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Barriers to Uptake of RTS, S Malaria Vaccine in a Malaria Endemic Area of the Western Kenya

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Abstract

Background: Globally in 2021, there were an estimated 247 million malaria cases in 85 malaria-endemic countries which accounted for over 619,000 deaths worldwide. An estimated 27 million malaria cases and 12,600 deaths attributed to malaria in Kenya in the year 2020 (1). In every 1000 live births, 84 die before attaining 5 years in Kenya(12). Despite the implementation of several malaria prevention measures, malaria infection is still high in Kenya with children under the age of 5 being most vulnerable. As a complimentary to the existing malaria prevention measured, there is a malaria vaccine for children under 5 years of age. However, there is a low uptake, especially the 3rd and 4th doses with limited information on the reasons for the low uptake. This study aimed at identifying reasons for the low uptake of RTS, S malaria vaccine in Muhoroni sub-county Kenya.

Methods: The study employed an exploratory study design. A purposeful sampling method was used to select participants for focus group discussions (FGDs) and the key informant interviews (KIIs). Four FGDs were conducted, 3 of them involved 25 parent/guardian whose children either completed or didn't complete the recommended 4 doses or didn't receive the vaccine at all, and 1 FGD involved 11 community health volunteers (CHVs). The KII involved 11 nurses in charge of maternal and child health (MCH) clinics. FGDs and KIIs guides were used for data collection. Data was analyzed thematically using NVIVO version 12.

Results: The gaps in malaria vaccine implementation are inadequate knowledge about the vaccine to both parents/guardians and nurses, vaccine side effects and high number of doses. Others are the poor attitude of health care providers, vaccine unavailability, understaffing of the health providers resulting in long waiting times, and migration to non-implementing sub-counties.

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Conclusion: Barriers for malaria vaccine uptake were: Inadequate knowledge about the vaccine, vaccine side effects and number of doses, poor attitude of health care providers, migrations, vaccine unavailability, long waiting queue due to staff understaffing, economic activities, cultural beliefs and inadequate trainings of nurses.

Keywords: Malaria vaccine, vaccine implementation, malaria endemic area.

1. Introduction.

1.1 Introduction to the problem.

Globally in 2021, there were an estimated 247 million malaria cases in 85 malaria-endemic countries, which accounted for over 619,000 deaths worldwide, this was a 12% increase from 2019 (2). WHO African region bears the highest burden of 95% of all cases, 96% of all deaths, and 79% in children under five (1, 3,4) .

In 2020, Kenya reported an estimated 27 million malaria cases and 12,600 deaths attributed to malaria (1)**.** Malaria infection is one of the leading cause of morbidity and mortality in Kenya, with approximately 25 out of 35 million Kenyans being at risk of Malaria (12). In every 1000 live births, 84 of them die before attaining 5 years in Kenya and malaria is one of the major cause of their deaths (12). In 2020, malaria prevalence in the Lake endemic zone in Kenya was 19% (5). This prevalence is still high despite Kenya implementing several prevention strategies including chemotherapy, insecticide-treated mosquito nets (ITNs); indoor residual spraying (IRS); accurate diagnosis and prompt treatment with artemisinin-based combination therapies (ACTs); and intermittent preventive treatment of pregnant women (IPTp) (6). As a complementary strategy to the existing malaria prevention in children, on April 24, 2017, the World Health Organization (WHO) announced steps to make the RTS, S/AS01E vaccine available to three sub-Saharan Africa (SSA) countries: Ghana, Kenya, and Malawi(13). The malaria vaccine known as Mosquirix, RTS, S/AS01, or simply RTS, S is the first vaccine proven to offer partial protection against malaria(14). In 2018 WHO launched a pilot implementation in Kenya, Ghana, and Malawi to further evaluate the safety, effectiveness, and real-world implementation of a malaria vaccination program, including to understand the feasibility and uptake of the four-dose primary series vaccine schedule (15). This pilot implementation of the RTS, S/AS01 vaccine (RTS, S) demonstrated its efficacy against clinical and severe malaria in children following a four-dose schedule starting at five months(16). The vaccine showed partial protection against malaria and has been found to reduce malaria incidence by 39% and 29% severe malaria among children aged 5–17 months after taking all four doses (13). Additionally, RTS, S/AS01E vaccine was associated with a reduction in overall hospitalizations, and hospitalizations due to malaria, severe anemia, and the need for blood transfusion (17).

On October 6, 2021, WHO recommended widespread use of RTS, S for children in sub-Saharan Africa and areas with moderate-to-high Plasmodium falciparum transmission as part of comprehensive malaria interventions (3, 18).WHO uptake target for all the RTS, S doses is

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90%(8). However, studies done have shown poor uptake of the RTS, S vaccine, especially the last two doses. A study done in Sunyani in Ghana in 2021, indicated that uptake of RTS, S 1st dose was 94.1%, 2nd dose 90.6% and 3rd dose 78.1%, no clear information about 4th dose was published (14), this shows that the third dose did not meet WHO target with no information captured about the fourth dose. A study conducted in Nigeria to assess the impact of vaccine stockouts on the uptake of vaccinations revealed that the dropout rate for RTS, S 1 and RTS, S 3 has been below 10% and this emphasizes the strong performance of the immunization program particularly in the first year of life although there are regional and district disparities (19). Occasional shortages of RTS, S vaccines at the facility level due to local distribution challenges in some districts affected availability and resulted in missed opportunities for vaccination (19).
A study done in the western region of Kenya which examined the malaria vaccine coverage estimation using age-eligible populations and service user denomination revealed that overall, service-based malaria vaccine coverage was 96%, 87%, 78%, and 39% for doses 1–4 respectively. Based on the population-derived denominator for age-eligible children, vaccine uptake was 78%, 68%, 57%, and 24% for doses 1–4, respectively (20). It is only the first dose of a service-based malaria vaccine that met the WHO target of 90%, the rest did not.

A study done in Muhoroni sub-county Kenya which was assessing uptake of RTS, S vaccine, and risk of malaria infection due to non-compliance among children 6-36 months in western Kenya showed a very poor uptake of the vaccine, the uptake was 72.1%, 66.8%,59.4% and 31.4% for the 1st,2nd,3rd and 4th dose respectively(21). This showed poor RTS, S uptake in this sub-county vaccine.

To achieve full vaccine protection, a child is required to receive 4 doses of RTS, S (At 6months, 7 months, 9 months and 24 months), high number of incomplete dosages as seen in various studies above is a major concern since these children won't get full vaccine protection (3). It is very important to achieve the WHO RTS, S uptake target of 90% for all the doses (14). It is therefore important to identify reasons for low malaria vaccine uptake in the Muhoroni sub-county, an endemic area of western Kenya. By improving the uptake, the children will have 39% vaccine protection hence reducing malaria prevalence in children and eventually malaria-related loss of life. This study therefore investigated the gaps in the implementation of the malaria vaccine which may lead to the poor uptake of this vaccine.

2. Method

2.1 Study area

The study was conducted in September 2023 in Muhoroni sub-county in Kisumu County, western Kenya (Figure 1). The sub-county is located 50 kilometres east of Kisumu City and is one of the seven sub-counties in Kisumu County namely, Muhoroni, Kisumu East, Kisumu West, Kisumu Central, Nyakach, Nyando, and Seme. Muhoroni is a mostly rural area, with a total population of 154,116 individuals, 76,770 males and 77,345 females. The sub-county spans an area of 667.30 square kilometers and the major economic activities of the residents are

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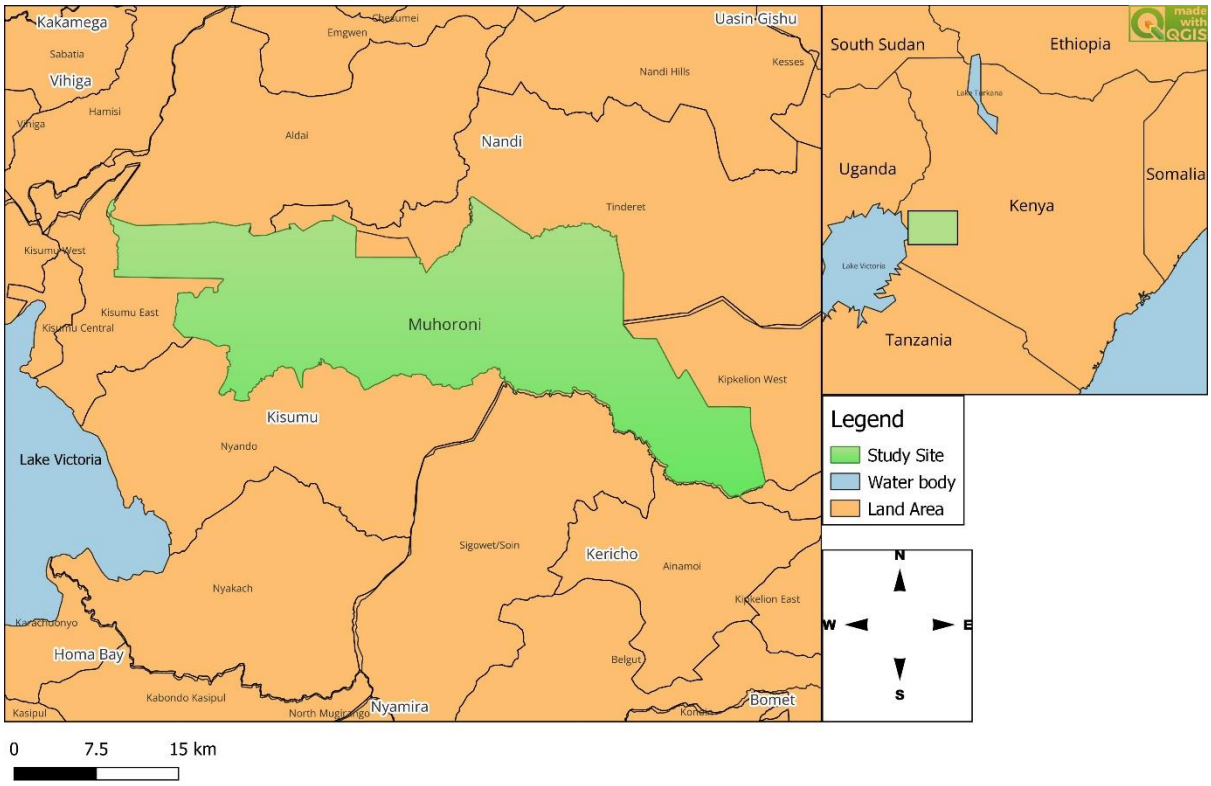
farming, mainly sugarcane and rice and small-scale trade. Malaria prevalence in Muhoroni sub-county is estimated to be around 18%(23). The subcounty was selected since it was the only rural sub county rolling out malaria vaccine in Kisumu County in 2019 with the rest (Kisumu east and Central) being in town and cosmopolitan set up, this was before the roll out was expanded to other sub counties. Muhoroniis swampy and prone to flooding during the rainy season. Malaria transmission in the area is perennial with an annual peak in May to July during the long rainy season (22) .

Figure 1. A Map Muhoroni sub-county, western Kenya.



2.2 The study population

The study population consisted of 25 parents/guardians of which, 10 were parents/guardians whose children completed the recommended 4 doses, 6 parent/guardian whose children did not complete the recommended 4 doses, 9 parents/guardians whose children did not receive any RTS,S dose, 11 Community Health Volunteers (CHVs), and 11 nurses in charge of maternal and child health (MCH) clinics where childhood vaccines are administered.

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2.3 Study design

This study used exploratory study design. Focus Group Discussions (FGDs, n=4) and Key Informant Interviews (KIIs, n=11) were conducted with the purposively selected respondents. The respondents for the FGDs consisted of four categories: parent/guardian and Community Health Volunteers (CHV). Category one consisted of parent/guardian whose children completed the recommended four doses of the malaria vaccine while category two consisted of parent/guardian whose children received less than the recommended doses and category three consisted of parents/guardians whose children did not receive any dose of malaria vaccine with the fourth category being CHVs. The respondents for the KIIs consisted of nurses in charge of maternal and child health (MCH) clinics. The parents/guardian were randomly selected from the CHV list of children had completed vaccine, had never received or received some doses of the vaccines in all the villages in 43 community units. Nurses were randomly picked from the health facilities in the five wards and CHVs were randomly picked from the list of CHVs in the 43 community units. The venue for FGDs was the respective health facilities where the parents/guardians were accessing routine health services, in a secluded room with minimal interferences, and at the offices of nurses in charge of maternal and child health (MCH) clinics.

2.4 Data collection

Caregivers, CHPs and Nurses in charge of MCH clinics were purposively selected for this study. Records for caregivers whose children were within the age of receiving malaria vaccine doses was derived from a mother study that looked at malaria vaccine uptake in Muhoroni. MCH clinics were randomly selected per ward and nurses in charge were interviewed. Data was collected using FGD and KII and the data collection tool was FGD and KII guide. There was a training on data collection and the tools were piloted in Kisumu East to test for Reliability and validity. The tools were reviewed and adjusted appropriately before the start of collection of data. Data generated from the pilot test was used to improve the instruments and processes for the main study. Sessions were audio recorded and moderated by the research assistants. FGDs and KIIs were used to generate information on the RTS, S vaccine. Trained undergraduate qualitative research assistants assisted with the data collection and data transcription. The data collection process was iterative, involving continuous recording, translation, transcription, and interpretation of data. Data collection ended upon attaining data saturation. Notably, two well-experienced data analysts were tasked with the interpretation and analysis of the data.

2.5 Data Analysis

Thematic analysis was used in data analysis. Analysis was primarily deductive and inductive. First, the audio recordings were manually transcribed and translated from the local language into English. Qualitative transcripts were coded for themes that arose from the data itself and then grouped these into different families of related themes. This was followed by a line-by-line, micro-analysis using open coding. The codes were then assembled into potential themes and a thematic chart was developed in MS Word. The themes were compared across the transcripts and specifically the different groups, to establish the range and similarities of the participants'

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perceptions and views. Interviews and discussions were coded, and we came up with a single codebook that was used in the analysis. We used NVIVO 12 software for analysis. *2.6 Ethical*

2.6 consideration

The study protocol was reviewed and approved by the Jaramogi Oginga Odinga University of Science and Technology Ethics Review Committee (JOOUST) reference number JOOUST/DVC-R10/ERC/E3 approval number: ERC36/3/23-05 and for National commission for Science, Technology and Innovation (NACOSTI) reference no-529996, licence no: NACOSTI/P/22/20843. Permission was obtained from Kisumu County director of health and sanitation and Muhoroni subcounty MOH before commencement of the study activities. Permission was also sought from local leaders verbally before entering their villages.

Before data collection, informed consent was sought from caretakers, CHPs and Nurses in charge of MCH to ensure voluntary participation in the study by the trained research assistants. The purpose, risks, and benefits of the study were explained to each study participant. Furthermore, the study participants were informed that they have the right to withdraw from the study at any point during the study period. Confidentiality was strictly observed by using unique study identifiers on the study questionnaires. The data obtained were kept on a password-protected computer, and only study personnel had access to the data. The interviews were conducted in closed secure rooms to ensure privacy. The participants were not exposed to any harm during the study. The participants who agreed to take part in the study were requested to either sign or thumbprint the informed consent form. All procedures were performed in accordance with the relevant guidelines and regulations from JOOUST ERC.

3. Results

3.1 Socio-demographic characteristics of study participants

Out of the 36 parents/guardians invited for the group discussions, 11 of them did not turn up. All the parents/guardians who participated in FGDs were female except one (24/25) and the majority were between the ages of 20-39 years and majority (18/25) had completed primary school education. 12 CHVs were invited for a group discussion, however, 1 of them did not turn up. There was a mixture of females and males CHVs who participated in the FGDs (7 Females and 4 Males). All the 11 healthcare providers who participated in the KIIs were female aged between 20 and 50 years and all of them had tertiary education. All the nurses had tertiary education.

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Sociodemographic Table 1.

Sociodemographic Table 1.					
	Three FGD for caregivers			***One FGD for CHV***	***KIIs for*** nurses in charge of maternal and child health (MCH) clinics
Category	Parents/guardians *of children who completed the recommended 4doses.*	Parents/guardians *of children who did not complete the recommended 4 doses*	Parents/guardians *of children who did not take any RTS, S vaccine*	*None*	*None*
Gender					
Female	9	6	9	7	11
Male	1	0	0	4	0
Age					
20-29	4	3	3	0	1
30-39	3	3	4	3	3
40-49	3	0	2	5	5
50 and above	0	0		3	2
Level of education					
Primary completes	5	4	9	Not asked (NA)	0
Secondary complete	4	2	0	NA	0
Tertiary complete	1	0	0	NA	11

3.2 Reasons for Low Malaria Vaccine Uptake

The study explored the reasons for low malaria vaccine uptake through understanding the health care/health provider's related factor, vaccine related factors, parents/guardian related factors and sociocultural/socioeconomic related factors as shown below.

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3.2.1 Healthcare /health providers related factors.

a. *Parents/guardians and CHVs perspective*

To begin with, healthcare providers-related barriers such as negative attitudes was one of the reasons for the low vaccine uptake. The respondents noted that some healthcare providers weren't talking politely to the caregivers hence discouraging them from taking their children for the vaccine. Moreover, the lack of provision of information about the vaccine was mentioned to be a barrier to its uptake. Some respondents shared that when they took their child to the health facility, some of the health workers did not provide information about the vaccine.

"You know these are our children and this is a vaccine that I as a parent, have taken the responsibility to bring him/her. And I am getting it for the first time. I ask you as the nurse presentI should be explained to before I consent to the child to be given. I cannot consent to the child being injected with something I don't know or am not aware of. But you get that some are not courteous enough to explain to you. She tells you, "You are not aware of the vaccine?". As far as I am aware, I should have the information about the vaccine. I might be aware that there is a vaccine for malaria but what is the purpose or why am I being vaccinated?". Female 29 years, parent/guardian.

There were some cases when the vaccine was not available in the health facility. The respondents mentioned that sometimes they were told either to come back after two weeks or to go to Kisumu because their respective health facilities did not have the vaccines. Besides, some of the health facilities had estimated timelines at which they were giving the vaccines. Once the timeline elapsed, the caregivers were turned away.

"You can go, and you find the vaccine unavailable. Most of the hospitals don't have the vaccine." Female 28 years, parent/guardian.

Time taken at the health facilities which was coupled with long queues in most cases discourages the caregivers from taking up the malaria vaccine thus the low vaccine uptake. Could be there were other parallel errands that the caregiver was supposed to be doing but instead took the whole day at the health facility.

"Another barrier is that sometimes they go to the facility when there are so many clients, and so they have to stay in the queue from around nine in the morning till two in the afternoon, this discourages them because they think that the next time, they go back they will find a long queue." Male 35 years CHV.

Distance to the health facility was a barrier in areas where the health facility was located outside the locality of the community. In most cases, the roads become impassable during the rainy seasons and the parents/caregivers may opt not to take their children for the vaccine.

"Like it had been said, maybe you lived near the hospital and maybe you moved and went far away from the hospital. So, you may lack the fare to go." Female 31 Years, parents/caregivers.

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Other barriers are the few staff at the health facility, there are few staff in the facilities making time spent during vaccination services to be longer since they will be attending to other patients or there will be no service provision when they don't show up at work. Lack of permission from work may also hinder the parents/caregivers from taking their children for malaria vaccine.

"Most of our dispensaries have only one nurse. The nurse can go for a meeting or training this means that when a parent/caregiver *comes there will be no one to serve them." Male 40 years* parent/caregiver.

b. *Nurses' Perspective*

Health facility related barriers such as longer waiting time, distance to the health facility, and health worker's attitudes in addition to socioeconomic-related challenges such as economic activities and, the role of partners, were used to explore convenience as a barrier to vaccine uptake. The sub-theme convenience had the highest number of references at one hundred and three coded in all the eleven scripts.

Long waiting time at the health facility -This was a major barrier to the parents/guardian. This was attributed mostly to the shortage of staff that resulted in one staff providing services for many clients.

Another barrier would be, maybe, we would have, because of the staff shortage, in our facilities, you may find long waiting time for the clients. When they come, they may take a long, if it is one worker giving the vaccination, it's the same worker doing the treatment, it's the same worker doing the antenatal services. So, the healthcare worker will be moving from there, to here, to here. So, a mother may stay for long, before they get the services. So, they may walk out and go home and not get the service or, they may wait and maybe not come next time to get the vaccine "Female 51 years nurse.

High workload especially in high-volume health facilities –This resulted in the exhaustion of the health workers who were not able to adequately create time to handle health-related issues of the caregivers concerning the malaria vaccine. The high workload was also experienced in health facilities that were understaffed and the health workers did not have enough time to explain to the mother malaria vaccine-related information that could boost the uptake.

"At times we do have, on Wednesdays and Fridays have high number of clients so when someone is exhausted, getting time to address some issues like malaria vaccine and talking to the parents about it, the time is limited." Female 26 years nurse.

Health workers' negative attitude –This made the caregivers feel uncomfortable to bring the child for the next dosage of the vaccine. The respondents noted that unfriendly health workers were a barrier to the caregivers honoring their next visit.

"Also, attitude contributes to the uptake of the vaccine. If a mother comes and maybe I have an attitude, she will feel like this nurse is not that friendly. So, you find that she won't come back

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after that six month, she will wait until the baby reaches nine months is when she will come for the measles vaccine, and then from there maybe you might talk to her to give the first dose of malaria and then she will just go away like that, and she will not come back." Female 26 years nurser.

Vaccine unavailability- Other health facility-related barriers included vaccine unavailability, especially in health facilities that experienced power outages. This then made the healthcare workers to outsource the vaccine to nearby health facilities that had reliable power.

"Storage is also fine because we have electricity most of the time. Maybe occasionally, we don't have and if we don't, we transfer to the next facility that has electricity. Female, 51 Years nurse.

There was constant staff turnover that led to a shift in the person offering the malaria vaccine from the trained one to the untrained one. This creates a created a knowledge gap, a lot of changes in various health guidelines do happen during the period in which the health care provider has been shifted to another department. In most cases, the untrained one received orientation or on-the-job training and was not fully equipped with all the knowledge and mostly could find challenges related to vaccine preparation and vaccine administration. Unless there is consistent refresher training, the health providers are not able to adequately deliver the services.

"OJTs are job training like the works that we're doing onsite, yeah, so yes, it could be a barrier it is it is a barrier because then they are not having adequate information in terms of in terms of the vaccine, in terms of the vaccine itself, what to tell the client what not to tell the client things like those, yeah." Female 43 years, nurse.

"You will forget a lot of things. If you work in OPD for maybe three months and someone else works in OPD for one year, when you come back you will get a lot of updates. That is the challenge." Female, 26 Years, nurser.

Limited Training created knowledge gap to nurses -Training was offered to the healthcare provider at the onset of the malaria vaccine rollout. Even so, there was a need for additional information that the respondents liked to have e.g. on the management of the side effects that the parent/guardian could give at home. In most cases, the parent/guardian was advised to give the child paracetamol in case of high fevers, but again paracetamol was previously not recommended for the measles vaccine, but now the 3rd dosage of malaria vaccine was mentioned to be given together with the measles vaccine.

"I think I need to get more information about the malaria vaccine, and the side effects. Before, the information we got here was that after administering the vaccine, you inform the mother the side effect is that the baby will experience fever so you will instruct the mother to go and give paracetamol. The previous knowledge I have is that paracetamol is not supposed to be given in a particular vaccine like measles. So, I am not sure if it is correct or if it is contradicted." Female 26 years, nurser.

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Furthermore, the respondent mentioned the need to train on the current updates on the dosage of the malaria vaccine since there was some contradicting information on the age category.

"We still need more updates as we go on. With people sometimes we tend to forget, especially the new updates that come at first. We used to stick to the first one, but now as time goes you can forget: Female 43 years nurse.

3.2.2 Vaccine related factors

We discussed the vaccine side effects and the number of dosages as a barrier to uptake.

i. Malaria Vaccine side effects

a. *Parents/guardians and CHVs perspective*

The major reason for low malaria vaccine uptake was the vaccine side effects. Most of the respondents mentioned their children experienced fever, vomiting, swelling on the arm, and appeared sick. They got discouraged once they saw the baby getting sick after receiving the malaria vaccine.

"I took my eldest child to get the vaccine. That doctor injected the child in a way that the drug went and accumulated there and got inflamed. It almost crippled my child. I went to another doctor, and he sucked them out. Even now, he walks but not properly." Female 31 years, parent/guardian.

b. *Nurses' Perspective*

The sub-theme explored the respondent's opinion on barriers to malaria vaccine uptake that were related to vaccine side effects, vaccine safety, and the vaccine dosage.

Side effects experienced by the children after receiving the malaria vaccine were one of the major barriers to the vaccine uptake. The respondents shared that most of the parents/guardians complained of high fevers that lasted between two to three days and convulsions after receiving the malaria vaccine. These affected the child's sleeping and feeding patterns thus making the parents/guardians shy away from bringing their children to take the malaria vaccine. A parent/guardian of a child experiencing high fevers after the malaria vaccine could highly spread the message in the community about the side effects of the vaccine hence hindering the vaccine uptake. One of the respondents described the malaria vaccine as a rough vaccine that still needs more research.

"The first time the malaria vaccine was introduced, there was a neighbor's child who was vaccinated, and you know the side effects like the fever, when they saw that, they decided that their child would not be vaccinated, we have tried to talk to them but till now they do not want it, so what can we do? They have refused, not because of religion, it is just by seeing the neighbors' child and thinking that their child will also experience the same thing." Female 43 years, nurse.

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"The most common side effects that we have heard of but are manageable. I am a health care worker, but I am a mother as well [laughs]. So, the most common side effect is fever and this fever is what makes these women shy away from bringing their babies for the second dose", Female 41 years nurse.

ii. Number of doses

a. *Parents/guardians and CHVs perspective*

Some respondents shared that the number of doses was too much for a child, but the health workers kept on explaining the four doses were given at an interval and why it was important for them to be completed. The respondents were concerned with why there were many doses of malaria vaccine and the criteria unto which the decision was settled at number four. Besides, other respondents mentioned that initially there were only three doses of malaria vaccine which later changed to four.

"The doses are a lot and usually it is frightening but the question is why is it that malaria has four doses? Why do the others have one dose?" Female 46 years, parent/guardian

b. *Nurses' Perspective*

There were mixed feelings about the dosage of the malaria vaccine as a barrier. The respondents shared that some of the parents/guardians upon explanation of the four dosages of the malaria vaccine took the instruction carefully and did not have a challenge. On the contrary, some parent/guardians felt that the four doses of malaria vaccine were a lot with the last dose stretched way too far after the child had completed all other routine vaccinations.

"The number of doses…maybe what could bar the guardian from bringing the child is just the separation between the 3rd and the 4th dose. Yes, because it's almost a year apart; it is 1 year and 2 months apart because from 9 months to…that one month close to three months apart. So, up to 2 years. So, you realize that by that time I would have forgotten as a parent that I needed to be taking my child back for the 4th immunization. But still, we see parents coming back, "Oh, it's 2 years", they are coming for a jab." Female 37 years,nurse.

3.2.3 Parents/ guardian related factors

Here we discussed factors caused by parents or guardian that bars them from taking their children to receive the full malaria vaccine doses.

i. Inadequate knowledge about the vaccine

a. Parents/guardians and CHV perspective

Knowledge and awareness of malaria vaccine among the parent/guardian was considered inadequate with minimal information on the target audience and the vaccine dosages. The respondents portrayed a sense of disconnect between the target audiences for the malaria vaccine as they mentioned different statements. Some respondents mentioned children above five years eligible for the vaccine while others mentioned that the eligibility was children who were six months and above. Further diverse opinions on the target audience included children from six

months being eligible, and children who were one year old being eligible too for the malaria vaccine. Most of the responses given by the target audience indicated there were gaps in the knowledge about who was eligible for the malaria vaccine. One thing is for sure, the respondents were aware it was to be given to children from the age of six months.

"The malaria vaccine as one of us has said, it's a vaccine that is given to children above the age of five to protect them against malaria. The first one is given when the child is six months, the second one at eight months, the third at nine months, and the last one at 24 months." Female 44 years parent/guardian.

The same lack of understanding was evident on malaria dosage, few respondents were aware of four doses which were given at six months, seven months, nine months, and the final dosage at twenty-four months. As noted below, other respondents were not sure of the age category mentioning the doses were given at six months, nine months, one year, and two years respectively.

"The first one is six months, the second one I think is one year, the third one is one year six months, and the fourth one is two years." Female 31 years, parent/guardian.

Additionally, in instances where a community has less information and the people around do not take their children for malaria vaccine, may hinder its uptake. The caregivers may fail to know about the malaria vaccine and thus not avail their children of the same. Furthermore, some parents/caregivers had children before the introduction of the malaria vaccine, they think that the malaria vaccine is too much.

"Those partners who had children before know the schedule for the other vaccines and when they get another child and the malaria vaccine is added to the schedule, they think that it is too much." Female 40 years, CHV

b. Nurses' Perspective

Some of the nurses were able to share the target audience for the malaria vaccine stating that it was given to children from the age of six months for the first dose, the second dose at seven months, third at nine months, with the last dose given when the child is two years old. However, some healthcare workers mentioned in blanket the target audience: that the malaria vaccine was given to all under five years old, given to all children below two years, given to children between 6 months and two years, given to children who had started the vaccine at six months, defaulted but are still under five years.

"Between six months to two years. Those can be started on the injection. Or those who started, and did not complete the dosage, you can give it if they are still less than five years." Female 36-year, nurse.

Furthermore, the respondents noted that the malaria vaccine was given to children who lived in specific counties such as counties in the former Nyanza region e.g. Kisumu and Homa-bay

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Counties. However, there were some contrary opinions that the malaria vaccine was now available in all the counties in Kenya. Additional contrary opinion was on the timing of the dosage whereas some respondents mentioned that the vaccine could be given to children under five years, few respondents felt that a child who was above two years old and hadn't started the vaccine yet was not fit as the target audience.

"Yes, initially when we were doing the pilot, we were saying any child below one year could start the vaccine, but in the new rollout, after the WHO gave the go-ahead to expand; the eligibility has changed to any child who is below two years, for the sub-counties that were expanded. Yes, any child below two years can be started on a malaria vaccine." Female 51 years' nurse.

Some respondents mentioned recent changes that had been made to the dosage of the malaria vaccine. They shared that the dosage guidelines were updated to allow even the children who missed the vaccine and were still under five years old to be given the vaccine, considering 4 weeks' intervals after the first and second vaccine, and eight-week intervals for the third dosage. However, it was keen to note that some respondents had two years as the cut-off age and this contradicting information could lead to low uptake of the malaria vaccine.

"But recently we had an update, and we were told that any client that is below 5 years old should get at least four doses of malaria vaccine. If the client has not started the vaccine, we start it and then we give it four weeks apart until they finish the four doses." Female 43 years nurser.

"That one is also a barrier because you know, if I don't have enough knowledge concerning a particular vaccine, giving it is a challenge to me or talking about it." Female 26 years nurse.

3.2.4 Sociocultural/socioeconomic factor

a. <u>Parents/guardians and CHVs perspective</u>.

Religious and cultural beliefs also contributed to the lack of confidence in the malaria vaccine hence the low uptake. There were rumors that the government had an unknown agenda with the vaccine because there were too many vaccines being introduced. Furthermore, cultural practices such as the use of herbal medicine made some of the respondents have no confidence in the malaria vaccine.

"There are some herbs that Luos gave to the child at birth. And that was regarded as a vaccine. So, there is no need to go to the hospital. But it is diminishing. But there are some people still using it. So, if you give birth in interior areas and you don't have the knowledge and people in your household use it, that is the one you will use." Female 23 years, parent/guardian.

Male partners were hardly available at homes therefore equipping them with knowledge about the vaccine was not easy. Furthermore, there were times when the male partners were not supportive in terms of not offering transport to the health facilities.

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"It also depends on our partners. You can tell him, "Tomorrow I need to take the child to the clinic". And he tells you he doesn't have the fare. And you can't walk to and from the hospital. You will end up not going." Female 23 years, parent/guardian.

b. Nurses' Perspective

Migrations - The study area was originally a settlement scheme that was characterized by a lot of migrations, thus affecting the uptake of the vaccine. Another migration was seasonal, for example during the Christmas season, some of the caregivers who were living in the semi-urban centers would move to the rural area.

"Yes, this is a settlement scheme, clients tend to move from one place to another. You find that even in the permanent register, they are giving you a phone number but when you call, you will not find that client, you don't know where they have gone." Female 43 years nurse.

The role of male partners who decided on whether the child could receive the vaccine or not wasn't predominant as most of the men were not involved in child welfare directly.

"Only females come. It is hard for the male to come. Occasionally they usually come with their wives but most of the time the mothers come on their own. Female, 36 Years nurse.

Economic factors such as routine activities were mentioned to be barriers as most of them were undertaken during the morning hours thus conflicting with the vaccination schedule. Most of the health facilities scheduled their vaccination activities to take place in the morning hours and the malaria vaccine is only potent for six hours after vaccine preparation, this then made it not possible for the caregivers who had to first attend to their routine activity to get the malaria vaccine. The caregivers gave priority to their routine activities and then later took their children for immunization.

The routine activities are also a contributing factor but as mothers, we do give immunization up to a particular time, some vaccines are only portent for six hours, so we will tell them to make sure they come before 1:00 pm or 12:30 midday and if a mother comes past that time, that day she will miss the vaccine. If you tell them that they can come tomorrow or the following day, then they feel like it's a challenge." Female 26 years, nurse.

Age, education level, and Ignorance were mentioned not to be barriers to malaria vaccine uptake. Some of the unlearned persons were not able to comprehend the importance of the malaria vaccine as compared to the learned ones. The same applied to some of the younger caregivers especially those who were still in school and did not have an easy time understanding the importance of the malaria vaccine. The respondent mentioned that some of the younger *parents/guardians* would like their children with their grandmothers who may fail to remember to bring the child for vaccination. Some of the caregivers were ignorant about the vaccine because of the knowledge.

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"Okay, for education status, those who are learned or a bit learned know the importance of immunization, once you talk to them, they will understand and they will cooperate but then those who are not learned, it is a challenge to convince them and maybe to discuss to them about the vaccine. Sometimes we can just talk about ignorance, some people are learned but then they will be like, some ten years back the vaccine did not exist, but people were just okay, so why now?" Female 37 years nurse.

Other confidence-related barriers included the number of vaccines which the caregivers felt has so far increased, thus leading to a lot of defaulting cases, lack of confidence in the vaccine because of the religious and cultural values

"They just refuse, they tell you that their religious beliefs do not allow them to be given the vaccine, but we don't just leave it at that, we send the CHVs to talk to them, if it is beyond the CHVs we send the community health extension workers just to find out what could be the problem." Female 53 years, nurse.

4. Discussion

This study identified the gaps in the implementation of the RTS malaria vaccine leading to low uptake even though the malaria vaccine has shown a positive effect in our study site and elsewhere(14). Healthcare/health providers factors, parents/guardian related factors, vaccine related factors and socioeconomic/sociocultural factors were discussed below.

The Parental related factors like inadequate knowledge and awareness about the vaccine came out to be a major gap in the vaccine uptake. Parents/Guardians have inadequate understanding of the malaria vaccine as there was a disconnect between the age eligibility and the number of doses to be taken at what age. Similar concerns were raised in a qualitative longitudinal study which was looking at RTS, S/AS01 malaria vaccine pilot implementation to understand immunization barriers and optimize uptake. The study found reasons for initially delaying the uptake of the vaccine included a lack of awareness and incorrect information about the malaria vaccine(15).
Healthcare/health providers related factors like limited training and refresher training also cause health providers to miss some changes and information about the malaria vaccine. These results showed a lack of uniform information about age eligibility for malaria vaccine among healthcare providers which was brought by a lack of training and refreshers to be at par with changers. These findings are like those of a study conducted in Ghana among healthcare providers to assess the success and challenges of the malaria vaccine implementation program (MVIP) and to provide recommendations for the introduction of new vaccines in the future. The study revealed that less than half [46.3%; (25/54)] of the vaccinating staff received pre-vaccine introduction training but almost all [94.4%; (51/54)] were able to constitute and administer the vaccine appropriately (24).
The negative attitude of the healthcare providers came out too as one of the barriers to RTS, S uptake. The respondents noted that some health providers weren't talking politely to the parents/guardians hence discouraging them from taking their children for the vaccine. Health providers also acknowledge some of their colleagues have bad attitudes towards the

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parents/guardians. However, they said this attitude could be brought about by high workload and pressure due to understaffing. They said that some staff, when overwhelmed with a huge workload, tend to show a bad attitude. This barrier was also reported in a study done in Kenya to understand immunization barriers and optimize the uptake of RTS, S(15). When a parent/guardian misplaces the MCH booklet or forgets about the dates, they fear going to the clinic due to cruel health providers.

Long queues and long waiting times at the MCH clinic play another role in lowering RTS, S uptake. Parents/guardians complained of taking too long to get vaccines due to long queues due to few health providers at the MCH. Understaffing was acknowledged by some of the health providers during KII as they said that there is a staff shortage which makes health providers at the MCH also provide services at the outpatient department. This makes mothers take a longer time before getting services. Distance to the health facility and bad terrain were a barrier in areas where the health facility was located outside the locality of the community. In most cases, the roads become impassable during the rainy seasons and the caregivers may opt not to take their children for the vaccine.

Other health facility-related barriers included vaccine unavailability, especially in health facilities that experienced power outages and those lacking adequate cold chain equipment like refrigerators. This makes providers reschedule the parents/guardians for another day when the vaccine is available. This demoralizes parents/guardians and some of them don't come back on the rescheduled date. A study done to identify challenges and lessons learned during the planning and early implementation of the RTS, S/AS01E malaria vaccine revealed that lack of functioning cold-chain equipment in health facilities, including insufficient and inadequate refrigerators, vaccine carriers and thermometers are among the barriers to RTS, S uptake (26).

Vaccine related factors like side effects of malaria vaccine also played a huge role in poor malaria vaccine uptake. Parents/Guardians' confidence was lowered by the vaccine side effects, most of the respondents mentioned their children experienced fever, vomiting, swelling on the arm, and appeared sick. They got discouraged once they saw the baby getting sick after receiving the malaria vaccine. This made them miss the subsequent doses or not start the vaccine at all. Vaccine side effects have been mentioned in several studies as one of the major barriers to malaria vaccine uptake as it is distressing for parents/guardians to see their children endure pain or become paralyzed (13, 25).

Furthermore, the number of vaccine doses was a barrier since some respondents shared that the number of doses was too much for a child. Their concern was that the 4 doses were many, and one could easily forget especially with the 4th dose. Since there is no vaccine being given at 24 months, without a reminder, parents/guardians might forget. The same findings were found in a study done in Ghana which explored the perspectives of defaulters and frontline health service providers which reported that for most mothers, the timing of the fourth dose presents a major challenge since the last vaccine in the EPI is taken in the 18th month, uptake of the fourth dose

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of the RTS, S at 24th months was affected (13). Another study in Ghana which explored the Challenges and lessons learned during the planning and early implementation of the RTS, S/AS01E malaria vaccine in three regions of Ghana reported that many of the health service managers and frontline health providers described the timing of the 4th dose of RTS, S/AS01E, given at 24 months of age, as a major challenge. Participants explained how the 15-month gap between the 3rd and 4th doses was too large for parents/guardians to remember to return to the vaccination clinic and that vaccinations given in the second year of life have poor coverage. Multiple participants discussed how they would have preferred this gap to be shortened, and that the 4th dose be combined with MCV-2 at 18 months (26).

Sociocultural/ socioeconomic factors like religious and cultural beliefs also contributed to the lack of confidence in the malaria vaccine hence the low uptake. There were rumors that the government had an unknown agenda with the vaccine because there were too many vaccines being introduced. Furthermore, cultural practices such as the use of herbal medicine made some of the respondents lack confidence in RTS, S vaccine. These findings were like the findings of a study to assess the barriers to implementation and uptake of the malaria vaccine in Ghana that found that there was poor acceptance of the vaccine by the population. The study revealed that the majority [92.5%;(87/94)] of caregivers were aware of the RTS, S introduction but only 44% (41/94) had accurate knowledge of the number of doses needed for maximum protection. (27).
Economic factors such as parents/guardians going to work in the morning give priority to a source of income as compared to taking the children for vaccination. This was coupled with a lack of male partner involvement in providing financial support in terms of transport for vaccination. A review done to understand the acceptance, availability, and feasibility of RTS, S/AS01 malaria vaccine pointed out lack of transport and long distance to the facility as barriers to RTS, S uptake (25).

Migration also played a huge role in poor RTS, and S uptake since some parents/guardians would move from implementing areas to non-implementing areas. This made children miss this vaccine since most of the time a child comes back to implementing areas when they are over age or sometimes, they don't come back at all. A longitudinal qualitative evaluation study for the malaria vaccine implementation program which was done to identify acceptance and adherence to a four-dose RTS, S/AS01 Schedule also reported a lack of access to the vaccine when parents/guardians traveled to locations outside of the pilot regions as one of the reasons as to why children missed RTS, S doses(3).

Limitations of the study

This study was in a small geographical area in a rural setting in Kisumu County and therefore the findings might not necessarily reflect the situation in the urban in other implementation counties in Kenya. The study had a small sample size even though data saturation was achieved. Future studies should focus on both rural and urban setting using a larger sample size.

Conclusions:

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There is inadequate knowledge about RTS,S vaccines, less confidence by parents/guardians about the malaria vaccine due to its side effects and the many numbers of doses. Healthcare and health provider's factors like bad attitude of health care providers is making parents/guardians shy away from going for vaccination, long queues at the clinic because of understaffing, vaccine unavailability causing re-scheduling of dates as well as inadequate refresher training of health care provider. Daily economic activities making parents not to take their children for vaccination as scheduled and migration to non-implementing sub counties also came out as barriers for RTS, S uptake.

Recommendations:

Adequate health education programs should be put in
place for both parents/guardians, healthcare providers and public at large about RTS, S malaria vaccine. There is also a need to explore task shifting and integration of the services to manage the workload for healthcare providers. There is need for resource mobilization to support the implementation of the vaccine to always make vaccine and storage facilities available in all the facilities. There is a need to sensitize the community about the importance of adherence to the 4-dose schedule. There is need for further research on making the vaccine user friendly. There is a need to come up with malaria vaccine implementation strategies that solves the barriers to the vaccine uptake hence boosting malaria vaccine coverage.

Abbreviation

CHPS-Community Health Promoters

FGD-Focus Group Discussion

KII-Key Informant Interview

MCH-Maternal and Child Health

NACOSTI- National commission for Science, Technology and Innovation

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Declarations

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Ethical declarations and consent to participate

The study protocol was reviewed and approved by the Jaramogi Oginga Odinga University of Science and Technology Ethics Review Committee (JOOUST) reference number JOOUST/DVC-R10/ERC/E3 approval number: ERC36/3/23-05 and for National commission for Science, Technology and Innovation (NACOSTI) reference no-529996, licence no: NACOSTI/P/22/20843. Permission was obtained from Kisumu County director of health and sanitation and Muhoroni subcounty MOH before commencement of the study activities. Permission was also sought from local leaders verbally before entering their villages.

Before data collection, informed consent was sought from caretakers, CHPs and Nurses in charge of MCH to ensure voluntary participation in the study by the trained research assistants. The purpose, risks, and benefits of the study were explained to each study participant. Furthermore, the study participants were informed that they have the right to withdraw from the study at any point during the study period. Confidentiality was strictly observed by using unique study identifiers on the study questionnaires. The data obtained were kept on a password-protected computer, and only study personnel had access to the data. The interviews were conducted in closed secure rooms to ensure privacy. The participants were not exposed to any harm during the study. The participants who agreed to take part in the study were requested to either sign or thumbprint the informed consent form. All procedures were performed in accordance with the relevant guidelines and regulations from JOOUST ERC.

Availability of data and materials

The data sets used and/or analyzed in this study are available from the corresponding author upon reasonable request.

Competing interest

Authors declared no competing interest

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Author contributions

IAO participated in the conceptualization and design of the study, seeking approvals, acquisition and supervision of data, drafting of the manuscript and critically revising the manuscript. She is the main PI for the Masters project design of the study. MO participated in statistical analysis

and interpretation of results. TK, JS, EA, EO and GA participated in the interpretation of results and critically revised the manuscript. All authors have read and approved the final manuscript.

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Additional information

Electronic Supplementary Material

Below is the link to the electronic supplementary material.
Supplementary Material

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