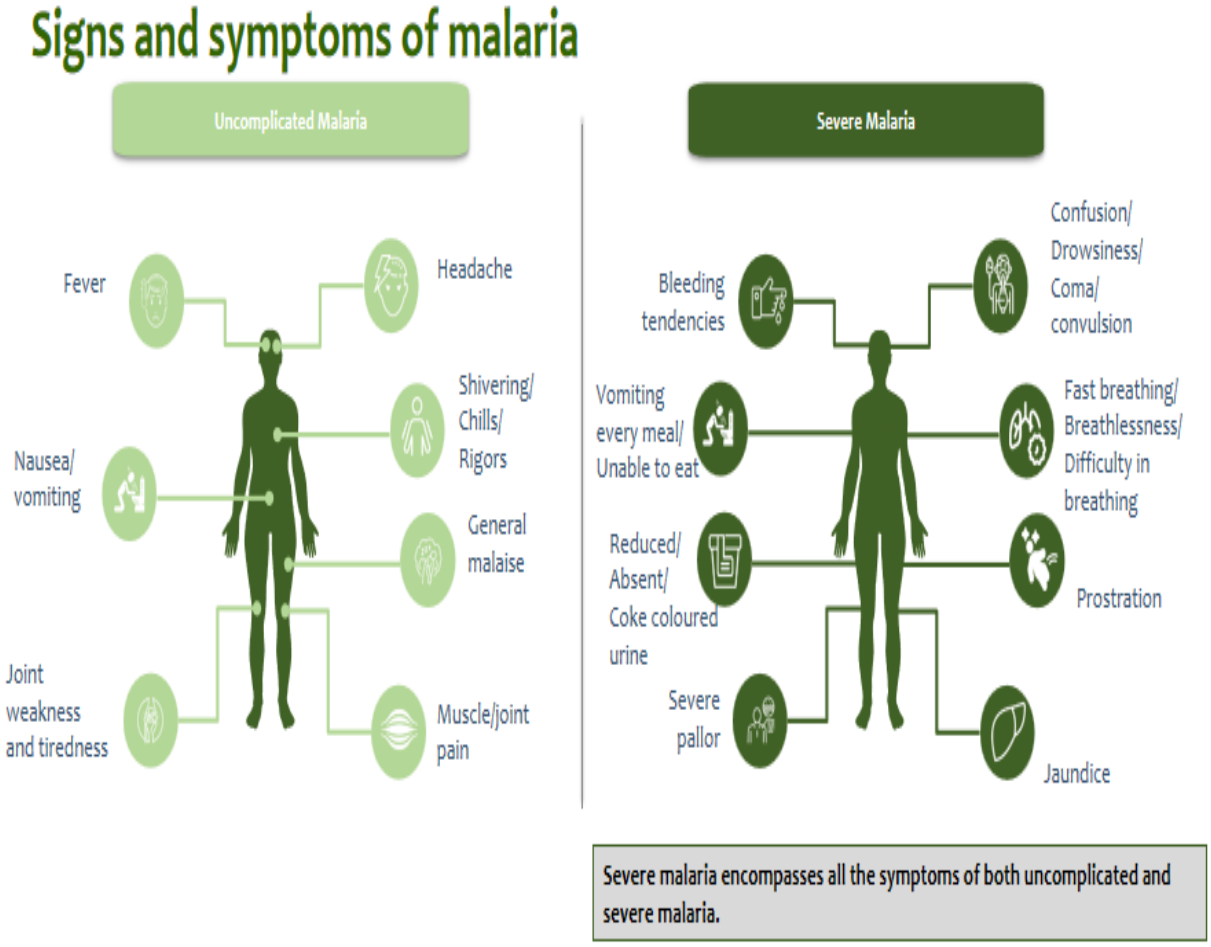


Figure 7: Signs and symptoms in the diagnosis of malaria

1.6 Treatment of Uncomplicated Malaria and Pre-referral Treatment of Severe Malaria

The objectives of prompt and effective malaria treatment are to:

- Cure the disease and eliminate the parasites from the body
- Prevent progression to severe disease or death
- Prevent transmission to others
- Prevent the parasites developing resistance to the malaria treatment
- Minimize adverse drug reactions.

The National Guidelines for diagnosis and treatment of malaria contains information on nationally recommended treatment that should be given for malaria. The current guidelines

recommend Artemisinin-based Combination Therapy (ACT) as the treatment for uncomplicated malaria. Artemether + Lumefantrine as a fixed dose combination (FDC) can be given twice a day for three consecutive days.

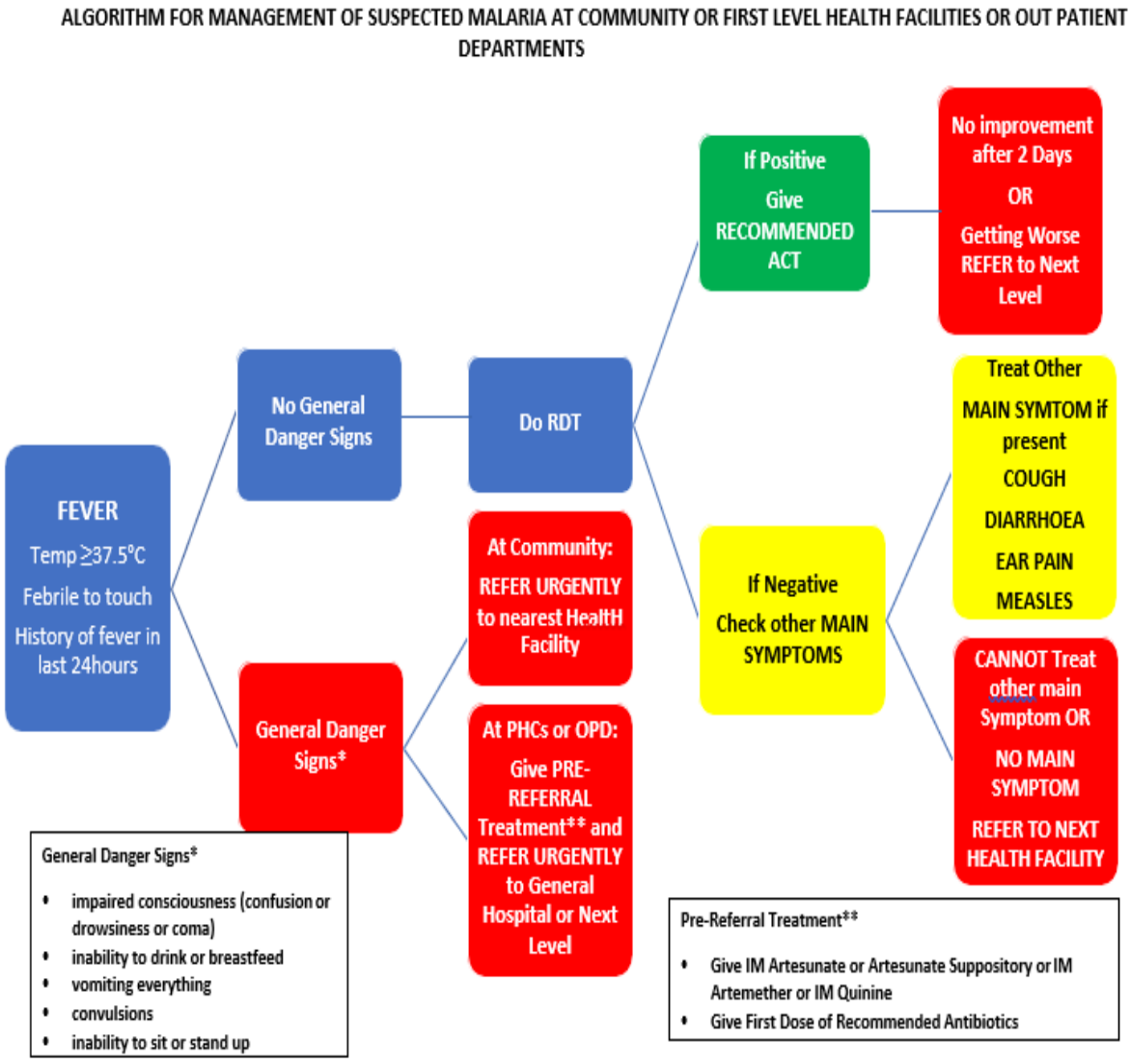


Figure 8: Algorithm for the Management of Suspected Malaria Cases

1.6.1 Alternate Medicines

Artesunate-Amodiaquine: Given once daily for three (3) consecutive days

Dihydroartemisinin-Piperaquine: Given once daily for three (3) consecutive days

Pyronaridine- Artesunate: Given once daily for three (3) consecutive days.

1.6.2 Treatment of severe malaria

All cases of severe malaria must be referred to the Secondary Level Health Care facility immediately after giving Pre-referral Treatment. A referral letter describing the symptoms, signs and treatment should be given to accompany the patient to the referral hospital.

Pre-referral treatment: In order of preference

Artesunate Injection: IM artesunate 3.0 mg/kg for children less than 20kg or 2.4 mg/kg for persons above 20kg as a single dose. Alternatives in order of preference are Rectal Artesunate, IM Artemether and IM Quinine

1.7 Prevention of Malaria

All malaria control interventions provide partial protection. Vaccinated children should continue with other preventive measures, such as sleeping under insecticide-treated nets throughout every night. The following are strategies deployed for malaria prevention;

1. Four doses of the malaria vaccine
2. Vector control,
3. Chemoprevention,
4. Environmental management.

1.7.1 Vector Control Measures

Vector control is the cornerstone of malaria prevention, targeting the *Anopheles* mosquitoes that transmit the disease. It refers to the methods used to prevent or reduce the spread of malaria by controlling the mosquitoes that transmit the disease. By reducing mosquito populations and preventing mosquito bites, the risk of malaria transmission can be significantly lowered.

1.7.1.1 Insecticide-Treated Bed Nets (ITNs)

Insecticide-treated bed nets (ITNs) are one of the most effective and widely used methods for preventing malaria. These nets are treated with insecticides that kill or repel mosquitoes, providing a physical and chemical barrier against mosquito bites while people sleep. Sleeping under an ITN can reduce the risk of malaria transmission by up to 50% and reduce child mortality by 20%.

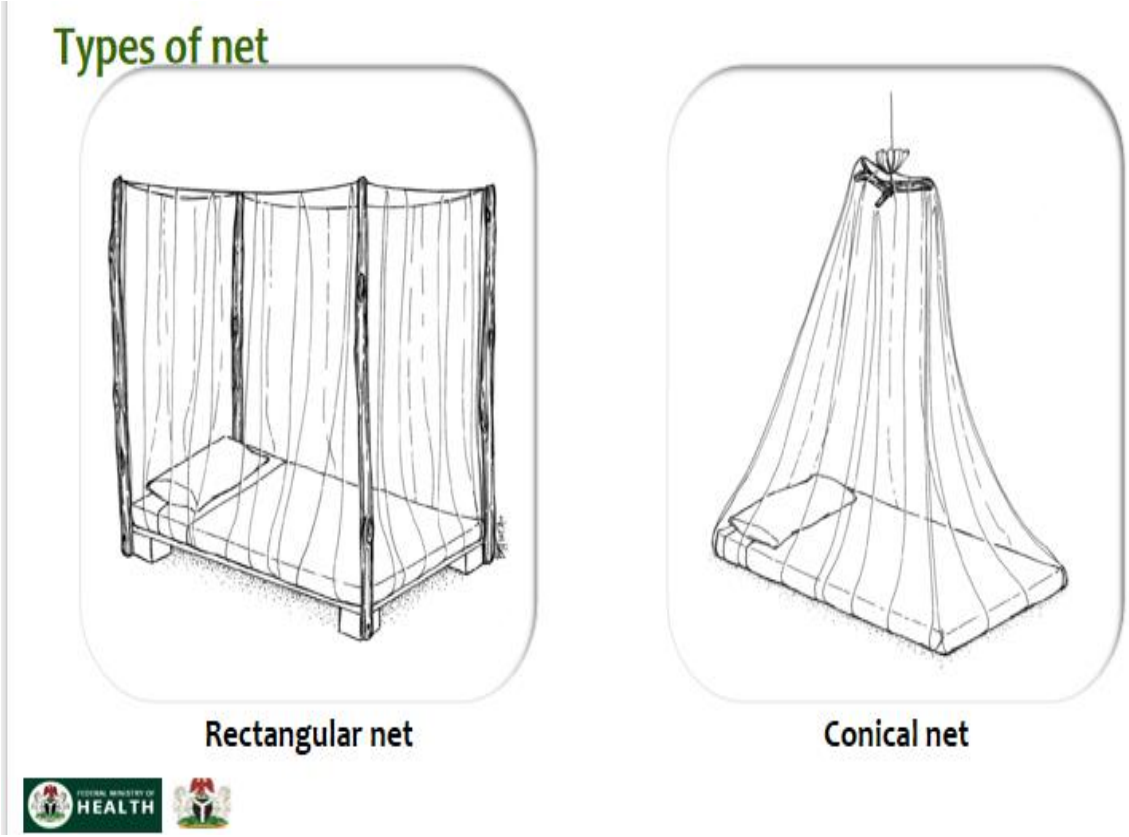


Figure 9: Types of ITNs

1.7.1.2 Indoor Residual Spraying (IRS)

Indoor residual spraying (IRS) involves applying insecticides to the walls and ceilings of homes, where mosquitoes are likely to rest. The insecticides used in IRS are long-lasting and can kill mosquitoes that come into contact with treated surfaces for several months.

1.7.2 Chemoprevention

Chemoprevention involves the use of antimalarial drugs to prevent malaria infection, particularly in high-risk groups such as travelers, pregnant women, and young children.

1.7.2.1 Intermittent Preventive Treatment in Pregnancy (IPTp)

Intermittent Preventive Treatment in pregnancy (IPTp) is used to prevent pregnant women from suffering from malaria. It is based on the assumption that pregnant women living in areas of high malaria transmission have malaria parasites in their blood or placenta, whether or not they have symptoms of malaria. Giving pregnant women IPTp reduces the chances that their baby will suffer the effects of malaria. It also reduces the chances that they will end up with maternal anemia or malaria.

IPTp with Sulphadoxine/Pyrimethamine (medicines in the form of tablets) is given at antenatal care (ANC) facilities or, sometimes, by a trained Community Caregiver. When a

pregnant woman takes IPTp she reduces her chances of giving birth to a small baby (Low Birth Weight), having low blood (anaemia), miscarriage and increases her chances of having a normal healthy delivery.

1.7.2.2 Seasonal Malaria Chemoprevention (SMC)

SMC is the intermittent administration of full treatment courses of antimalarial medicines during the high malaria transmission season to prevent malaria.In Nigeria SMC consists of the administration of four - five monthly courses of Sulphadoxine Pyrimethamine and Amodiaquine (SPAQ), to children between 3 and 59 months during the rainy season.

The objective of SMC is to maintain therapeutic antimalarial medicine concentrations in the blood throughout the period of greatest malarial risk. There are two child dose ranges of SPAQ:

- Infant dose for 3 to 11 months: SP 250mg/12.5 mg and AQ 75mg
- Child dose for 12 to 59 months: SP 500mg/25 mg and AQ150 mg

1.7.2.2.1 Benefits Of SMC

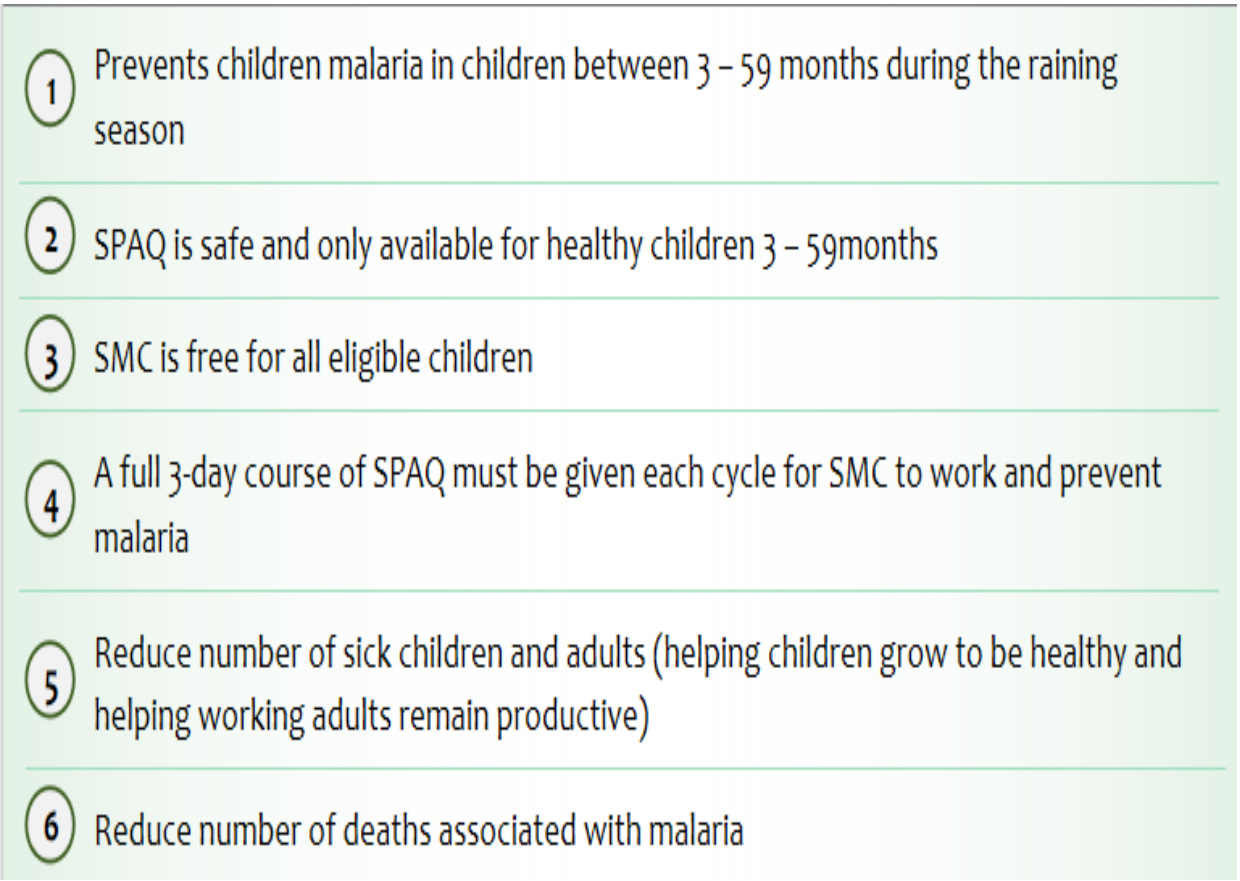


Figure 10: Benefit of Seasonal Malaria Chemoprevention.

In regions experiencing highly seasonal malaria transmission, it is advisable to schedule malaria vaccine administration shortly before the onset of the rainy season. This strategic timing aims to maximize malaria vaccine coverage among vulnerable populations, enhance coordination with SMC administration to leverage key messages and reminders to promote vaccine uptake, facilitate checks on vaccination status.

1.7.2.3 Perennial Malaria Chemoprevention

Perennial malaria chemoprevention (PMC) is the administration of a full treatment course of an antimalarial moderate to high perennial malaria transmission settings. The goal of PMC is to protect young children by establishing preventive antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the age of greatest risk of severe malaria. Previously, this recommendation referred to intermittent preventive treatment in infants (IPTi).

The name has been changed to PMC because the updated recommendation no longer limits the intervention specifically to infants and reflects the malaria transmission settings in which the intervention should be considered. PMC schedules should be informed by the age pattern of severe malaria admissions, the duration of protection of the selected drug, and the feasibility and affordability of delivering each additional PMC course.

The Expanded Programme on Immunization (EPI) platform remains important for delivering PMC. Other methods of delivery can be explored to optimize access to PMC and integration with other health interventions. PMC is currently being piloted in Nigeria and in the pilot, it is administered according to the following schedule: 10 weeks, 14 weeks, 6 months, 9 months, 12 months, and 15 months. When scaled up, the 6-month and 15-month PMC doses can be co-administered with the second and fourth doses of the malaria vaccine, respectively.

Additionally, considerations can be made for more flexibility to adjust the PMC schedule for optimal alignment with the malaria vaccine schedule. Sulfadoxine-pyrimethamine (SP) has been widely used for chemoprevention in Africa, including for PMC.

1.7.2.4 Prophylaxis Antimalarial Drugs for Non-immune travelers

For individuals traveling to malaria-endemic areas, taking preventive antimalarial drugs (prophylaxis) is an important measure to avoid infection. Commonly used prophylactic drugs include atovaquone-proguanil, among others.

1.7.3 Environmental Management

Environmental management focuses on reducing the breeding sites for mosquitoes and involving communities in malaria prevention efforts.

1.7.3.1 Elimination of Mosquito Breeding Sites

Mosquitoes breed in stagnant water, so eliminating or managing these sites can significantly reduce mosquito populations. This can be done by regularly emptying, cleaning, or covering containers that collect water, such as buckets, flowerpots, discarded tires, drainage of swamps, proper waste disposal, and improving water management systems, etc.

1.7.3.2 Community Awareness and Participation

Community involvement is critical for the success of malaria prevention efforts. Educating communities about the importance of vector control, the proper use of ITNs and IRS, and the elimination of breeding sites can empower individuals to take action in their own homes and neighborhoods. Public health campaigns, school-based programs, and community meetings are effective ways to raise awareness and encourage participation in malaria prevention activities. When communities are actively engaged in these efforts, the overall impact on malaria transmission can be substantial.

1.8 Key Points to Note

- Nigeria accounts for 27% of global malaria cases, with the highest prevalence in the northwest. Transmission occurs year-round with seasonal variation.
- Malaria is **caused** by the Plasmodium parasite, primarily Plasmodium falciparum in Nigeria. Other species include P. vivax, P. ovale, P. malariae, and P. knowlesi.
- Predominantly spread by bites from infected female Anopheles mosquitoes. Other less common modes include blood transfusion, congenital transmission, organ transplantation, and shared needles.
- Common symptoms are cyclical fever, chills, sweat, headaches, and vomiting. Severe cases can lead to cerebral malaria, anemia, and organ failure.
- Diagnosis requires microscopy or rapid diagnostic tests (RDTs).
- Preventing malaria requires a multifaceted approach that combines vector control, chemoprevention, personal protection, environmental management, and vaccination.
- Malaria is preventable and curable but can rapidly progress to severe malaria and death when not treated.
- Children with fever should be tested for malaria promptly and given appropriate treatment.

2. MODULE 2: MALARIA VACCINE

Learning objectives

At the end of this section, participants will be able to:

- Understand the characteristics and dosage requirements of the R21/Matrix-M malaria vaccine
- Demonstrate knowledge of vaccine handling and storage requirements
- Outline the cold chain requirements for vaccine transportation and storage
- Perform vaccine needs forecasting and inventory management
- Implement vaccine accountability and waste management procedures

Two malaria vaccines (RTS, S/AS01 and the R21 Matrix-M) are currently recommended for use in children living in malaria endemic areas, prioritizing areas of moderate and high malaria transmission (RTS,S and R21)

Table 1: R21/MATRIX M (CYVAC) PRESENTATION

Vaccine group	**Malaria**
Serotypes	Plasmodium falciparum
Vaccine trade name	R21/MATRIX M (CYVAC)
Vaccine type	A subunit recombinant protein vaccine
Number of doses required	4- Doses
Minimum dosing interval	4 weeks between the first 3 vaccine doses and at least 6 months interval between the 3rd dose and the 4th dose.
Route of administration	Intramuscular injection
Presentation and vaccine vial monitor (VVM) type	2-dose vial (1 mL of 0.5mL/dose) liquid No reconstitution needed R21 is with VVM14
Preservative and handling of opened multi-dose vials	No preservative: opened vials of this vaccine should be discarded six hours after opening or at the end of the immunization session, whichever comes first

Reconstitution and dosage	No reconstitution needed. The vial contains TWO doses of vaccine (0.5mL/dose): 1 vial contains 1 mL or 2 doses of vaccine.
Storage requirements	2–8°C; should not be frozen; protect from light; shelf-life 24 months at 2–8°C.

Table 2: R21/MATRIX M (CYVAC) VACCINE CHARACTERISTICS

Secondary packaging	**Carton**
Vials per carton	Contains 50 vials of two doses each Dimensions: 18.5 x 9.5 x 4.0 cm
Doses per carton	50 pairs of vials x 2-dose vial = 100 doses
Cold chain volume per dose	7.03 cm^3/dose (in secondary packaging)
Shelf-life	24 months at +2°C -8°C
Manufacturer	Serum Institute of India Pvt. Ltd.

Figure 11: R21/Matrix-M (CYVAC) Vaccine Vial

2.1 R21/Matrix-M (CYVAC) Vaccine Handling

R21/Matrix-M vaccine management should follow the same procedures as other Liquid vaccines in the cold chain. The vaccines should be stored in designated refrigerators upon receipt and confirmation of the quantity delivered between +2° to +8°C at all levels of ISC (Immunization Supply Chain). The vaccine SHOULD NEVER BE FROZEN as they are exceptionally sensitive to temperatures lower than +2°C and lose efficacy if frozen. If there is suspicion that the vaccine may have been frozen, a shake test should be performed. Each vial of 1 ml contains 2 doses (0.5mL/dose). **The vaccine vial monitor (VVM) is located on the vial cap.**

One Secondary carton of R21/Matrix-M consists of 50 vials (100 doses). The vaccine should be discarded 6 hours after opening the vial, OR at the end of a vaccination session – whichever comes first.

2.1.1 Vaccine Vial Monitor (VVM)

Exposure of the R21/Matrix-M vaccine to excessive heat can also reduce the potency of the vaccine. To check previous heat exposure incidences, the VVM on the vaccine vial cap will indicate the total heat exposure of the vaccine in the past and its colour may change over time within the supply chain. If the colour of the inner square is the same colour or darker than the outer circle, the vaccine has been exposed to excess heat and should be discarded according to the guidelines for disposal of unusable vaccine vials. VVMs help to ensure that

heat-damaged vaccines are not administered, and to decide which vaccines should be used first or be safely kept after a cold chain breakdown occurs, thus, minimizing unnecessary vaccine wastage.

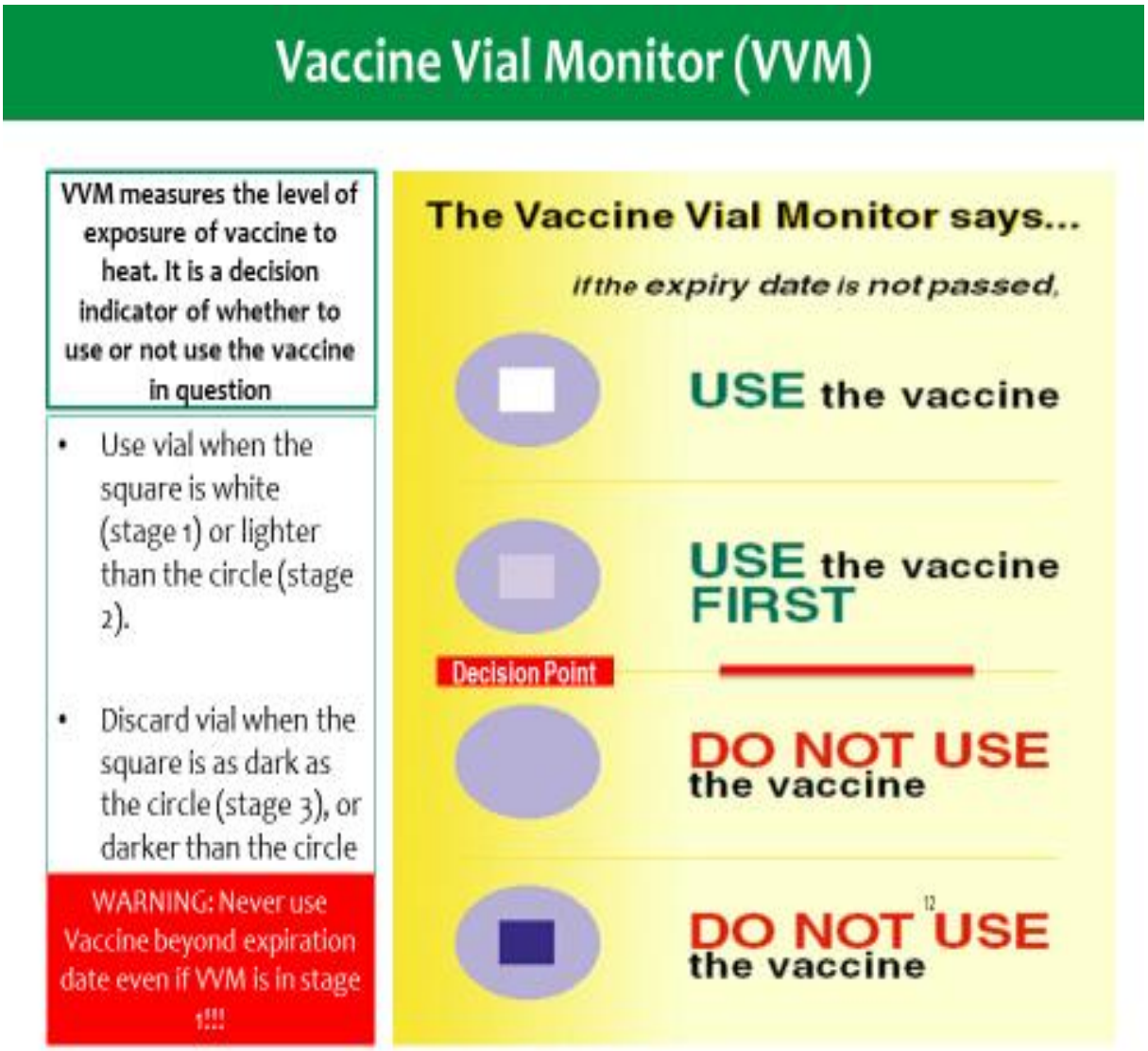


Figure 12: Vaccine Vial Monitor Interpretation

2.2 Malaria vaccine storage

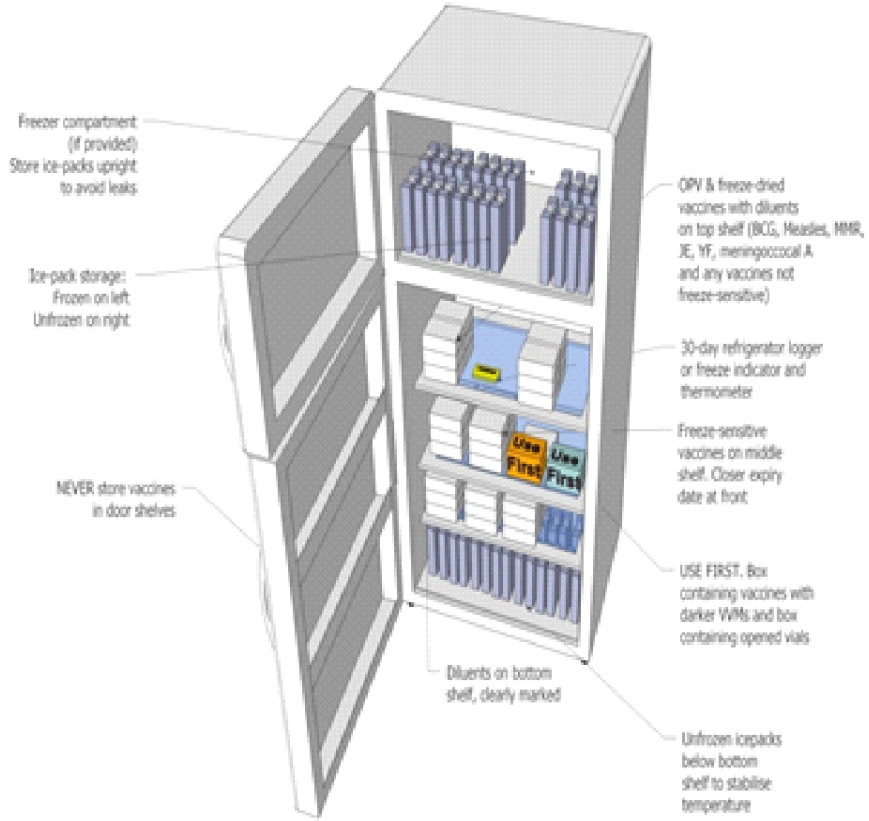


Figure 13: Vertical refrigerator

OPV, Measles, Yellow fever, BCG and MenA should be stored in the top compartment near the evaporator.

Rota, PCV, Td, Penta, HepB, R21/Matrix-M and HPV should be stored in the middle away from the evaporator.

RETURNED VIALS and Diluents for BCG, Measles, Yellow Fever, R21/Matrix-M and MenA must also be stored below.

Always insert temperature device in the Middle of the packed vials.

Icepacks for keeps are to be kept in the bottom compartment.

Always insert temperature device in the Middle of the packed vials.

Icepacks for keeps are to be kept in the bottom compartment.

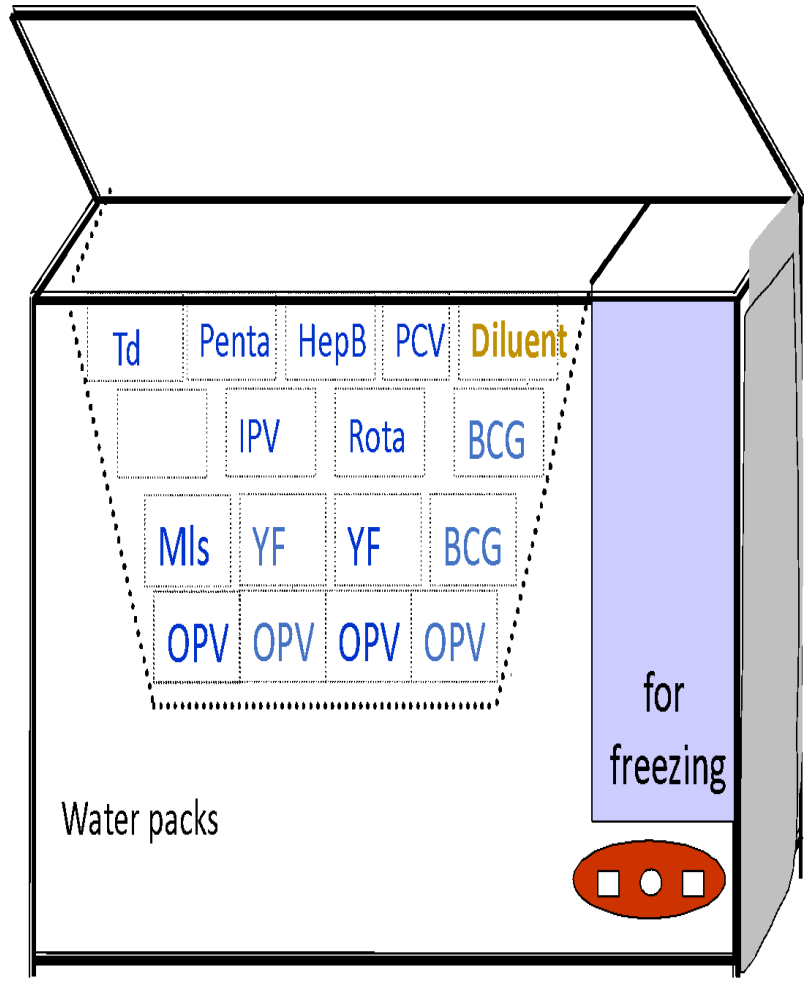


Figure 14: Horizontal Refrigerator

Vaccines should always be stored in the basket provided for this purpose.

OPV, Measles, Yellow fever, BCG, MenA should be stored in the lower part in the basket.

Rota, PCV, Td, Penta, HepB, R21/Matrix-M, HPV and diluent should be stored on the Top inside the basket.

Always insert temperature device in the Middle.

Icepacks are to be kept in the side compartment.

2.2.1 Cold Box

A cold box is an insulated container that can be lined with ice packs to keep vaccines and diluents in the required temperature range during transport or for short-term contingencies. Depending on the model, cold boxes can be used to store vaccines for periods of up to two days or more when there is no electricity available, when the health facility refrigerator is out of order, or when a passive device is needed while the refrigerator is being defrosted. Once packed, cold boxes should not be opened until the vaccine is needed.

Cold boxes can be used to carry monthly vaccine supplies from LGA stores to the health facility and from the health facility to outreach sessions if a vaccine carrier is too small. In general, a cold box in a health facility should be large enough to transport at least a one-month supply of vaccines.

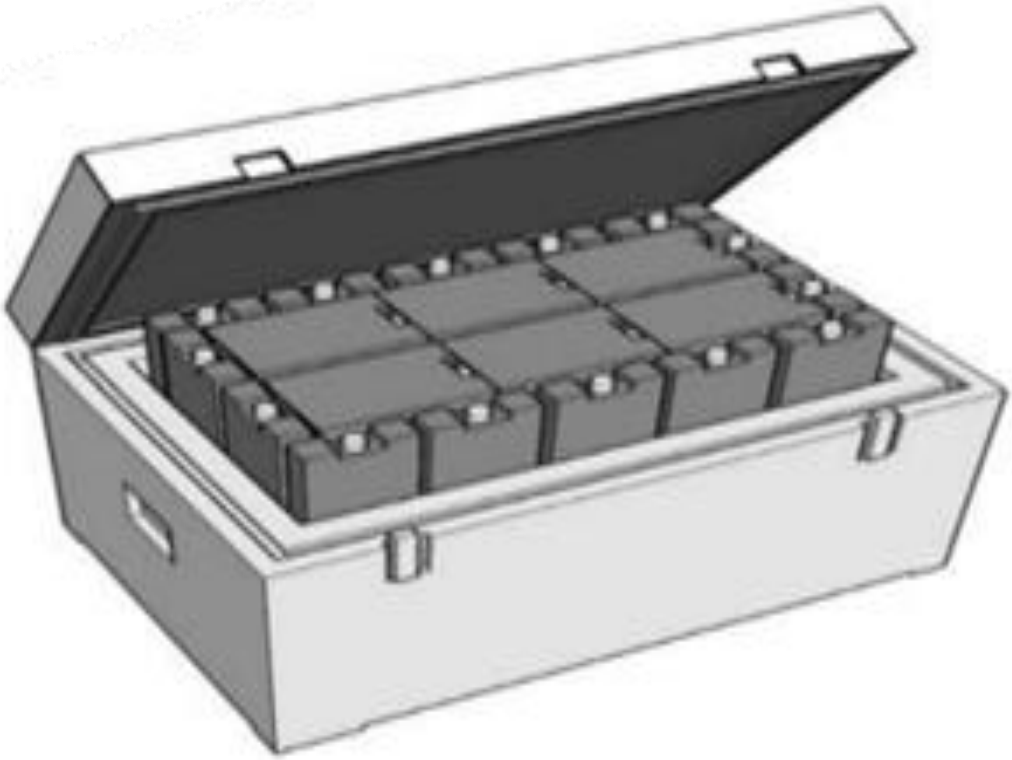


Figure 15: Cold box

2.2.2 Vaccine carriers

Vaccine carriers are smaller than cold boxes and easier to carry. Current prequalified vaccine carriers with appropriate ice packs can maintain recommended temperature of up to 6 hours and with conditioned ice packs. Vaccine carriers are generally used for the following purposes:

- To transport vaccines and diluents to outreach sites and store them during health facility immunization sessions.
- To store vaccines temporarily when the health facility refrigerator is out of order or is being defrosted.
- To transport monthly vaccine supplies from the LGA store to small health facilities.

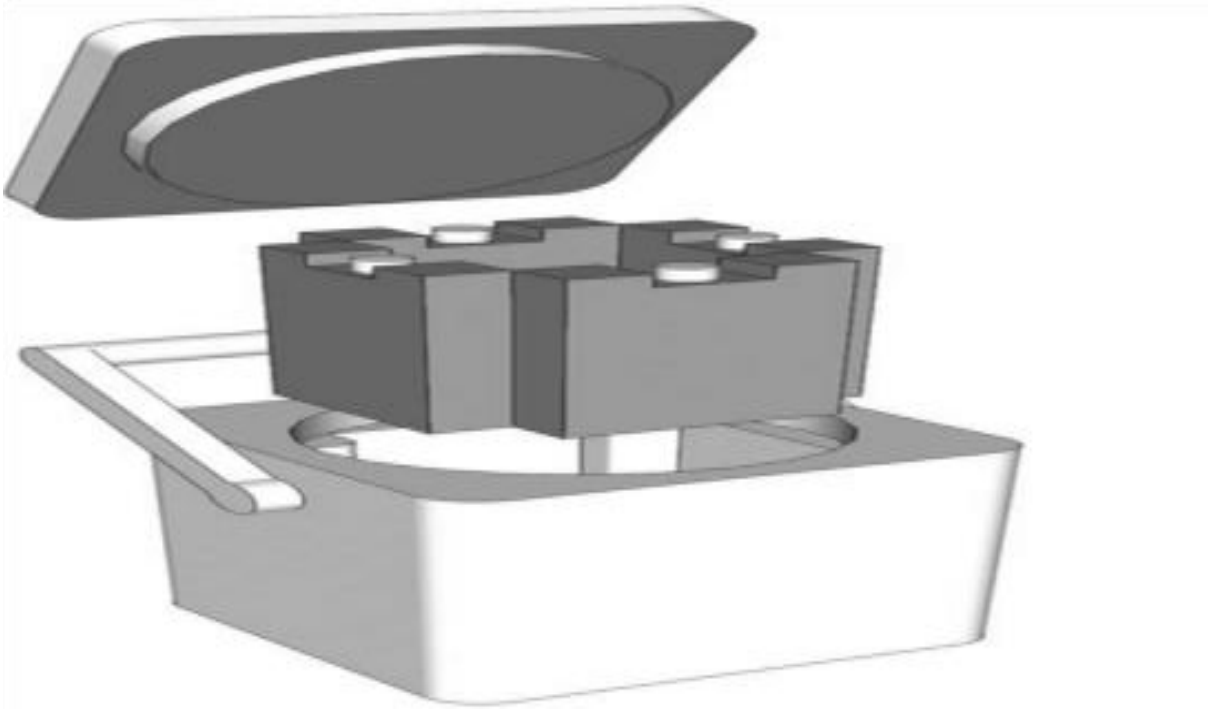


Figure 16: Vaccine Carrier

2.2.3 Ice packs

Ice packs are flat, leak-proof plastic containers that can be filled with water. They are used to line the inside of the cold box or vaccine carrier. Ice packs are used to keep vaccines at the required temperature range inside cold boxes and vaccine carriers. To protect the vaccines, it is important to use the correct number and size of ice packs and to follow the instructions printed inside the lid of the container. To ensure optimal performance, the WHO recommends the use of PQS pre-qualified ice packs. Health facilities must have a minimum of two complete sets of ice packs for each of their cold boxes and vaccine carriers so that one set can be frozen in the freezer/refrigerator while the other set is being used in the cold box or vaccine carrier. To reduce the risk of vaccine freezing, coolant/ice packs should be frozen and conditioned for use in cold boxes and vaccine carriers.

Figure 17: Ice Packs

Note that taking ice packs out of the vaccine carrier will shorten their ability to retain the cold chain within recommended temperature range.

A foam pad is a piece of soft sponge-like material that fits precisely on top of the ice packs inside a vaccine carrier while still permitting the lid of the vaccine carrier to be fully closed. The foam pad is provided by the manufacturer of the vaccine carrier. The foam pad usually has slits in which vaccine vials can be inserted securely and protected. The foam pad should be used during an immunization session to securely hold open vials, while protecting unopened vials in the cool chamber below inside the carrier.

Opened vials of all vaccines can be protected from heat damage for longer periods during immunization sessions if they are fitted into the slits in the foam pad. Even with a foam pad, however, it is important to keep the vaccine carrier lid closed whenever possible to conserve the inner temperature.

Health workers should use the pad supplied with the vaccine carrier and try to keep it clean and free from dirt or dust.

Figure 18: Foam Pad in Vaccine Carrier

2.2.4 Temperature Monitoring Devices

It is essential to monitor and record the temperature of vaccines throughout the supply chain. This is the only way to prove that vaccines have been kept at the right temperature range during storage and transport. Temperature monitoring also shows any problems with equipment and procedures.

Each vial contains a vaccine vial monitor (VVM) to indicate cumulative exposure to heat. The VVM provides a warning when the vaccine is likely to have been degraded and should be discarded. R21/Matrix-M vaccine has been certified for VVM type 14. It is important to highlight that the VVM does NOT alert about vaccine freezing and only the shake test determines if the vaccine has been frozen or not.

2.3 Forecasting for the Malaria Vaccine

Forecasting is estimating the quantity of vaccine (doses), diluents, and injection equipment (e.g., syringes, needles, and safety boxes) required for a population over a specified supply period. In the context of the introduction of the malaria vaccine forecasting will ensure that the right quantities are estimated and adequately supplied in good and acceptable quality at all levels – national, zones, states, LGAs, health facilities (fixed or outreach sites), and at the point of conduct of immunization sessions.

Advantages of accurate forecasting/estimation of vaccines needs:

- Increases efficiency of vaccine use, and reduces wastage

- Eliminates or reduces vaccine shortage or overstock in the system
- Minimizes vaccine stock out thus reducing the number of unimmunized children.
- Enhances the capacity of districts to develop more accurate micro plans
- Leads to accurate estimation of financial resources when creating budget lines for purchasing vaccines
- Assists in monitoring the progress of immunization about the target coverage
- Efficient control of immunization programs by managers

Doses required for the annual supply are based on the size of the target population, estimates of vaccine coverage of the first, second, third, and fourth dose, number of doses per schedule, and vaccine wastage rate.

2.3.1 Estimating vaccine needs based on the target population method

To estimate vaccine needs based on the target population, several parameters are required:

- Target population
- Number of doses per schedule
- Targeted Immunization coverage
- Wastage rate

2.3.1.1 Target population

The target population can be obtained by multiplying the total population estimate from NPopC by the percentage of the corresponding age bracket of surviving infants 6-18 months which is 3.2% of the total population for routinization based on the NSIPSS 2.0 document. However, these age groups are purely informative and may vary considerably from one country to the other depending on demographic pattern and the prevailing national immunization policy.

2.3.1.2 Number of doses per immunization schedule

For the R21/Matrix-M Vaccine, the WHO recommended wastage rate is 7%. The wastage factor can be calculated using the wastage rate with the formula below.

Wastage factor = 100 / (100 - wastage rate)

For R21, the wastage factor is:
Wastage factor = 100 / (100-7) = 100/93 = 1.08

Once the above parameters have been determined, it is possible to calculate vaccine needs based on the target population. Thus, the formula for the need of vaccines.

Target Population X Target Coverages X Number of Doses per schedule X wastage factor

Note that doses 1,2,3 and 4 target coverage will differ from each other as the Penta vaccine dropout rate applies to malaria vaccine needs.

Table 3: Parameters for Malaria Vaccines Estimation

	Malaria vaccine	**Parameter to use**	**Year 1**	**Year 2**	**Year 3**
1	Estimated target population (implementing areas only)	3.2% of surviving infants			
2	Target immunization coverage (doses 1 to 4)	Dose 1: 84% Dose 2: 81% Dose 3: 78% Dose 4: 75%			
3	Number of doses in schedule (4-dose)	Refer to Table 4 on page 43	3	4	4
4	Estimated wastage factor^	Wastage rate 7%	1.08	1.08	1.08
5	Buffer for the first year	25%	0.25	0	0

6	Total number of doses required	Multiplication of lines 1*2*3* 4 for each year			
7	number of auto-disable syringes required (0.5mL)	10% wastage rate			
8	Number of safety boxes required	1 safety box holds 100 used Syringes			

Example

Zaramaganda LGA is one of the 23 LGAs in Kongo State, with a total population of 528,689 spread over 10 wards. 371,105 of this population are living in the urban area of Zaramaganda LGA (dense population), and 70,520 are living in the rural area or scattered settlements. The expected Malaria vaccine coverage in the LGA is 84% for the first schedule, 81% for 2nd schedule, 78% for 3rd schedule, and 75% for the 4th schedule at a wastage rate of 7%. Estimate the Malaria vaccine doses required for the LGA.

Answer

Target population = 3.2/100 x 528,689 = 16,918

Wastage Factor = 100 / (100 – 7% wastage rate) = 1.08

Target Coverage = 84% for first schedule; 81% for 2nd Schedule; 78% for 3rd schedule and 75% for the 4th schedule

Number of doses per schedule = 1

Target Population X Target Coverages X Number of Doses per schedule X wastage factor

First Schedule =16,918 X 0.84 X 1 X 1.08

= 15,348 doses

Second Schedule =16,918 X 0.81 X 1 X 1.08

= 14,800 doses

Third Schedule =16,918 X 0.78 X 1 X 1.08

= 14,252 doses

Fourth Schedule =16,918 X 0.75 X 1 X 1.08

= 13,704 doses

Therefore, the malaria Vaccine needed for Kongo LGA is the addition of all the calculated vaccine needs for the schedules: 15,348+14,800+14,252+13,704

= 58,104 Doses

Estimating Auto-Disable Syringes 0.5ml

Total number of AD syringes required = Total Number of Doses x wastage factor

Thus, total number of AD syringes required: 58,104 X 1.1 = 63,914 Pcs

Estimating safety boxes

For example, Number of safety boxes required: Number of 0.5ml AD syringes required divided by 100 x 1.1(wf)

= 63,914 X 1.1/100 =703.1 Safety boxes (~704 Safety boxes)

Note: 1 safety box can hold approximately 100 syringes with needles

Each carton contains 25 safety boxes

Therefore, for 704 safety boxes, 704 /25 = 28.2 Cartons = 28 cartons and 5 Pcs

704 /25 = 28.2 Cartons = 28 cartons and 5 Pcs

2.3.2 Vaccine Accountability

Vaccine accountability ensures that vaccine management principles are followed to avoid wastages and eliminate or minimize stock out. This means being competent to perform assigned roles and responsibilities that will optimize vaccine management. It also attracts rewards and sanctions. Poor vaccine accountability leads to un-noticed expiry, VVM change, general wastages of vaccines and devices, stock out, and low immunization coverage.

To ensure proper vaccine accountability, Health Workers should conduct the following:

Regular physical stock count at all levels of immunization Supply Chain (iSC)

- National/Zonal Cold Store – Quarterly
- State – Monthly
- LGA and Health facility – Weekly
- Documentation and return of all empty and unusable vaccine vials when collecting vaccines during conduct of routine immunization services.
- Return of all unopened vaccine vials, safety boxes and devices to the apex HF/ward/LGA CCO after every session depending on the vaccine collection point.
- Proper data entry into VMA1a & 1b, and other vaccine management tools
- Proper data entry of monthly health facility vaccine utilization summary
- Hold regular data review and validation meetings
- Submit monthly vaccine utilization report to the next level
- Weekly submission to the OpenLMIS from the LGA level.

2.4 Cold Chain Equipment Maintenance

Regular maintenance of cold chain equipment is critical for maintaining equipment uptime which is required for ensuring availability of potent vaccines for service delivery. This requires prompt and regular conduct of planned preventive (as detailed in the Planned Preventive Maintenance [PPM] guidelines) and curative maintenance. Efficient and effective preventive & curative maintenance will minimize the number and frequency of cold chain equipment breakdown.

2.5 Waste Management

Improper management of health-care waste poses a significant risk to patients, health-care workers, the community, and the environment. Management of waste from routine injection requires appropriate local solutions. The first step is to review the amount of waste to be discarded as malaria vaccine being a 2-dose per vial is expected to generate high wastes. Estimate the quantities of AD syringes to be disposed of by the health facility, per year and per month. As part of the pre-introduction assessment, programme should assess the

additional waste management needs with the new vaccine and determine whether their current waste management system is able to cope with this increase, or whether adjustments are needed (for example, incinerators need to be repaired or expanded, or additional ones need to be built).

Health facilities must manage the increased waste well by appropriately filling safety boxes with sharps like needles; appropriate disposal of other categories of waste; and transporting the filled safety boxes securely upwards to the ward, LGA, and state holding points where they are centrally incinerated. Used vials should also be accounted for and transported upwards to the LGA and state cold stores where they are destroyed through the Boil, Crush, and Bury methods.

2.6 Key Points to Note

- The malaria vaccine is an injectable vaccine.
- 1 vial contains 1mL (2 doses) of vaccine.
- 1 dose is 0.5mL.
- The vaccine should be discarded 6 hours after opening (because it has no preservative) OR at the end of a vaccination session – whichever comes first.
- The main purpose of VVM is to ensure that heat-damaged vaccines are not administered.
- R21/Matrix-M is freeze sensitive and light sensitive.
- Vaccines should be stored in a refrigerator between +2^{o}C and +8^{o}C.
- Do not open the refrigerator door often.
- Regularly monitor the temperature of the refrigerator.
- When using ice packs in cold boxes and vaccine carriers, they should be conditioned to reduce the risk of vaccine freezing.
- Vaccines with early expiration dates and VVM at discard point (or nearing discard point) should be kept at the front of the refrigerator to be used first.
- Doses required for annual supply are based on; the size of the target population, estimates of vaccine coverages, number of doses per schedule, and vaccine wastage rate.
- Vaccine accountability ensures that vaccine management principles are followed to avoid wastages and eliminate or minimize stock out.
- Regular maintenance of cold chain equipment is critical for maintaining equipment uptime in ensuring the availability of potent vaccines for service delivery.
- Storage requirements for a vaccine can be calculated by multiplying the number of doses/vials needed times the packed volume.
- Health facilities must manage the increased waste well by appropriately filling Safety Boxes with sharps like needles, and appropriate disposal of other categories of waste.

- Used vials should also be accounted for and transported upwards to LGA and state cold stores where they are destroyed through the Boil, Crush, and Bury methods.

3. MODULE 3: MALARIA VACCINE SCHEDULE AND ELIGIBILITY

Learning objectives

At the end of this section, participants will be able to:

- Describe the recommended malaria vaccine schedule
- Screen clients for malaria vaccine eligibility

Nigeria will introduce the malaria vaccine in a phased manner into the routine immunization schedule in two states by Q4 2024 with plans for scale up to the remaining states plus FCT in subsequent year/s. The phase 1 introduction will happen in all the eight (8) LGAs in Bayelsa state and in all the twenty-one (21) LGAs in Kebbi state. The malaria vaccine, which is a two-dose vial vaccine, will be launched by November 2024.

Children will receive **four (4)** doses of the vaccine. The recommended schedule is first dose at 5-months (up to 11 months if late), second dose at 6-months, third dose at 7-months and the fourth dose at 15-months (up to 23 months of age or after if late), based on the updated routine immunization schedule.

Table 4: Updated routine immunization schedule

	Child Age												
Vaccines	Birth	6 wks	10 wks	14 wks	5 mo	6 mo	7 mo	8 mo	9 mo	12 mo	15 mo	18 mo	20 mo
BCG	1												
Hep B0	1												
Oral polio	1	2	3	4									
DTP-HepB-Hib (penta)		1	2	3									
Pneumococcal conj.		1	2	3									
Rotavirus		1	2	3									
Inactivated Polio		1		2									
Meningococcal A conj.									1				
Measles									1		2		
Yellow Fever									1				
Malaria vaccine [Nigeria]					1	2	3				4		
Vitamin A						1			2				
Growth Monitoring		1	2	3	4	5	6				7		
Deworming													
LLIN distribution											1		

The proposed schedule is based on three key careful considerations including clinical efficacy, scientific evidence and programmatic considerations.

3.1.1 Clinical Efficacy

Phase 3 clinical trials have shown that children who receive the vaccine from 5 months of age have higher efficacy rates compared to those who start at 6-12 weeks. This evidence-based approach ensures our children receive optimal protection as early as possible at 5 months.

3.1.2 Scientific Evidence

Systematic reviews from the World Health Organization's Strategic Advisory Group of Experts (WHO SAGE) confirm that administering the vaccine before maternal immunity wanes, around 6 months, does not interfere with maternal antibodies. Furthermore, the WHO recommends giving the 4th dose within 6-12 months after the 3rd dose for longer protection, implying that scheduling Dose 4 closer to 2 years of age prolongs protection.

3.1.3 Programmatic Considerations

Aligning with existing EPI schedules, our vaccine administration will coincide with children's monthly visits, providing opportunities for catch-up vaccinations and increased uptake of MCV2 and LLIN distribution. Specifically, administering the 4th dose at 15 months of age strikes a balance between programmatic considerations and optimal protection.

In light of these evidence, Nigeria has adopted the 5-month first dose schedule to ensure early protection before maternal immunity wanes, reducing morbidity in children at 6 months. This thoughtful approach underscores our commitment to protecting our children from malaria.

The malaria vaccine schedule provides additional visits/touchpoints for the caregivers to bring their children for malaria vaccination. Therefore, to ensure adequate uptake and completion of the malaria vaccine, the HCW should:

- Include malaria vaccination and control during health talk.
- Patiently inform caregivers of the additional touchpoints/visits and importance of completing the 4^{th} dose.
- Emphasize that additional visits/touchpoints provide opportunity for defaulters to receive missed vaccines.
- Emphasize that completion of the 4^{th} dose for maximum protection.
- Remind caregivers of the 6 key RI messages:
- Inform caregivers of the benefit of routine immunization, what vaccine was given and what it prevents.
- Inform caregivers of the number of times to come back for subsequent vaccination.

- Sensitize caregivers on the possible side effects and what to do when they occur.
- State date of next visit and need to always bring along CHC.
- Inform caregivers of the place of next RI session.
- Stress the need to bring the child for immunization even if he/she is ill.
- Ensure to integrate RI visits with other PHC services such as administration of vitamin A, nutritional supplements (CMAM), deworming, growth monitoring, provision of LLINs, malaria chemotherapy, etc.
- Know that malaria vaccine can be administered together with other RI antigens.
- Note that if a client missed any dose of malaria vaccine, it can be given together with other RI vaccines, provided the child is within the age limit of 5 - 11 months for the first dose and >5 - 23 months for subsequent doses. (Any child that begins malaria vaccination should receive all four doses).

Table 5: Scenarios for screening for correct administration of malaria vaccine

S/N	Likely scenario	What to do	Record keeping
1	Children who come for the first dose at the appropriate age of 5 months.	Vaccinate child with first dose of malaria vaccine Inform caregiver of the exact date for the 2nd dose (4 weeks after the first dose vaccination) Inform caregiver of the number of visits to complete malaria vaccine and all age-appropriate RI vaccinations and childhood interventions. Screen the child for whatever vaccines they might have missed.	Fill the Child immunization register Tally correctly on the immunization tally sheet Fill clients' CHC and indicate date vaccination was given
2	Children who come for the first dose at less than 5 months	Educate caregiver on the eligible age to receive the malaria vaccine Inform the caregiver to bring the child for vaccination at 5 months. Provide children with other malaria interventions or refer children to other facilities where other malaria prevention interventions are carried out.	Advice caregiver to keep CHC and present it during vaccination visit

		Provide health talk on malaria prevention and case management. Screen the child to help catch up on missed vaccines.	
3	Children who come for the first dose at age greater than 5 months	Vaccinate child with first dose of malaria vaccine only if child is less than 12 months. Inform caregiver of the exact date for the 2nd dose (4 weeks after the initial vaccination) Inform caregiver of the number of visits to complete the malaria vaccine and all age-appropriate RI vaccination. Screen the child to help catch up on missed vaccines.	Fill the Child immunization register Tally correctly on the immunization tally sheet Fill clients' CHC and indicate date that the vaccination was given
4	An 11-month-old child visits the health facility, and you notice they have not received any MV doses.	Vaccinate the child with the first dose of the MV. Inform caregiver of the exact date for the next dose Inform caregiver of the number of visits to complete malaria vaccine and all age-appropriate RI vaccination. ● Dose 2 at 12 months (4 weeks after dose 1) ● Dose 3 at 13 months (4 weeks after dose 2) ● Dose 4 at 19 months (at least 6 months after dose 3) Screen the child to help catch up on missed vaccines.	Fill the Child immunization register Tally correct on the immunization tally sheet Fill clients' CHC and indicate date the vaccination was given
5	A 9-month-old child is brought to the clinic to receive the measles and yellow fever vaccines. You notice he received	Vaccinate the child with the second dose of the malaria vaccine. It can safely be given at same 'time as the measles and yellow fever vaccines. Advise the mother to return in 4 weeks for malaria vaccine dose 3 (when the child is 10 months of	Fill the Child immunization register Tally correctly on the immunization tally sheet

	the 1st dose of the malaria vaccine when he was 6 months old, but no other dose since then.	age) and to return for MV dose 4 at 16 months of age. Screen the child to help catch up on missed vaccines.	Fill clients' CHC and indicate date the vaccine was given
6	A 20-month-old child shows up at the health center for malaria vaccination (MV) with their sibling. They have received two previous malaria vaccine doses at 11 months and 18 months.	Vaccinate the child with the third dose of the malaria vaccine. Inform caregiver of the exact date for the next dose (i.e. caregiver to return in 6 months for dose 4 when the child is 26 months). Screen the child to help catch up on missed vaccines.	Fill the Child immunization register Tally correct on the immunization tally sheet Fill clients' CHC and indicate date the vaccine was given
7	Children less than 23 months who missed any dose for any reason after collecting a dose of the malaria vaccine.	Vaccinate the child with the next dose of malaria vaccine, maintaining a minimum of 4 weeks between doses (at least 6 months between dose 3 and 4) and ensure completion till the 4th dose. Inform caregiver of the exact date for the next dose Inform caregiver of the number of visits to complete malaria vaccine and all age-appropriate RI vaccination. Screen the child to help catch up on missed vaccines.	Fill the Child immunization register Tally correct on the immunization tally sheet Fill clients' CHC and indicate date the vaccination was given
8	Children greater than 23 months who had started malaria vaccination before 11 months and defaulted on any doses for any	Vaccinate the child with the next dose of malaria vaccine, maintaining at least 4 weeks interval between doses (at least 6 months between dose 3 and 4), and ensure completion till the 4th dose.	Fill the Child immunization register Tally correctly on the immunization tally sheet

	reasons **Ensure to record the doses the child received in the appropriate columns of the RI data tools	Inform caregiver of the exact date for the next dose Inform caregiver of the number of visits to complete the remaining malaria vaccine doses and all age-appropriate RI vaccination. Screen the child to help catch up on missed vaccines.	Fill clients' CHC and indicate date the vaccination was given
9	Children greater than 23 months who have not received any dose of malaria vaccine.	Do not vaccinate as the child is already above the eligible age for vaccination Educate caregivers on the importance of routine immunization and other measures to prevent malaria. Screen the child to help catch up on missed vaccines.	Advice caregiver to keep CHC appropriately
10	A 7-month-old child comes to the clinic to receive the first dose of malaria vaccine. The child is HIV positive with no symptoms.	Vaccinate child with the first dose of malaria vaccine. Inform caregiver of the exact date for the 2nd dose (4 weeks after the initial vaccination), and the 3rd dose (4 weeks after the second dose) and the 4th dose at least 6 months after the 3rd dose. Inform caregiver of the number of visits and specific dates to complete the malaria vaccine and all age-appropriate RI vaccination. Screen the child to help catch up on missed vaccines.	Fill the Child immunization register Tally correctly on the immunization tally sheet Fill clients' CHC and indicate the date vaccine doses and date was given.

3.2 Eligibility screening for malaria vaccine

To screen clients for eligibility, HCWs are to:

- Confirm from client/caregiver the age of the client before vaccination, inform caregiver that **the first dose is at 5 months, second dose at 6 months which is 4 weeks interval after the first dose, third dose at 7 months and fourth dose at 15 months.**

- If the age of the child is unknown, The HCW will estimate the age of the child using strategic events and verify as appropriate through the caregiver.

The malaria vaccine is administered according to a specific schedule to ensure optimal protection. The recommended schedule is: the first dose at 5 months of age, the second dose at 6 months, the third dose at least 4 weeks after the second dose, and the fourth dose at 15 months.

If a child misses any dose, it is important to catch up as soon as possible. Administer the missed dose, maintaining a minimum of 4 weeks between doses. Additionally, some flexibility is allowed for late administration: the first dose can be given up to 11 months of age, and the fourth dose at 15 months or later - at least 6 months after dose 3 to prolong protection.

After administering each dose, record the dose and date given. Emphasize to caregivers the importance of continuing other malaria prevention measures. Finally, schedule the child's next vaccine visit to ensure timely completion of the vaccination series.

Key Points to Note

- The malaria vaccine will be introduced into RI schedule by Q4 2024.
- The recommended schedule is: the first dose at 5 months of age, the second dose at 6 months, the third dose at least 4 weeks after the second dose, and the fourth dose at 15 months or later - at least 6 months after dose 3 to prolong protection.
- Give the first dose at 5 months of age, if the child is late, the first dose can be given up to 11 months of age.
- Give the 2nd and 3rd doses, maintaining a minimum of 4 weeks interval.
- Provide dose 4 at 15 months or later - at least 6 months after dose 3 to prolong protection.
- Screen each child for eligibility before vaccination.
- Remind the caregiver to bring the child to receive the four doses for maximum protection.

4. MODULE 4: MALARIA VACCINE ADMINISTRATION AND CONTRAINDICATIONS

Learning Objectives

At the end of this session, participants will be able to:

- Organize RI sessions including malaria vaccination
- Understand how to screen clients for eligibility before the administration of malaria vaccine
- Understand contraindications of the malaria vaccine
- Understand how to integrate malaria vaccines with other malaria control interventions
- Describe the recommended malaria vaccine schedule

4.1 How to organize RI sessions including malaria vaccination

Vaccination sessions for malaria vaccines will be integrated with those organized for childhood routine immunizations. As with other vaccines, immunization sessions should have all the necessary supplies and materials for effective delivery. Supplies include chair and table, running water and soap/alcohol-based hand sanitizer, stock of vaccines in vaccine carriers with foam pads, droppers (for OPV), ice packs, cotton wool, auto-disable syringes, reconstitution syringes, safety boxes with closed lids, waste bags for garbage, and information, education and communication (IEC) materials. All forms and monitoring tools should be brought to every vaccination session, including the vaccination registers, tally sheets, child health cards and AEFI forms (in case of adverse reactions).

A typical space for RI sessions should have a waiting area (if possible, in shade), table, vaccine carrier, health education/information and return appointment.

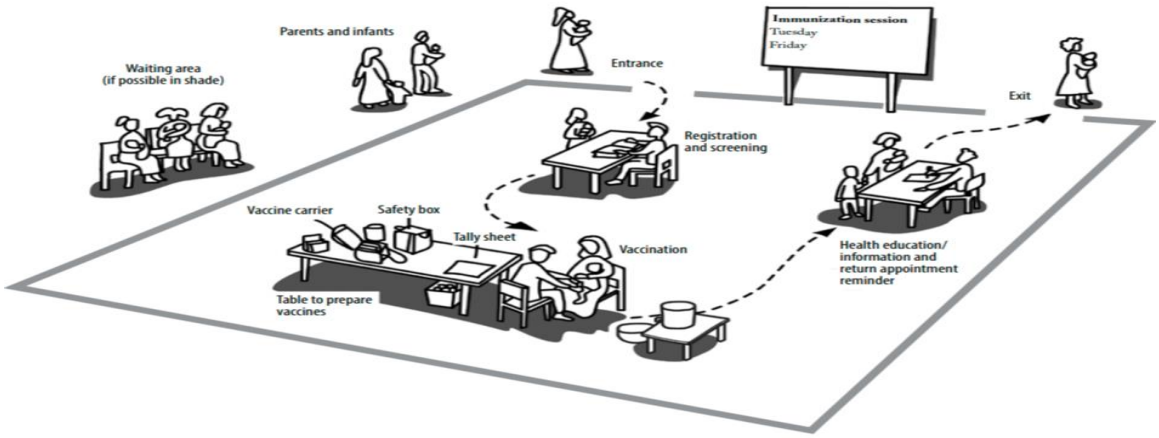


Figure 19: Example of an Immunization Site

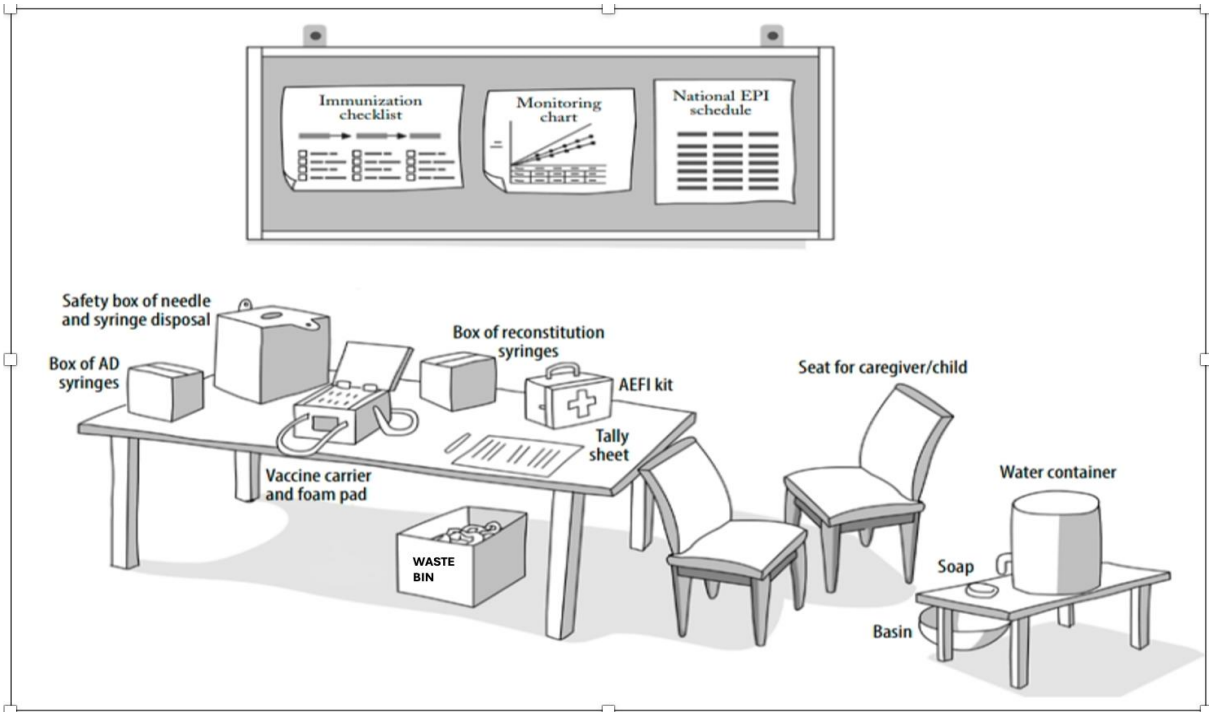


Figure 20: Immunization station: example of the arrangement

4.2 Steps in administering malaria vaccine before session

- The HCW is expected to work with community structures to identify sites, date, and time for outreaches and communicate the same to town announcers or community mobilizers to inform communities.
- Town Announcers, VCMs or other community mobilizers should inform the community about the new vaccine and other RI antigens. Ensure adequate communication with communities, urban slums, nomadic settlements, etc., on date and time of visit by vaccination team. Share with them a standard message for caregivers to bring their children for vaccination based on age eligibility. (all children 5 - 11 months of age should come for dose 1).
- Review the vaccine requirements for the planned session and ensure it is based on the updated microplans.
- Prepare the necessary logistics for the session.
- Ensure adequate cold chain including Giostyle, conditioned ice packs,
- Ensure the availability of devices such as AD syringes, waste bag for garbage, safety box
- Ensure the availability of Data tools such as tally sheets, immunization register, vaccination cards, AEFI line-list and reporting forms, VM1 a & b, IEC materials.

4.2.1 The steps to follow to screen clients for eligibility before the administration of malaria vaccine

- Verify child's age on the immunization card.If the child does not have an immunization card but has come to the health facility before, check the register and fill out a new card.
- If the child is new to the health facility and does not have an immunization card, ask the caregiver for the history of vaccines the child has received and fill out a new card.
- Verify which vaccines the child has received by reviewing the immunization card
- Check for BCG scar if there is no record or recall.
- Proceed to the next step and vaccinate the child if there is no card or recall (but issue new card).
- Verify all vaccines the child needs at this session
- Follow the current national routine immunization schedule:
- If eligible for more than one vaccine, give the different vaccines at appropriate sites during the session
- Never give more than one dose of the same vaccine at one time
- If the vaccine is overdue, do not restart the schedule; simply provide the next needed dose on the series and schedule for a next visit (if any) at recommended intervals.
- Children aged 5 to 11 months are eligible for dose 1.
- Maintain at least 4 weeks interval between doses 1, 2, 3
- Provide dose 4 at 15 months or later - at least 6 months after dose 3 to prolong protection.

4.3 Steps in administering malaria vaccine and other antigens during sessions

Preparing to Vaccinate:

- Use aseptic techniques to prepare vaccines
- Wash hands with soap and running water and dry hands thoroughly
- Prepare vaccines individually for each child
- DO NOT PREFILL SYRINGES!!!
- Ensure the client is in a comfortable position

Vaccines Reconstituting:

- The Malaria vaccine does not need reconstituting.
- Withdraw 0.5ml using the AD syringe.

4.3.1 Positioning the Child for Vaccination

Unexpected motion at the time of injection can lead to needle-stick injuries. This may occur more often with children who are not positioned properly before injections are given. Choice of position depends on the number of vaccines to be given, age of child and materials available. The aim of positioning is to keep the child still and the caregiver and vaccinator comfortable. Try different positions to find the one that suits you best.

The figure below is an illustration of positioning children for vaccinations to minimize the risk of needlestick injuries. Check whether caregiver is willing to hold the child while the injections are given

Figure 21: Positioning the Infant for Vaccination

Good injection technique includes administering all injectable vaccines with a single use/auto-disable (AD) syringe. To use AD syringes correctly, remember that the plunger of an AD syringe can only go back and forth once; so:

- Do not draw up air to inject into the vaccine vial when filling the AD syringe
- Do not aspirate first when you insert the needle into the infant for the injection
- Position the needle for intramuscular injection (at angle 90 degrees) **on the**
- **outer part of the upper right thigh** (Dispose used needle and syringe into the safety box).
- Observe client for at least 15 minutes after the vaccination for AEFI and follow proper AEFI procedures if applicable.
- Advice client and caregiver on possible AEFI and the need to report to the facility:
    - Reassure caregiver that minor reactions are common and indicate good response to the vaccine

- Instruct caregiver to give extra fluids in form of breast milk or fresh water to child
- Instruct caregiver that paracetamol may be given and specify dose and timing
- Remind caregiver to avoid pressure on the injection site
- Explain to caregiver that placing a cold damp cloth on the swollen site eases pain
- Tell caregiver to bring the child to the health facility if condition worsens

- Remind the caregiver of the six key Messages:
  - What vaccines(s) were given
  - The number of visits a child still needs to be fully immunized
  - What side effects may occur and how to treat them
  - The place and time of the next immunization
  - To bring the child back for immunization even if he/she is sick
  - The need to take good care of the immunization card and bring it during the next visit
- Malaria vaccine specific messages:
  - Potential side effects include fever (seek treatment) and pain or mild swelling at injection site
  - A less common adverse event is for a child with fever to have convulsions
  - Date of return and importance of receiving all 4 malaria vaccine doses
  - The vaccine will reduce malaria, but will not prevent all episodes of malaria.
  - Continue to use an insecticide treated net every night and seek prompt diagnosis and treatment for fever.

4.4 Steps in administering malaria vaccine and other vaccines after sessions

- Materials must be stored safely or disposed of after immunization sessions. Equipment and sites must be cleaned and maintained for their next use.
- Discard or Store Opened Vials: The malaria vaccine is a liquid vaccine and does not contain any preservatives, hence it should be discarded after six hours or at the end of the session; whichever comes first (refer to the national policy on open multi-dose vials and act accordingly)
- Pack all remaining un-opened vaccine vials into the vaccine carrier
- Return vaccines to the refrigerator/SDDs/Apex facilities/LGA (check VVM) to ensure the vaccines cold chain is maintained. For facilities that have refrigerators, return vaccines with acceptable VVMs to the first basket. While for facilities that do not have refrigerators, vaccines should be returned into the cold box, stored for 72 hrs. with conditioned icepacks, and then taken to the Apex facility using the Gio-style.

- Remember to put empty vials and opened vials of reconstituted vaccines in a separate container for transport to a disposal site
- Clean the vaccine carrier and ice packs, then return ice packs to the freezer section' where applicable
- Return other supplies
- Dispose of used vaccine vials and injection equipment safely
- Leave the vaccination site clean and tidy
- Do not leave anything behind that might be a health threat to the community
- Clean and return tables and chairs to their appropriate place.
- If it is an outreach session, thank the local people that helped to organize the session and remind them of the date of next session.

4.5 Assess possible contraindications.

4.5.1 Malaria vaccine contraindications

Malaria vaccine is not recommended for use in a child with known severe hypersensitivity to the following:

- Previous dose of malaria vaccines
- Previous dose of Hep B 0 and any of the mentioned vaccine components
- Fever above 38.5°C.
- Other Malaria Vaccine component

For the first dose of a vaccine, assess the general status of the child to rule out signs of serious illness. For a subsequent dose in a vaccine series, ask the caregiver whether any adverse events, including anaphylaxis, occurred following the previous dose(s).

Note the following

- A minor illness, including respiratory tract infections and mild diarrhea is not a contraindication.
- Do not give vaccines if the caregiver objects to immunization even after explanation; ask them to come back when the child is well.
- Malnourished or HIV-positive infants can be vaccinated with malaria vaccine using the recommended schedule except advised against by a clinician.
- The malaria vaccine is administered on the **right upper thigh** of the client.

4.6 Integration of Malaria Vaccine with Other Vaccines, Childhood Interventions, and Missed Opportunities for Vaccination (MOVs)

The introduction of the malaria vaccine into Nigeria's routine immunization schedule presents an important opportunity to enhance existing childhood intervention programs. By

strategically aligning the malaria vaccine schedule with other childhood vaccinations and interventions, we can maximize reach and minimize missed opportunities for comprehensive healthcare.

4.6.1 Key integration points in the schedule

The chosen schedule for the malaria vaccine has been designed to align with other critical interventions at the following ages:

- **6 Months:** malaria vaccine Dose 2 (MV2) alongside Vitamin A supplementation and growth monitoring, optimizing both malaria prevention and nutritional support during this visit.
- **15 Months:** malaria vaccine Dose 4 (MV4), along with ITN distribution and the second dose of the Measles Containing Vaccine (MCV2). This integrated approach at 15 months provides both immunization and vector control benefits.

4.6.2 Missed Opportunities for Vaccination (MOVs)

Without integration, children can miss scheduled vaccinations and interventions when visiting clinics for other health needs, such as:

- Curative care visits for ailments like diarrhea or respiratory infections
- Growth monitoring sessions
- Nutritional support or supplementation visits
- Deworming programs

Likewise, children who attend vaccination appointments may miss other essential services, such as:

- Vitamin A supplementation
- Deworming tablets
- Growth monitoring and promotion
- ITN distribution
- SMC, etc.

4.6.3 Integration Strategies

To reduce missed opportunities, the following strategies are recommended:

- **Co-administration**: Deliver multiple vaccines and interventions at the same visit, especially at key integration points (e.g., 6, and 15 months).
- **Bundled Services:** Package services like vaccination, growth monitoring, and nutrition interventions to ensure comprehensive care.
- **Facility-Based Integration:** Offer malaria vaccination alongside other interventions at the same health facilities.

- **Community-Based Integration:** Engage community health workers to provide integrated services through outreach and mobile clinics.
- **Optimized Scheduling:** Coordinate the malaria vaccine schedule with other childhood interventions to avoid gaps.

4.6.4 Benefits of integration

An integrated approach to vaccine delivery offers several advantages:

- Increases vaccination coverage and timeliness
- Enhances the uptake of complementary interventions
- Reduces logistical costs and enhances efficiency
- Strengthens the overall health system
- Improves health outcomes by providing comprehensive care for children

4.6.5 Implementation considerations

To ensure successful integration of the malaria vaccine with other interventions, it is essential to:

- Train healthcare workers: Equip staff with the knowledge and skills for integrated service delivery.
- Manage supply chains: Ensure a steady supply of vaccines, nutritional supplements, and other necessary resources.
- Monitor and Evaluate: Track the effectiveness of integrated services to identify gaps and improve outcomes.
- Engage the community: Educate caregivers on the benefits of combined services and encourage participation.

Integrating the malaria vaccine with other childhood interventions is essential to maximize health benefits and minimize missed opportunities for vaccination and other health services. Adopting these integration strategies will help healthcare workers deliver a more holistic package of preventive care, ensuring comprehensive protection for children against malaria and other diseases.

4.7 Recording Data

Steps to follow to complete infant immunization and reminder cards

- Write the date of each vaccine administered in its corresponding section on the card
- Mark the next immunization due date on the card if another dose is needed
- Refer to the vaccine introduction manual to check how to record new vaccines, if they are not included in the form (applicable only if revised data tools with the new vaccines are not available)

- Use the immunization card to update the reminder card
- Return the immunization card to the caregiver
- Explain to caregiver that the immunization card must be kept safely and in good condition
- Remind the caregiver that the card should be taken to all the child's health care visits for review
- Prepare a summary of the session
- Calculate total number of vaccines given, supplies used and stock remaining for inclusion in monthly report data

Preparing a defaulter tracking list

- At the end of each session, use the immunization register to make a list of children who were due for vaccines but did not attend the session.
- Inform community members; for example, WDC members, VCMs, HCW, etc. who help with defaulter tracking of the infants on the list. Ask them to mobilize the defaulters for the next immunization session.

4.7.1 Role Play

- Select 2 health workers (vaccinator + recorder)
- Select at least 2 mothers with children to serve as clients
- Select a town announcer

4.8 Key Points to Note

- Integrate malaria vaccine with other routine childhood vaccinations.
- Ensure all supplies are ready, including vaccines, syringes, ice packs, and data collection tools.
- Set up a waiting area, table, and health education space.
- Coordinate with community structures and mobilizers to announce vaccination schedules.
- Review vaccine requirements, ensure a cold chain, and prepare necessary devices and data tools.
- Verify child's age and vaccination history before administration.
- Check for any contraindications, such as severe allergies to vaccine components.
- Use aseptic techniques and single-use syringes; position child to prevent needle-stick injuries.
- Advise caregivers on possible minor reactions and steps to take if symptoms worsen.
- Align malaria vaccine doses with other interventions like Vitamin A at 6 months and ITN distribution at 15 months.

- Co-administer vaccines to reduce missed opportunities and enhance service coverage.
- Dispose of materials safely, return unopened vials to cold storage, and clean the vaccination site.
- Record vaccine data and update reminder cards; track defaulters for follow-up.
- A minor illness, including respiratory tract infections, mild diarrhea is not a contraindication.

5. MODULE 5: MONITORING AND EVALUATION OF THE MALARIA VACCINE INTRODUCTION

Learning Objectives

At the end of this session, participants should be able:

- To fill malaria vaccine sections in the RI data tools correctly
- To estimate coverage and Drop Out for Malaria vaccination
- To analyze and monitor trends of Malaria vaccination and other antigens
- To document AEFIs for Malaria vaccination

5.1 RI/HMIS Data Tools Capturing Malaria Vaccine and other Antigens.

The data tools for collecting and reporting data on malaria vaccinations are:

- Child Health Card
- Child Immunization Register
- Immunization Tally Sheet
- Health Facility Immunization Monthly Summary Form
- NHMIS Monthly Summary Form (Version 2019)
- Vaccine Management Tools (VM1a and 1b, VM2 & VM3)
- NHMIS Monthly Health Facility Vaccine Utilization Summary Form (Version 2019)
- AEFI forms (reporting, line listing, investigation and summary form)

5.2 How to record Malaria vaccine data using the RI/HMIS data tools

Malaria vaccinations for children should be documented similarly to other vaccines within the immunization program. During the vaccination session, all administered doses must be tallied immediately on the tally sheet and summarized at the end of the day. The date of each dose should be recorded on both the Child Health Card and the Child Immunization Register immediately following vaccination. Additionally, the next appointment date should be marked and clearly written on the Child Health Card. During the vaccination session, all administered doses must be tallied on the tally sheet and summarized at the end of the day.

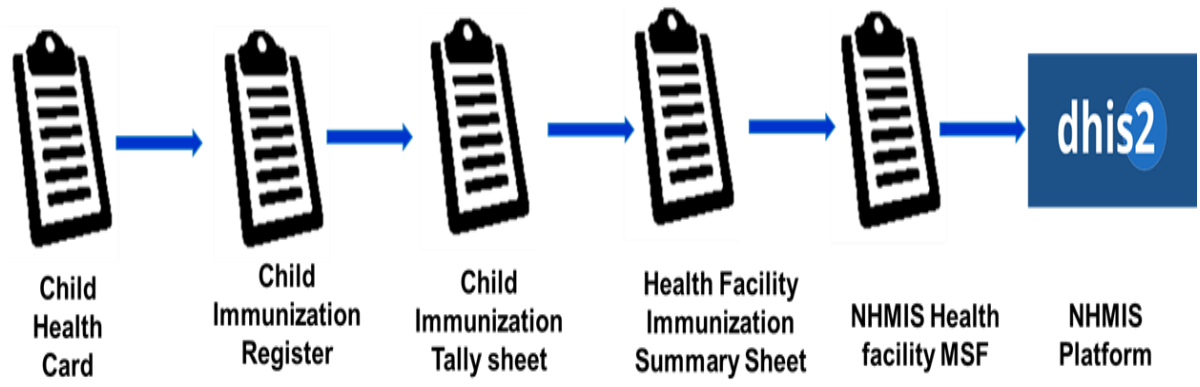


Figure 22: RI Data flow along the NHMIS data tools for Child Immunization in Nigeria

When a child arrives at the health facility, it is crucial to assess their age and previous vaccination history before determining which vaccine doses to administer. Accurate reporting and updating of Child Health Cards, as well as the Child Immunization Register and Child Immunization Tally Sheet. are therefore vital. It is also essential to remind parents of upcoming appointments and emphasize the importance of completing the full immunization schedule.

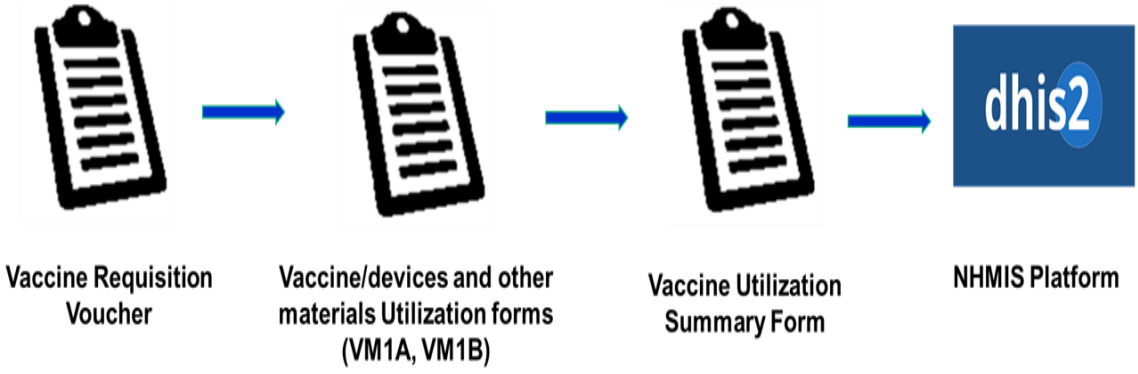


Figure 23: RI Data flow along the NHMIS data tools for Vaccines Utilization and Inventory Management in Nigeria

To optimize coverage and minimize missed opportunities, children should be vaccinated at every encounter with a health facility. Health workers should send reminders to caregivers when their children are due for immunization. Default tracking systems, which provide monthly records of children who were due but did not turn up for immunizations for each health center, should be reinforced to ensure regular follow-up. Engaging community leaders, elders, and community health workers in these efforts can significantly reduce the number of defaulters. Social mobilization is key to ensuring all children are reached and dropout rates are minimized.

Table 6: Malaria vaccine data tools and how to fill or use them

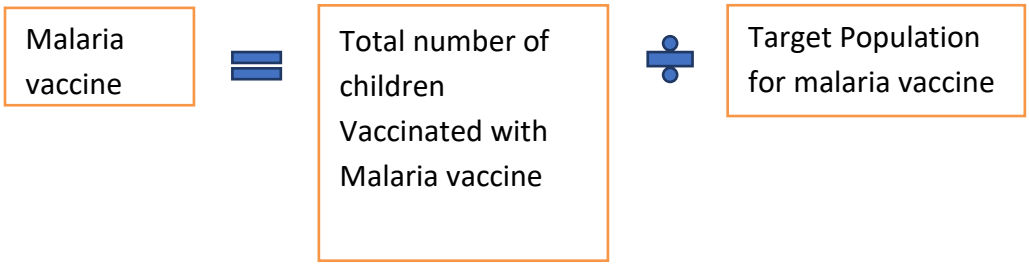
Tools	How to fill them properly
Child Health Card	Capture the child's socio-demographic data correctly. Immediately a child receives the Malaria vaccine, record the date vaccine is given and date of next visit appropriately in the row for the Malaria vaccine. Ensure all required data are correctly filled on the child health card.
Child Immunization Register	New client: Document the child's information in the appropriate settlement where the child resides. Record the date the vaccine was given in the appropriate column Follow up client: On the immunization register, identify the settlement where the follow-up child resides. Identify the child's name in the settlement Record the date of vaccine given in the appropriate column This will help in tracking defaulters.
Immunization Tally Sheet	Tally immediately after vaccination in the appropriate section of the tally sheet Ensure the number of children recorded on the tally sheets match with the number documented on the child immunization register and the health facility immunization summary
Health Facility Immunization Summary Form	At the end of every immunization session, summarize the total number of children vaccinated per antigen from the tally sheet and fill in appropriately in the immunization summary form.
VM1 A&B	Before the commencement of the immunization session, fill in the opening balance and doses/quantity of vaccines/devices received on VM1 A&B.

	After the immunization session, fill in the appropriate number of vaccines utilized
Monthly Health Facility Vaccine Utilization Summary Form	At the end of every month, summarize the doses of vaccines received and opened from VM1 A in the monthly health facility vaccine utilization summary
VM2	At the LGA level, summarize information captured on VM1 A from each HF into VM2 and openLMIS
VM3	At the LGA level, summarize information from the VM2 and vaccine stock ledger into VM3

It is important to ensure that cases of AEFI are monitored together with coverage of Malaria vaccine doses and for all antigens. This would ensure that at any point in time, several dimensions of expected safety and impact of vaccination are assessed and improved upon in the immunization program. Refer to section 6.5 for other forms that need to be filled in for AEFI.

5.2.1 Calculating Coverage for Malaria Vaccine

Malaria vaccine coverage is estimated as shown below: Note that the denominator is the target population (surviving infant: 3.2% of the total population) in the year.



Example

Gwandu LGA in Kebbi State had 54,100 surviving infants in the year 2024. The LGA introduced the Malaria vaccine in November 2024 and recorded a total of 2,104 children vaccinated. What is the coverage for the Malaria vaccine for the month of November 2024?

Answer

Coverage of Malaria Vaccine = number of children vaccinated in a specific period divided by the surviving infants during that year =

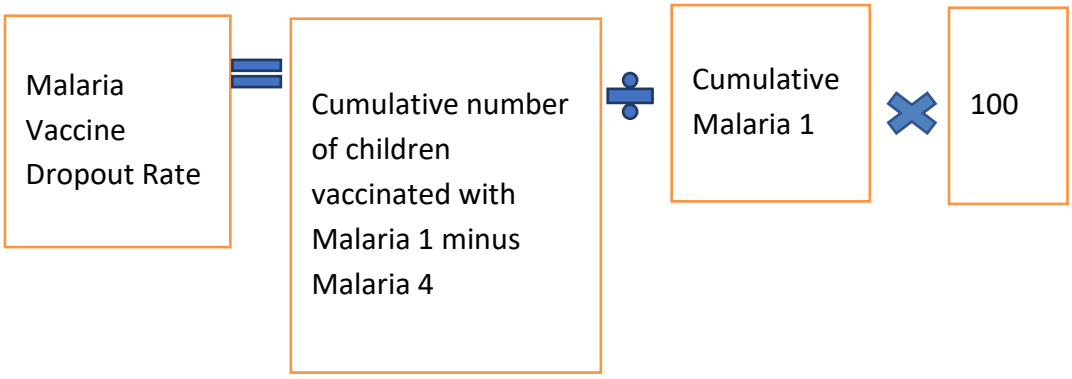
Divide the annual target by 12 months to determine the monthly target for November 2024 (=54,100/12 =4,508)

Then divide the number of children vaccinated with Malaria vaccine by 4, 508 and multiply by 100 to know the monthly coverage

(2,104/4,508) *100 = 46.67%, Approximately 47%

5.2.2 Calculating Dropout Rate for Malaria Vaccine

Malaria vaccine dropout rate is estimated as shown below: Note: Dropout rate is expected to be below 10% for a well-functioning immunization system.



Example
In the Bolo health facility in Brass LGA of Bayelsa State, 50 children were vaccinated with the first dose of the Malaria vaccine (Malaria 1), and 40 with the fourth dose of Malaria vaccine (Malaria 4) in November 2024, kindly calculate the Malaria Vaccine Drop Out Rate for Bolo H/F

Answer
Using the formula above, the Malaria vaccine Drop Out Rate will be (50-40)/50 *100 = 20%

20% is far above the expected drop-out rate of below 10%. In this case, the facility should try to ensure children who are vaccinated come back to receive subsequent doses. This can be achieved by improving the quality of services within the facility and improving defaulter tracking.

5.2.3 Key Points for Accurate Documentation of Malaria Vaccinations

- Initial Documentation: Record the child's information in the immunization register during their first contact with the health facility.
- Child Health Card: Transfer the same information into the Child Health Card immediately.
- Immediate Tallying: Tally the vaccination on the tally sheet right after administering the vaccine.
- End-of-Session Summary: At the end of each vaccination session, transfer the information from the tally sheet to the immunization summary form.
- Monthly Reporting: Summarize the facility's data on the monthly reporting forms. Also, update the vaccine stock balances on the relevant Vaccine Management (VM) forms
- A child greater than 23 months who had started malaria vaccination before 11 months and defaulted on any doses for any reason must be vaccinated for the next dose and documented in the appropriate column for that dose irrespective of his/her age.
- Update Adverse Events Following Immunization (AEFI) forms. Note: Adhere to zero reporting for AEFI where applicable. Send all summary forms to the Local Government Area (LGA) office.

- LGA Data Review: LGAs should review the data submitted by health facilities and accurately enter it into the LGA summary forms.
- DHIS2 Data Entry: LGAs should input the same information into the DHIS2 platform within the specified timelines (between the 1st and 15th of the reporting month).

6. MODULE 6: SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) DURING MALARIA VACCINE INTRODUCTION

Learning Objectives

At the end of this session, participants should be able:

- To understand the basic concepts, definitions, and types of AEFI
- To describe the process of AEFI, reporting, line listing, investigating, documenting, and data flow
- To handle and manage AEFI
- To know the roles of AEFI committees and coordinating teams at all levels.

6.1 Definition of AEFI

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable, unintended sign, abnormal laboratory finding, or symptom or disease.

6.1 Classifications of AEFI

AEFI is classified into 2

- Regulatory classification and
- Cause-specific classification

Regulatory Classification

- Non serious AEFI
- Serious AEFI

The cause-specific classification includes five categories

- Vaccine-Product related reaction
- Vaccine-quality defect related reaction
- Immunization error related.
- Anxiety related reaction
- Coincidental

6.1.1 Non-Serious AEFI

An event that is not 'serious' and does not pose a potential risk to the health of the recipient occurs within 2hrs of injection, resolves after a short period, poses little danger. 'Serious' is not synonymous with 'severe' (i.e. intensity or severity of the event)

6.1.2 Serious AEFI

This is defined as an event causing a potential risk to the health/life of a recipient leading to the following:

- Hospitalization or prolongation of existing hospitalization (e.g., encephalopathy, seizures, aseptic meningitis)
- Persistent or significant disability or incapacity (e.g., paralysis)
- Life-threatening
- Congenital Malformations
- Death

Table 7: Categories of AEFI (WHO cause specific definition)

Category	**Description**
Vaccine product-related reaction	An AEFI caused or precipitated by a vaccine due to one or more of the properties of the vaccine product itself. Example: Extensive limb swelling following pentavalent vaccination.
Vaccine quality defect-related reaction	An AEFI caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer. Example: Failure by the manufacturer to completely inactivate a batch of IPV leads to cases of paralytic polio.
Immunization error-related reaction	An AEFI that is caused by inappropriate vaccine handling, prescription, or administration, and thus by its nature is preventable. Example: Transmission of infection by the contaminated multi-dose vial.
Immunization anxiety-related reaction	An AEFI arising from anxiety about immunization. Example: Vasovagal syncope (fainting) in an adolescent during/following vaccination.
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error, or immunization anxiety. Example: A fever occurs at the time of the vaccination (temporal association) but caused by malaria. Coincidental events reflect the natural

	occurrence of health problems in the community with common problems been frequently reported

The malaria vaccine is safe and well tolerated. However, the following are some AEFI that may occur within 7 days post vaccination (mainly within 2-3 days)

- Fever
- Irritability
- Pain and swelling at injection site
- Febrile convulsions

Possible Programmatic Causes of AEFI are listed below.

- Not checking expiry date of the vaccine & diluents before reconstitution
- Not checking the VVM status of the vaccine
- Reconstitution of lyophilized vaccine using wrong diluents
- Use of unsterilized injection devices
- Wrong route of administration
- Reconstituting cold vaccine with warm diluent

6.1.3 AEFI reporting, investigation & line listing

Reporting AEFI will be done using the AEFI tools by manually filling out the tools and uploading on electronic platforms (Medsafety app and DHIS2 AEFI module), the following methods will apply;

- Health workers fill the paper reporting form for every AEFI, either serious or non-serious
- The LGA DSNO collect all AEFI reports from the health workers (in hospitals) and from the supervisor (from vaccination sites)
- The LGA DSNO enters the filled forms into the Medsafety app and sends the paper form to the state DSNO
- The State DSNOs gets the downloaded line list from the National Pharmacovigilance Center domiciled at NAFDAC Headquarters in Abuja, Nigeria.
- The frequency is weekly. Contact mail for the Pharmacovigilance Focal Person is pharmacovigilance@nafdac.gov.ng
- The state DSNO uploads the aggregate number of cases from the downloaded line list into DHIS2 after comparing with original line list.
- Community members can relay cases to health workers at vaccination posts/health facilities
- Clients can also self-report using the MedSafety App

Note: All serious AEFI must be stabilized, reported, referred for complete investigation and management in General hospitals which serve as a referral center

6.2 AEFI detection and/or notification

Prior to starting the immunization session, prepare by ensuring you have the following:

- Contact information of your supervisor
- Vaccine AEFI reporting forms
- AEFI kit with drugs to manage adverse events

Note that symptoms and signs of a severe reaction usually occur within 15 minutes. Mild side effects such as fever or injection site pain, redness or swelling are common and usually short in duration.

6.3 AEFI Management / Reporting

Reassure caregivers, show empathy and explain:

- The vaccine is safe and reduces the number of times children get sick from malaria
- An AEFI may not necessarily be caused by the vaccine; there can be other causes
- If the AEFI is serious, reassure and stabilize; do not give incorrect / false information (Refer to section 6.7 on page 75 for how to manage serious AEFI).
- Alert your supervisor immediately if there is an AEFI
- Complete the AEFI reporting form within 24 hours
- Report ALL AEFI using the standardized forms
- Answer completely all the questions on the reporting form

Why do you report an AEFI?

- To inform the occurrence of the event to the health care system i.e. from the first level to the higher levels for decision making.
- To collate data from all cases reported in a given geographic area
- To determine if there is a pattern in the occurrence of the event
- To follow up cases to ensure the client is provided care

6.3.1 AEFI line listing

All cases of AEFI will be line listed using the line listing tool and submitted through designated channels. All nonserious and serious cases are line listed. Once an AEFI is reported, it must be line listed, and the form submitted through the designated channels at the end of the day. The line list will be compared by the state DSNO to the downloads from Vigiflow. Only health workers (team supervisors, WFPs, LGA DSNOs) line list AEFI and submit through designated channels at the end of every day.

6.3.2 Reporting process of AEFI

All AEFI, whether non serious or serious, must be line listed and reported immediately by the Health Worker in- charge to the LGA DSNO by sending the AEFI reporting form and through phone calls. Community members can also report to the nearest health facility.

It is the responsibility of the National Coordinating Committee (NCC) to analyze the data and convene a meeting of AEFI National Expert Committee (NEC) to classify cases within 70 days. The outcome of classification is shared with the states, and other stakeholders then recorded in the national pharmacovigilance database.

Health workers should note that the Investigation form is extremely important, as this will form the basis on which the causality assessment will be conducted by the Expert Committee. Each next level focal point should ensure that the forms are completely and correctly filled to avoid missing information.

6.4 AEFI investigation

Only serious AEFI and clusters are investigated. The report of a serious AEFI or a cluster of AEFI should be investigated as early as possible, ideally within 24 hours of notification. Investigation is done to determine potential cause(s) and corrective measures are taken to prevent future occurrence.

The LGA DSNO in turn liaises with the SEPID/SDSNO to conduct investigation of all serious cases and sends report to the State Epidemiologist (SEPID): (FP to State AEFI Committee) The SEPID/SDSNO is expected to compile and sends reports of serious AEFI to AEFI NCC Surveillance Secretariat (aefitwg@gmail.com) domiciled at NPHCDA.

Reasons for investigation

- To identify the details of vaccine(s) administered and to determine the timing between administration of the vaccine and the onset of the event
- To confirm the reported diagnosis or establish a diagnosis
- To document the outcome of the reported adverse event
- To identify the cause of the AEFI
- To determine whether a reported event is a single incident or one of a cluster and, if it is part of a cluster, where the suspected immunizations were given and what vaccines were used
- To examine the operational aspects of the program
- To determine whether similar events are occurring in individuals who have not received the same vaccine

6.5 Data tools for AEFI documentation

AEFI surveillance data tools are available at all levels to document AEFI processes and events, the basic tools are outlined below

- **AEFI Reporting form:** The AEFI form is filled in whenever a case of AEFI is reported. The form captures information on the person, the vaccination and specific vaccine(s) administered, and the AEFI experienced. The form should be available on all vaccination sites and in all health facilities.
- **AEFI Line Listing form:** the line list form is an aggregate of all the AEFI cases reported from that vaccinate post showing critical details contained in each AEFI reporting form collated from the post.
- **AEFI Investigation form:** The investigation form provides information on basic details of person(s) and health facility, relevant patient information prior to immunization, details of first examination of serious AEFI case, details of vaccines provided at the site linked to the AEFI on the corresponding day, immunization practices at the place(s) where concerned vaccine was used, cold chain and transport details and a community investigation aspect.
- **Laboratory Request Form:** This provides basic details and is filled in whenever samples have been obtained. It is mandatory to accompany the reporting and investigation form with results obtained whenever causality assessment is required.

6.6 Contents of AEFI Kit

AEFI kits in all sites must be inspected to ensure that there is no expired medication in the kits. The minimum requirement for each site is listed below.

- <u>At the vaccination center:</u>
  - Hydrocortisone
  - 2 ml syringes and needles
  - Cotton wool
  - Analgesics e.g. Paracetamol
  - Water for injection
- <u>At Designated /Referral Health Centers:</u>
  - 5% Dextrose saline (2 x 500mls)
  - Pediatric Dextrose saline (2 x 500mls)
  - Hydrocortisone injection
  - Adrenaline injection
  - Normal saline infusion
  - IV cannula
  - Cotton wool
  - Ambu Bag
  - Gloves

- 5ml syringes and needles
- Water for dilution/ injection

Figure 24: AEFI Kits and content

6.7 Management of AEFI

It is important that during the integrated vaccination, all posts are equipped with AEFI Kits and health workers can recognize, manage, and refer AEFI cases to the designated health facilities tied to that post as may be required.

- **Non-serious AEFI** etc should be managed by the health worker by tepid sponging, giving analgesic, and observation of the client.
- **Serious AEFI** should be stabilized, reported, and immediately referred to the identified health facility for AEFI management.
- **Anaphylaxis** is a serious AEFI that may rarely occur after any injection. The patient becomes unconscious with signs of shock and breathing problems. If this occurs, the steps described below should be followed immediately:

- Call for help and attend to the patient immediately
- Reassure the patient's relations
- Check for breathing and a heartbeat
- If the patient is not breathing, secure the airway and ventilate
- If there is no heartbeat, perform cardio-pulmonary resuscitation (CPR)
- Give adrenalin 1:1000 at a dose of 0.01ml/kg up to a maximum of 0.5ml to be injected intramuscularly (or subcutaneously in very mild cases)

Table 8: Dosage for Adrenaline by Age

Age	**Dosage for Adrenaline**
Months < 2 years	0.0625 ml = 1/16 of a ml
2 – 5 years	0.125 ml = 1/8 of a ml
6 – 11 years	0.25 ml = ¼ of a ml
>11 years	0.5 ml = ½ of a ml

What should a health worker do if there is a case of AEFI reported?

- **For non-serious cases**
  - Reassure the patient.
  - Fill the reporting form
  - Contact the DSNO.
  - Commence treatment based on the symptoms
    - For mild to moderate fever (<37.5°c)
      - *Tepid sponge*
      - *Paracetamol if it persists*
    - For pain at site of injection
      - *Cold compress*
      - *DO NOT USE ICE BLOCK*
  - Advise the patient to return if the condition worsens or if there is no improvement.
- **For serious AEFI**
  - Reassure the patient, stabilize, report, alert and refer cases to designated referral centers for case management of serious AEFI.
  - Submit the reporting form to the LGA DSNO,
  - Investigation team led by the LGA DSNO should initiate case investigation with the support of the state epidemiologist /State DSNO and fill investigation form completely and appropriately

- LGA DSNO: To forward investigation forms to the state Epidemiologist /State DSNO, who will forward the information to the NCC on the same day.
- Evacuate the patient to the referral hospital with the reporting form. The LGA DSNO to ensure that the investigation form once available is added to the patient's folder in the reference hospital.
- Ensure adequate follow-up and Proper feedback to all levels. A crisis communication team should be in place to handle communication during a crisis with the aim of ensuring public confidence in immunization services is maintained. It should be a joint team to include members from the communication team.

6.8 AEFI committees at the National, State and LGA levels.

6.8.1.1 National Expert Committee (NEC)

At the national level, the highest body is the National Expert Committee (NEC). The NEC is responsible for the evaluation of the performance of the AEFI surveillance, of investigated AEFI (causality assessment) and of any signal detected (data mining). It is also involved in the investigation of serious AEFI and the supervision of reference hospitals. The NEC is supported by the National Coordinating Committee (NCC) on AEFI which provides technical support on the implementation of AEFI surveillance in the country. The NEC submits its results to the NPHCDA for the NITAG and to the NAFDAC.

Membership: Academia and other pool of experts.

6.8.1.2 National Coordinating Committee (NCC)

The NCC receives reports of all AEFI and investigates serious and unusual AEFI (clusters, cases of public concern). The NCC ensures that regular supervision is ongoing and the performance of the AEFI surveillance is being improved accordingly. It also provides the interface between the National Expert Committee and clinicians in charge of suspected serious AEFI for investigation and appropriate treatment.

Membership

- WHO
- FMOH
- NAFDAC
- NPHCDA as secretariat.

6.8.1.3 State/LGA AEFI Committees

The AEFI Committees at the State and LGA are responsible for the overall coordination of all matters relating to AEFI. They conduct regular supervision, follow up that a

pharmacovigilance supervision form is filled whenever a joint supervision is conducted and also monitors the performance of all LGAs.

Membership (State)

- DDCI
- State Epidemiologist
- DSNO
- SIO
- Clinician/Pediatrician
- Lab scientist
- Health Educator.

Membership (LGA)

- DPHC
- DSNO (secretary) of the committee
- LIO
- Health Educator

7. MODULE 7: DEMAND GENERATION/ADVOCACY, COMMUNICATION, AND SOCIAL MOBILIZATION (ACSM) FOR MALARIA VACCINE INTRODUCTION

Learning objectives

At the end of the module, you will have learned to:

- Identify, map, and effectively engage diverse stakeholders, including government officials, healthcare providers, and community leaders, to foster support for the malaria vaccine introduction and increase its acceptance within the community.
- Develop skills in creating clear, concise, and culturally appropriate key messages about the malaria vaccine's benefits, safety, and role in malaria prevention.
- Explore various community engagement activities and techniques to mobilize community support for vaccination efforts and encourage participation in malaria prevention initiatives.
- Understand how to develop and implement effective risk communication and rumor management strategies to address misinformation and vaccine hesitancy.
- How to design and implement monitoring and evaluation frameworks

7.1 Introduction

Demand Generation, encompassing Advocacy, Communication, and Social Mobilization (ACSM) interventions is essential for a successful introduction and uptake of a new vaccine including the malaria vaccine.

Parents and caregivers will be provided with key messages on:

- Malaria vaccines, such as the development process for the malaria vaccine, its benefits, safety and efficacy, the value add of the vaccines as a tool when taken alongside other tools e.g. ITNs, potential side effects.
- Malaria prevention and treatment in general, and iii) the need to continue to use other available malaria control measures.

Additionally, the demand generation interventions aim to boost the vaccination uptake, increase public awareness, engage key stakeholders such as government officials and community leaders, as well as address vaccine hesitancy by dispelling myths, fake news or misinformation and ensuring the public receives accurate information.

Effective communication and community engagement will raise awareness, manage risks, and significantly increase vaccine acceptance and uptake, ultimately reducing the burden of malaria. This training module will equip participants with the knowledge and skills needed to

engage stakeholders including communities, communicate key messages, and support malaria vaccine introduction.

Objectives

Participants in this training will learn:

- How to identify, map, and engage stakeholders effectively,
- Develop and communicate key messages about the malaria vaccine and other complementary tools
- Engage communities to support the vaccination introduction and demand for the vaccines.
- Develop risk communication and crisis management strategies to routinely collect, analyze and address rumours about the vaccine or crises that may arise.

Key Concepts

The ACSM strategy for malaria vaccine demand encompasses three primary components:

- Advocacy
- Communication
- Social Mobilization

Advocacy involves identifying and engaging influential leaders and stakeholders and other interest holders to support, promote, and champion the malaria vaccine introduction and administration. Communication ensures the right messages reach the right audience through the most effective channels. Social Mobilization focuses on involving communities and stakeholders in promoting the vaccine and ensuring widespread acceptance.

7.2 Engaging Stakeholders

Stakeholder engagement is the foundation of any successful ACSM strategy. It involves identifying relevant stakeholders, understanding their influence and interests, and actively involving them in the vaccine introduction process. Effective stakeholder engagement ensures that all key players, from government officials to community leaders, are aligned in their support for the malaria vaccine and influence public opinions and behaviors positively, in support of the vaccine. Engaging right from the planning stages to implementation and follow up stages is critical to ensure effective coverage and malaria vaccine uptake.

7.2.1 Identifying and Mapping Stakeholders

As part of the pre-implementation activities to be conducted, all potential stakeholders, including government officials, healthcare workers, community and religious leaders, teachers, and organizations like CSOs, NGOs, and CBOs should be identified and listed. Once identified, categorize these stakeholders based on their influence and interest in the vaccine

rollout. Prioritizing engagement with those who have influence and interest is crucial for success. Similarly, the mapping process should identify stakeholders whose interests may conflict with, or oppose the vaccine introduction, in order to understand their concerns and mitigate them.

7.2.2 Engagement Strategies

Stakeholder Engagement will happen at different levels (National, State, LGA and ward). Engaging stakeholders requires a tailored approach. Some stakeholders identified will be engaged through advocacy meetings to discuss the benefits of the malaria vaccine and to secure their support. While more technical stakeholders such as healthcare workers, CSOs/CBOs, and media will be engaged through workshops and training sessions as they are positioned to educate groups on their roles in the vaccine rollout. Regular communication and information sharing will be maintained throughout the vaccine introduction to keep stakeholders informed and engaged.

Based on existing data on Immunization knowledge, attitudes, perceptions, barriers, and enablers, develop an evidence-based contextualized communication plan for the state or LGA. Develop a clear audience segmentation to identify the most appropriate message and channel of communication for each target audience. A costed crisis communication plan should also be integrated within the communication strategy to address any AEFIs, myths, misconceptions and resistance that may arise from the vaccine.

7.3 Advocacy

Advocacy is a process. It is about influencing decision-makers and key stakeholders to support the malaria vaccine introduction and administration. To do this effectively, clear advocacy plans should be developed to include well defined goals and smart objectives aimed at priority audience, crafting persuasive messages, choosing the right activities, and indicators for monitoring progress.

7.3.1 Defining Goals

Start by clearly articulating what you want to achieve. For instance, your goal might be to secure additional funding from the Government or private sector for the vaccine rollout. Once the goal is set, identify the decision-makers who can help you achieve it, such as government officials, health policymakers, philanthropists or donors.

7.3.2 Developing Messages

Your messages should be clear, concise, and tailored to your audience's characteristics, needs, and roles. For example, when addressing government officials, emphasize the public health benefits, cost-effectiveness, and potential for reducing malaria-related mortality and

morbidity. When speaking to community leaders, focus on the positive impact on community health and well-being and their crucial role in promoting the vaccine. or the media emphasize benefits, access points and focal persons for the vaccines across all levels.

Advocacy in Action:

Consider a situation where the national government is hesitant to allocate additional funding for the malaria vaccine due to budget constraints. In this scenario, you might organize a high-level meeting with the State Governor, supported by HCH, a coalition of health NGOs and CSOs. By presenting compelling evidence, you could persuade the Governor to reallocate funds to support the vaccine rollout.

Potential resource: SMART Advocacy Guide.

7.3.3 Communication

Effective communication is essential to ensure that the public understands the benefits of the malaria vaccine, believes it is safe and efficacious, trusts the vaccination process, feels confident in their ability to obtain the vaccine, and actively participates. To achieve this, disseminating messages through the most effective communication channels and monitoring the impact of your efforts are crucial. Additionally, enhancing access to vaccination by addressing access barriers and ensuring equitable access to malaria vaccine services for vulnerable populations is another critical strategy.

7.3.4 Defining behaviors and communication objectives

Core elements of an effective vaccine communication plan are clearly defined behaviors and communication objectives for identified priority audience. Objectives should be specific, measurable, achievable, realistic and time-bound (SMART). The objectives should also guide tailored message development and inform the selection of indicators to track and measure progress as vaccine introduction and administration rolls out.

Primary behaviors of interest for priority audience that can be tailored to contexts, based on needs and gaps assessed and identified are outlined below:

- Seek malaria vaccine for their children.
- Adhere to the malaria vaccination schedule.
- Continuous use of other malaria control interventions (i.e. ITNs).
- Seek prompt care for fever.

Among providers offering the malaria vaccine, there are five primary behaviors:

- Promote malaria vaccine acceptance, timely and full vaccination according to the schedule among caregivers of eligible children.

- Promote the use of other malaria control interventions and continued care seeking for fever among caregivers.
- Administer the malaria vaccine in accordance with national guidelines.
- Share information about the malaria vaccine.
- Monitor, address, and report mis/disinformation or information voids about the malaria vaccine as well as AEFI cases.

7.3.5 Selecting Communication Channels

Different audiences respond to different communication channels. Mass media, such as television and radio, can reach a broad audience with high-impact messages.

Evidence supports the effectiveness of carefully deployed mass media channels in increasing knowledge, including functional awareness on where and how to obtain services, influencing norms and promoting communal action in support of a behavior.

Social media is particularly effective for engaging younger audiences and urban populations. Interpersonal communication channels, including compound meetings, dialogues, household visits, local events and others, allow for in-person message delivery that can be tailored to cultural and individual contexts and are very effective for teaching skills or addressing misinformation and misperceptions. Additionally, interpersonal communication by trained healthcare workers ensures that individuals receive accurate information directly.

Effective communication strategies often deploy a mix of channels, maximizing exposure among priority audiences, delivering harmonized messages across channels which in turn creates the needed reinforcement at an intensity that spurs intention and action. Channel-mix plans, developed for specific contexts, identifies the types of communication channels that best reach the priority audience, based on past impact, audience needs and preferences, and channel availability. It also includes recommendations for how to combine different channels based on the advantages and disadvantages of each, and the fit between the message and the channel, as well as the appropriate timing and scheduling of the messages.

For instance, in rural communities, where access to healthcare may be limited during peak malaria seasons, you might emphasize the vaccine's role in protecting children. This message could be delivered through religious gatherings, and village meetings, where local leaders discuss the benefits of the malaria vaccine and answer community members' questions.

7.4 Social Mobilization

Social mobilization involves engaging communities and stakeholders to actively support the malaria vaccine introduction. It is a collective effort by diverse stakeholders to ensure optimal vaccination uptake in a target population by generating and sustaining demand for vaccines, using community-based participatory approaches. This process ensures that the vaccine

reaches the target population and that community members are motivated to participate in the vaccination campaign.

7.4.1 Building Community Support

To mobilize communities effectively, start by identifying community leaders and influencers who can advocate for the vaccine. Engage these leaders in discussions about the vaccine's benefits and address any concerns they may have. By securing their support, you can leverage their influence to encourage community members to participate in the vaccination campaign.

7.4.2 Community Engagement Activities

Organize community events, compound meetings, community dialogues, announcements in religious houses, rallies/roadshows, etc. where information about the malaria vaccine can be shared. These events provide opportunities for direct interaction with the community, allowing for questions to be answered and concerns to be addressed. Additionally, partner with local organizations, such as CSOs and CBOs, and leverage other community structures to extend your reach and reinforce your messages within the community.

7.5 Monitoring and Evaluation

Monitoring and evaluating communication efforts are crucial for ensuring effectiveness. Conduct a baseline survey before implementation to gauge current awareness and attitudes toward the malaria vaccine. Rapid, agile survey methodologies are encouraged to improve timeliness of data availability for continued adjustment to strategies and messages. Agility can be achieved by incorporating data collection on how audiences think, feel, intend to or act on the messaging provided during community-level interpersonal communication activities or through short telephone or social media polls, repeated over a period of time to aggregate data that inform message, communication channel or overall strategy shifts.

The WHO six prioritized questions on behavioral and social drivers (BeSD) adapted for the malaria vaccines can be rapidly incorporated into existing community listening tools. After your communication activities, evaluate their impact by measuring changes in awareness, attitudes, and vaccine uptake. This ongoing assessment allows you to adjust your strategies as needed to maximize their effectiveness.

7.6 Risk Communications (Rumor Management) for Malaria Vaccine

Risk communication and rumor management are crucial aspects of promoting the malaria vaccine and addressing any concerns or misconceptions that may arise. Existing risk communication teams at the national and sub-national levels should be equipped to manage risk communication for optimal program performance.

Rumors and misconceptions, if unchecked, can quickly spread beyond the local area and negatively impact malaria vaccine acceptance.

7.6.1 Steps to follow for effective risk communication and rumor management

- Activate the risk communication team, where inactive.
- Identify the source and understand the context of the rumor (extent and type of messages circulating about the malaria vaccine) and.
- Determine the individuals or groups disseminating the rumor and devise strategies (either directly manage or through higher officials) to educate them.
- Determine the causes of the rumor—whether it stems from a lack of information, religious/cultural bias, political opposition, personal beliefs, or propaganda.
- Collate accurate messages tailored to addressing the rumor.
- Engage the sources of the rumor to enlighten them and seek to diffuse the misinformation.
- Target and sensitize prominent and credible opinion leaders (community leaders, institution leaders) in the affected locations and seek their support to address the rumor.
- Identify and utilize every appropriate occasion (community celebrations, peer-to-peer interactions, social functions) to disseminate information on the malaria vaccine.
- Liaise with the state ACSM team to address rumors and disseminate accurate messaging through available channels.
- Identify media sources that have propagated misinformation and use the same platforms to disseminate correct information.
- Continue to track and address myths and misconceptions about the malaria vaccine by monitoring social media, online platforms, and community listening.
- Evaluate the effectiveness of your risk communication and rumor management strategies. Monitor vaccine uptake rates, conduct surveys or focus groups to assess public perceptions, and adjust your messaging or approach as needed.

Other areas of focus include:

- Leverage crisis communication structures at all levels to effectively coordinate and manage crises.
- Ensure prompt and effective management of Adverse Events Following Immunization (AEFI) and establish functional referral systems for expert management.
- Continuously sensitize the public and create awareness on the importance of malaria vaccination through available channels.

- Collaborate with relevant Ministries, Departments, and Agencies on rumor management

7.7 Key Messages

The following summarizes the key message themes around promotion of malaria vaccination and other malaria preventive measures and the desired outcomes for each audience derived from the country's malaria vaccine introduction communication plan. These themes address the knowledge, attitudes, and practices gaps identified in the preliminary findings from the recently concluded malaria vaccine rapid assessment conducted in Kebbi state.

7.7.1 Key messages for primary audiences - parents and caregivers

Key messages	Desired outcomes
● The FMOH through the NPHCDA is introducing a malaria vaccine into Nigeria's routine immunization schedule in phases, starting with Bayelsa and Kebbi states, to reduce morbidity and mortality of children due to malaria. ● Malaria is a vector-borne disease caused by malaria parasites spread from person to person through the bite of the infected female Anopheles mosquito. ● Malaria incidence can be reduced by vaccinating eligible children with the malaria vaccine, which is provided free of charge in public health facilities. ● It is important that your child receives all doses of the malaria vaccine (provide accurate information on the month's interval between the 1st dose and other doses). ● Take your children aged 5-15 months for immunization with the malaria vaccine at nearby public health facilities. ● Your child can receive the malaria vaccine together with other routine vaccines. ● Multiple vaccinations have been shown to be safe, your child will be more protected from malaria when they get vaccinated and continue to use other preventive measures, such as LLINs, for improved protection. ● During the phased introduction, some states may have the opportunity to introduce the vaccine, and other states may not introduce the vaccine until a later date. This will help the NPHCDA learn how to best scale up	● Acceptance of and demand for malaria vaccine. ● Sustained use of other malaria interventions. ● Compliance with the schedules of malaria vaccination and other routine vaccines in the RI schedule. ● Understanding the importance of completing the malaria vaccination for optimum protection ● Understanding the importance of multiple malaria prevention through vaccination and use of other malaria interventions. ● Reduced rumors and misinformation on the malaria vaccine

the introduction of the malaria vaccine into the routine immunization schedule. ● During the phased introduction, it is important that your child receives all the four doses and properly indicate in the child's immunization card to enable the health authorities understand how to best scale-up the malaria vaccine introduction into the routine immunization schedule.	

7.7.2 Key messages for secondary audiences - healthcare workers

Key messages	**Desired outcomes**
● The FMOH through the NPHCDA is introducing a malaria vaccine into Nigeria's routine immunization schedule in phases, starting with Bayelsa and Kebbi states, to reduce morbidity and mortality of children due to malaria. ● Malaria is a leading killer in children younger than 5 years. In Nigeria, one in every 1000 under 5 deaths can be attributed to malaria. ● Malaria infection in children can be prevented by immunization with the malaria vaccine. It will be offered free of charge to all targeted children in public health facilities, along with other routine vaccines. ● The malaria vaccine will be given in 4 doses - 4 weeks apart for the first 3 doses, and the 4th dose at 15 months of age. ● The malaria vaccine is safe, even if administered with other vaccines in the routine immunization schedule. ● Inform caregivers of the benefits of vaccination against malaria (prevention of malaria illness). ● The malaria vaccine has a high safety profile; however, it will be important to monitor and report any adverse events following immunization. ● Reassure caregivers of the safety of the malaria vaccine, and advice about possible side effects (adverse events following immunization) and when to seek care from a service provider. ● Inform caregivers that the child should continue to sleep under an LLIN every night, during every season for maximum protection from malaria. ● Arrange the return date for the next vaccination.	● Acceptance of the vaccine among health workers ● Healthcare workers advocate for malaria vaccine uptake to targeted populations and the general public as a preventive strategy. ● Health workers administer malaria vaccines to eligible populations as per guidelines. ● Reduced rumors and misinformation on the malaria vaccine

● During the phased introduction, some states may have the opportunity to introduce the vaccine and other states may not introduce the vaccine until a later date. This will help the NPHCDA learn how to best scale up the introduction of the malaria vaccine into the routine immunization schedule. ● Inform caregivers that during the phased introduction, it is important that their child receives all the MV doses and properly indicate in the child's immunization card to enable the health authorities understand how to best to scale-up the malaria vaccine introduction into the routine immunization schedule	

8. MODULE 8: GENDER AND MALARIA VACCINE INTRODUCTION

Learning objectives

At the end of the module, you will have learned to:

- Understand basic concepts regarding sex, gender and how these affect health
- Identify gender barriers and think through how these could impact the successful introduction of the malaria vaccine
- Make sure immunization programmes are gender-responsive

8.1 Understanding the difference between Sex and Gender

In the context of health, it is essential to understand the distinction between *sex* and *gender*, as each concept has different implications.

- **Sex** is a biological characteristic. It refers to biological attributes, physical and physiological features, and is generally assigned at birth based on the appearance of external anatomy or genitalia. These characteristics typically include aspects like chromosomes, hormone levels, and reproductive organs.
- **Gender**, on the other hand, is a social construct. It encompasses norms, roles, and relationships that vary significantly from one society to another and can evolve over time. Gender is often hierarchical and frequently reflects unequal power dynamics, impacting various social and health outcomes.

8.2 Gender and reaching the unreached

Gender does not exist in isolation; it intersects with various other social and individual characteristics, such as race, ethnicity, religion, age, disability, geography, education, culture, income, and sexual orientation to influence social inequalities and health outcomes. These intersections can either hinder or facilitate access to health services, including vaccinations, by shaping individuals' experiences, resources, and perceived barriers.

Scenario 1: a father with higher socioeconomic status may have the education, financial means, and confidence to take his child for vaccination, knowing he will be supported and respected in this decision. However, a father from a low-income background may face stigma or feel reluctant, fearing judgment or even ridicule from his community for doing the same.

Scenario 2: Imagine a young mother in a conservative community where women are expected to stay at home and focus on household duties. In this community, men usually make the decisions about healthcare, and women need permission from their husbands to travel or visit health centers. If this young mother’s child needs a vaccination, she may face several

barriers. She might have to wait for her husband's permission to take the child to the clinic, and if he's busy or doesn't prioritize the vaccination, there could be delays. Additionally, the clinic may be far away, and if there is no public transportation or if it is considered unsafe for her to travel alone, she might not be able to go.

Such examples highlight how multiple social factors can work together to either empower or create barriers for individuals in accessing health services. Understanding these dynamics is important, especially when introducing new vaccines like the malaria vaccine.

Exercise: Consider other examples of how gender may intersect with other factors to impact health outcomes. For example:

- How might a woman from a rural, low-income background face additional challenges in accessing vaccination services?
- In what ways could cultural norms around gender roles in different communities affect immunization practices?

8.3 Gender and malaria in Nigeria

In Nigeria, men, women, boys, and girls can have different risks and challenges when it comes to malaria. Below are some key points:

- **Household duties and mosquito exposure:** women often have household chores like cooking in the evening or early morning, which are peak mosquito-biting times. This puts women at a high risk of getting malaria than men who may be indoors during these times. However, on the flip side.
- **Employment, evening get-togethers, and mosquito exposure:** men often work or socialise outside during the day, especially in agricultural or manual labor roles, which increases their exposure to mosquitoes during peak biting times. This places men at a high risk of contracting malaria compared to women who may be indoors during those hours, engaging in household duties or other indoor activities.
- **Sleeping arrangements and Net use:** in some families, men may sleep outside or take insecticide-treated nets (ITNs) for themselves, leaving women and children unprotected. Sleeping without a net increases the risk of mosquito bites and malaria.
- **Self-medication and healthcare visits:** men in Nigeria often treat themselves for malaria at home instead of going to a health clinic, which can delay proper treatment. Women, who often care for children, are more likely to visit health facilities regularly, even when malaria is not suspected.

- **Health facility use:** women are more likely to take children to clinics, which helps children get treatment sooner. Men are less likely to go to a clinic unless they feel very ill, which can lead to worse outcomes.

8.3.1 Implications for malaria programs

Malaria programs in Nigeria can be more effective by recognizing these gender differences. For example:

- Providing more mosquito nets or creating safe indoor cooking options could help protect women.
- Encouraging all family members, including men, to sleep under nets can reduce malaria risk.
- Health campaigns can educate men on the importance of getting timely treatment instead of self-medicating.

What are gender-related barriers to immunization?

- Gender impacts immunization both on the demand side, through people's health seeking behaviours, and the supply side provision of health services.
- Gender barriers to immunization operate at multiple levels, from the individual and the household to the community and health systems.

Figure 25: Supply versus demand side for gender and immunization

Source: Why gender matters: immunization agenda 2030. Geneva.2021

Demand-side gender barriers (health seeking behaviors)

- Limited decision-making autonomy
- Lack of control over time/resources (including mobile phones)
- Mobility restrictions (sociocultural, security)
- Lower education & health literacy
- Gender-based violence (GBV) and harmful practices (including child marriage)
- Lack of men's/father's involvement in care

Supply side gender barriers (provision of services)

- Cultural/religious preference for female vaccinators

- Poor working conditions/gender discrimination/workplace harassment - high staff turnover
- Inconvenient service hours
- Poor treatment/service experience (e.g. toward young mothers or male caregivers)
- Limited representation of women in managerial and decision-making positions

Discussion

- Do you face any gender barriers in carrying out your work?
- Do you have suggestions or ideas that could address these?

8.4 Addressing Gender barriers to improve childhood vaccination in Nigeria

In Nigeria, various gender-related barriers affect men and women's ability to access healthcare services for themselves and their children. Understanding these barriers is essential to creating effective vaccination programs that reach more families and protect children against diseases like malaria. Below are some common barriers and potential strategies to address them:

8.4.1 Barrier 1: Limited mobility, time, and access to resources for women

In many communities, mothers are regarded as the primary caregivers for young children. However, many women often lack the resources, time, and mobility to access health services. This limitation restricts their ability to bring their children in for vaccinations and to seek care for themselves.

Adapting vaccination services to address this barrier:

- **Bring vaccines closer to women:** offer vaccines at locations women already visit, such as local markets, community gatherings, and places of worship.
- **Provide flexible vaccination hours:** consider extended or flexible hours for vaccination clinics, making it easier for women who have busy schedules or limited mobility.
- **Tailor communication plans:** develop communication strategies that are tailored to the local community and involve women and girls in their design, ensuring that messages are accessible and relevant.

8.4.2 Barrier 2: Social expectations around masculinity limit men's engagement in child healthcare

In many communities, social expectations around masculinity can create barriers for men seeking healthcare. Men may be expected to prioritize work and financial responsibilities

over personal health, which can lead them to delay or avoid seeking healthcare services, including vaccinations for their children. Additionally, health facilities are often set up in ways that focus on maternal and child health, which can make men feel out of place or unwelcome when they accompany their children for vaccinations.

Strategies to address this barrier:

- **Flexible health services:** offer flexible clinic hours, such as evening or weekend vaccination times, to accommodate men's work schedules.
- **Male-focused outreach programs:** develop outreach programs specifically targeting men, emphasizing their role in supporting family health and encouraging them to participate in health-related decisions.
- **Male-friendly healthcare spaces:** make health centers more welcoming to men by ensuring they feel included and valued when they visit, possibly through male-friendly communication materials and involving male healthcare workers or volunteers in these programs.

8.5 Key Points to Note

- Gender-related barriers and gender inequality can prevent adults, both men and women, and prevent children, both boys and girls, from getting vaccinated.
- Gender barriers to immunization affect both the demand for vaccination and the provision or supply of those services.
- Make sure vaccination services are gender-responsive to help improve the performance of the programme.
- Men and women are affected by gender barrier:
    - **Men** may miss critical opportunities to learn about and engage in their children's healthcare, reinforcing a cycle of disengagement and limiting their awareness of health needs.
    - **Women** often bear the full responsibility for taking children to health facilities, even if they lack the resources, time, or support to do so effectively, leading to delays or missed vaccinations for their children.