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EVALUATING COVERAGE OF MALARIA VACCINATION WITH RTS, S AMONG CHILDREN AGED 6-24 MONTHS IN SELECTED SUB COUNTIES IN THE MALARIA-ENDEMIC WESTERN KENYA REGION, 2019 – 2022
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ABSTRACT

***Objective*: To assess malaria vaccination coverage, dropout rates, and proportion of unimmunized children aged 6-24 months in the malaria lake endemic zone, Kenya.**
***Design*: A retrospective cross-sectional study using routinely reported national program data from health facilities (2019 – 2022).**
***Setting*: The study was conducted in 26 selected sub-counties of the Malaria Lake endemic zone, Kenya.**
***Participants*: Children 6-24 months of age residing in the malaria lake endemic zone, Kenya.**
***Intervention*: Vaccination using malaria vaccine (RTS, S) dose 1 to 4.**
***Main outcome measures*: Malaria vaccination coverage, malaria vaccine dropout rate, and proportion of unimmunized children.**
***Results*: There was a gradual increment in the uptake of malaria vaccine (RTS, S) doses 1 to 4 during the study period. The uptake of malaria vaccine (RTS, S) 4 was 50% of the desired 80% coverage. The dropout rate progressively declined between malaria vaccination (RTS, S) 1 to 3 within the threshold of 10%. Dose 4 showed the highest dropout rate (57%). There was a decline in the proportion of unimmunized children below 1 year over the study period.**

Conclusion: **Malaria vaccine coverage was satisfactory in doses (1, 2, 3), while uptake of dose 4 was low by two years at (37%). This calls for strategies aimed at enhancing malaria vaccination integration in the second year of life. Additionally, there is a need to unravel factors associated with high dropout rates and devise measures for minimizing or eliminating dropout. Enhancing community engagement and advocacy is potentially key for better coverage and maximum protection.**

INTRODUCTION

Malaria is a vector-borne disease transmitted through the bite of female anopheles mosquito infected with the malaria parasite. The intensity of transmission generally varies as a function of parasite prevalence in the human population and the feeding habits, density, and survival rates of mosquito vectors. In Sub-Saharan Africa, important contributing factors to the burden of malaria include weak health systems with limited access to quality prevention and treatment services, health inequities, and lack of address to vulnerable and marginalized populations. Approximately 95% of malaria cases and deaths occur in Sub-Saharan Africa. This is occasioned by *Plasmodium falciparum,* and most occur in African children under five years of age (1).

The Kenya Malaria Strategy (KMS) 2019-2023 outlines the goal of the Division of National Malaria Program to reduce malaria incidence and deaths by at least 75 percent of the 2016 levels by 2023. The objective is "*To protect 100 percent of people living in malaria risk areas through access to appropriate malaria preventive interventions by 2023*" (2). Among the strategies deployed in the Lake Endemic zone include routine distribution of long-lasting insecticidal nets, indoor residual spraying in targeted areas, larval source management in targeted areas, provision of at least three doses of sulphadoxine-pyrimethamine (SP) to pregnant women attending antenatal clinic, case management of suspected malaria cases and, more recently, the introduction of malaria vaccine in selected sub-counties in a phased pilot implementation.

Vaccine development efforts have focused on preventing illness from *P. falciparum* and, to a lesser extent, *P. vivax*. The RTS, S/AS01 is the first and currently the only malaria vaccine recommended by the World Health Organization (WHO) following a positive scientific opinion from the European Medicines Agency in July 2015. A phase III trial was conducted in 7 Sub-Saharan African countries, including Kenya, among children aged 6-12 weeks and 5-17 months. In this trial phase, for children who received a fourth dose 18 months after the third dose, vaccine efficacy against clinical malaria was 39%, against severe malaria 29%, against severe malaria anemia 61% and reduced the need for blood transfusion by 29%. Results suggested that three doses alone did not affect the overall incidence of severe malaria, with a protective effect in the first 18 months balanced by an increase in cases from 18 months to the end of the trial. Children in areas with moderate to high malaria transmission who received 3 or 4 vaccine doses benefitted for at least seven years after vaccination. They did not have an excess risk of clinical or severe malaria. It's worth noting that in such areas, the highest risk for severe malaria is during the first few years of life when the vaccine provides the greatest protection (3).

The pilot implementation of the malaria vaccine was launched in Kenya on 13

September 2019 and implemented in 26 selected sub-counties in the lake endemic malaria zone from October 2019 to February 2023. The counties that constitute the lake endemic malaria zone include Busia, Kakamega, Bungoma, Vihiga, Kisumu, Siaya, Homabay and Migori (4)

The selection of the sub-counties was based on parasite prevalence, proximity to main hospitals for case management, and ability to provide sufficient children within 12-18 months. The 4-dose schedule recommended was at 6 months, 7 months, 9 months, and 24 months of age, as shown in Figure 1 (5)

Figure 1: Malaria Vaccine Dosing Schedule in Kenya (Source: Training Package for Malaria Vaccine Implementation (Ministry of Health)

The purpose of the pilot implementation was to assess the feasibility of administering the recommended four doses of the vaccine in children within the Expanded Program for Immunization (EPI) settings and to assess the vaccine's potential role in reducing childhood deaths and its safety profile in the context of routine use. The Ministry of Health guidance was to offer the first dose of RTS S to children aged 6 to 12 months during the launch of the pilot implementation. The divisions of immunization and malaria have scaled up vaccination to 25 more sub-counties in the lake endemic zone from March 2023. The country's vaccine coverage threshold is 80%, and dropout rate at 10%.

The current study aimed at evaluating coverage of malaria vaccination with RTS, S among children aged 6-24 months in selected sub-counties from the lake endemic malaria zone. Specifically, the study aimed to review the uptake of a malaria vaccine, RTS, S 1 to 4 doses, RTS, S drop-out rates, and the proportion of unimmunized children in Kenya between 2019 and 2022.

- *Unimmunized*- Child aged 6-24 months in selected sub counties of lake endemic malaria zone who had not received any of RTS, S malaria vaccine
- *Drop Out* – Child aged 6-24 months in selected sub counties of lake endemic malaria zone who had received the first dose (RTS, S 1) but not any subsequent doses.
- *Fully Immunized* – Child aged 6-24 months in selected sub counties of lake endemic malaria zone who had received four doses of RTS, S malaria vaccine.

S

METHODS

Study Design:

A retrospective cross-sectional study using routinely reported national program data from health facilities.

Study setting:

General: Kenya is centered at the equator and exhibits a bi-modal rainfall pattern with long rains between March and May and short rains between October and December. The diverse geography of the country, influenced by altitude, rainfall, and proximity to both Lake Victoria and the Indian Ocean, affects malaria epidemiology and zoning. Kenya is home to all four species of plasmodium parasites (*falciparum, vivax, malaria, and ovale*) that infect humans. The plasmodium parasite, which causes the most severe form of malaria, accounts for more than 99% of malaria infections in Kenya. The vaccine focuses on preventing illness from *P. falciparum*.

Specific: According to Kenya Malaria Indicator Survey (KMIS) 2020, approximately 70% of the Kenyan population is at risk for malaria, with 13% to 15% of outpatient consultations attributed to malaria. The malaria prevalence in Kenya is 6%, while lake endemic malaria zone is 19%. Children under age five and pregnant women are most at risk. The percentage of children aged six months to 14 years testing positive for malaria was 6% in 2020, the prevalence of *P. falciparum* parasite among children with malaria was 76% in 2020, and the percentage of malaria-positive children with anemia was 3% in 2020. A temperature suitability index (TSI) for malaria transmission shows that Lake Victoria and coastal regions have ambient temperatures ranging from 19 to 27 degrees celsius, suitable for malaria transmission, and have the necessary amounts and seasonality of rainfall to sustain lengthy transmission periods (6). This study was conducted in 26 sub-counties in the lake endemic zone, which experiences a stable high malaria burden with intense transmission throughout the year (Figure 2). There were 663 vaccinating health facilities within the sub-counties that implemented vaccination.

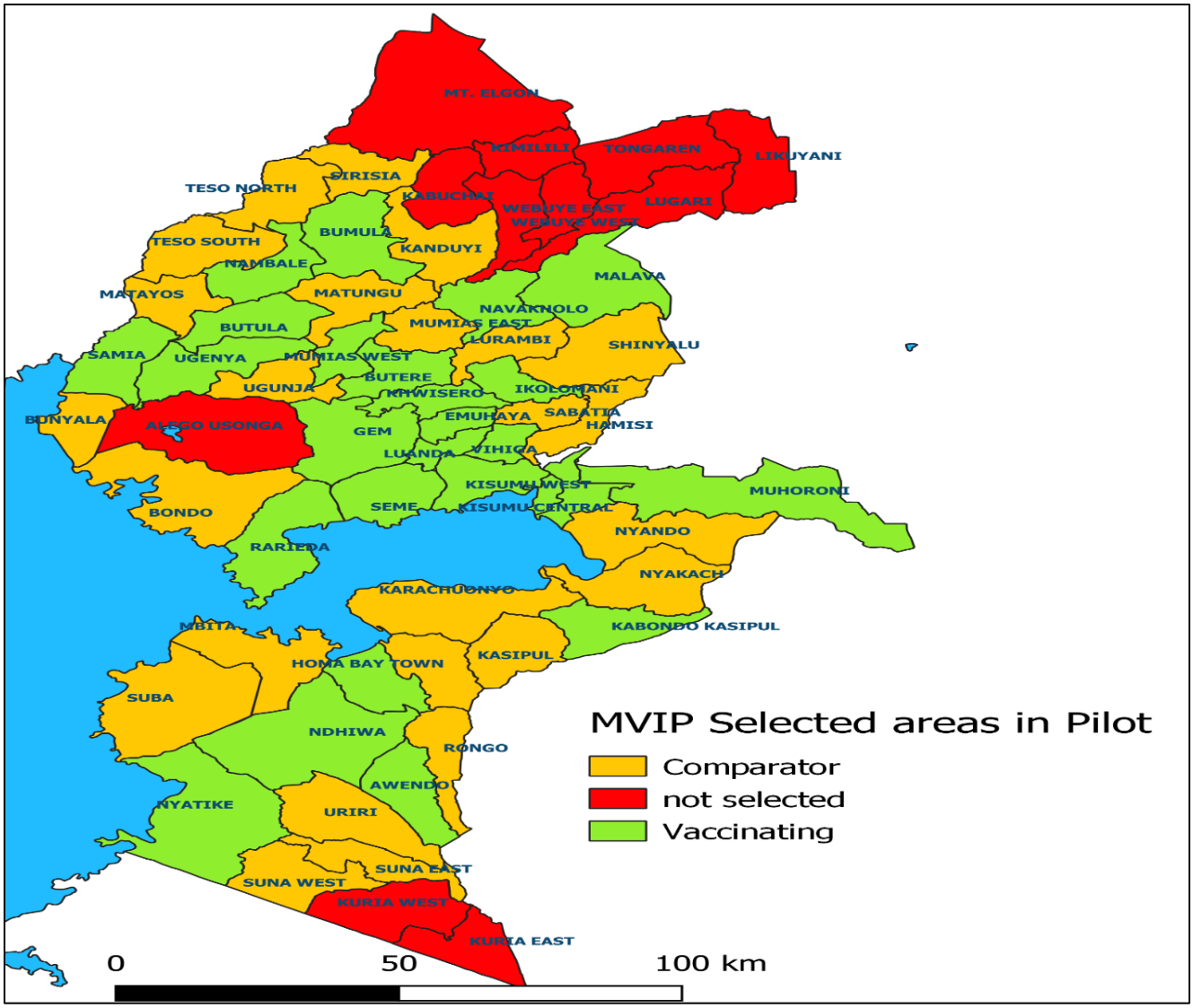

Figure 2: Map showing vaccinating sub-counties in the Lake Endemic zone.
Source: Training package for malaria vaccine implementation (Ministry of Health)

Study population

All children aged 6 to 24 months eligible for the malaria vaccine reported in Kenya Health Information System 2(KHIS2) from the 26 selected sub-counties in the lake endemic malaria zone (2019 to 2022). Data Variables The dependent variables for evaluating coverage for malaria vaccination included the number of children aged 6-24 months receiving malaria vaccine RTS, S 1 to 4 doses, and unimmunized children.

Sources of Data:

The malaria vaccine data was routinely captured at the health facilities' child welfare clinics, recorded onto the mother-child health booklet (MOH 216) and immunization registers (MOH 510). This was then aggregated monthly into a malaria vaccine summary form and submitted to the sub-county level for entry into the Kenya Health Information System 2 (KHIS2). The study used routine data on malaria vaccination reported in the KHIS2, which had validation capacities. The data was

restricted to the 26 sub-counties implementing the pilot phase of malaria vaccination.

Data Analysis and Statistics

All the abstracted data were subjected to cleaning, verification, validation, consistency cross-checks, and data analysis using Microsoft Excel Spreadsheets v16.33 (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics, including absolute numbers and attendant proportions, were used to summarize the data. The Kenya Ministry of Health guidance on malaria vaccine coverage and dropout (Box 2) was used. To get unimmunized children, the number vaccinated less target population under one year was applied.

Calculating Annual Immunization Coverage

Malaria Vaccine 1 Coverage= Number children received dose 1 X100
Total number of infants < 1yr. of age

Malaria Vaccine 1 Coverage= Number children received dose 4 X100
Total number of infants (previous year)

Calculating Number of Unimmunized Children:

Unimmunized Children = Target population – Number of children vaccinated

Malaria Vaccine 1 – Malaria vaccine 2 dropout rate

Cumulative doses of (RTS, S)1-Cumulative doses of (RTS, S)2 X100
Cumulative doses of (RTS, S) 1

Malaria Vaccine 3 – Malaria vaccine 4 dropout rate

Cumulative doses of (RTS, S) 3-Cumulative doses of (RTS, S) 4 X100
Cumulative doses of (RTS, S) 3

Box 2: Calculation of Malaria Vaccine (RTS, S) Coverage, drop and Unimmunized

Source: Training package for malaria vaccine implementation (Ministry of Health)

Ethical Considerations

Scientific and ethical clearance for the study was obtained from the Maseno University Scientific and Ethics Review Committee (MUSERC) (Approval Number: MUSERC/01234/23). Permission to use the assessment data was sought from the National Malaria Control Program (NMCP). Personal identifier information was omitted from the data collection tools to ensure patient confidentiality.

RESULTS

The coverage of RTS, S1 in the malaria lake endemic zones was 37% in 2019 and increased to 83% by 2022. RTS, S 2 and RTS, S 3 had initial low coverage of 24% and 7% which improved to 77% and 72% respectively. RTS, S4 coverage was 37% in 2022 (Table 1). Evaluation undertaken on uptake of RTS, S malaria vaccine by counties reflects a similar trend with improved uptake over the years, but in Vihiga county, uptake seemed lower. There was a low uptake of RTS, S 4 in all the counties (Supplementary File S1).

Table 1

Malaria Vaccine (RTS, S) Uptake in the Malaria Lake endemic zone, Kenya, 2019-2022

Malaria Vaccine (RTS, S)	**2019**	**2020**	**2021**	**2022**
Total Population (N) RTS, S (n)%	146002	123374	126657	132577
RTS, S 1	54574 (37)	98687 (80)	104959 (83)	109829 (83)
RTS, S 2	34485 (24)	92275 (75)	95225 (75)	101607 (77)
RTS, S 3	10122 (7)	86403 (70)	85443 (67)	95277 (72)
RTS, S 4	18 (*)	2441 (2)	37291 (30)	47274 (37)
**Considered too early for calculation of meaningful coverage estimates for RTS, S 4th dose* *Source KHIS accessed on 28th February 2023*				

The drop-out rate for RTS, S 1, 2, and 3 showed percentages towards the national threshold of 10%. However, the decline in the drop-out rate of RTS, S 4 from 98% to 57% still remains unacceptably high from the country's desired threshold (Table 2).

Table 2

Malaria Vaccine (RTS, S) Dropout rate in the Malaria Lake endemic Zone, Kenya 2019 -2022

Malaria vaccine (RTS, S)	**2019** **n (%)**	**2020** **n (%)**	**2021** **n (%)**	**2022** **n (%)**
RTS, S 1	54574	98687	104959	109829
RTS, S 2 dropout rate	20089 (37)	6412 (6)	9734 (9)	8222 (7)
RTS, S 3 dropout rate	44452 (81)	12284 (12)	19516 (19)	14552 (13)
RTS, S 4 dropout rate	*	96246 (98)	67668 (64)	62555 (57)
**Considered too early for calculation of meaningful dropout rate for the RTS, S 4th dose* *Source: KHIS accessed on 28th February 2023*				

An additional calculation of the dropout rate was made by scrutinizing the RTS and S doses. The dropout rate between RTS, S doses 1 to 2, and 2 to 3 were within the WHO 10% desired threshold. There is a high dropout between doses 3 and 4 at 50%, way above the desired threshold (Supplementary File S2).

The number of unimmunized children progressively declined over the three years (2019-2022) from an initial 63% to 17% amongst the children less than one year.

Table 3

Proportions of Unimmunized children in the malaria lake endemic Zone, Kenya 2019-2022

Unimmunized children <1yr.	**2019** **n (%)**	**2020** **n (%)**	**2021** **n (%)**	**2022** **n (%)**
Target Population <1yr.	146002	123374	126657	132577
RTS, S 1	54574	98687	104959	109829
*Unimmunized children	91428 (63%)	24687 (20%)	21698 (17%)	22748 (17%)
**Unimmunized- Child aged 6-12 months who had not received any dose of RTS, S malaria vaccine* *Source KHIS accessed on 28th February 2023*				

DISCUSSION

This study sought to evaluate coverage of Malaria vaccination with RTS, S among Children 6-24 months in Selected sub-counties from the Malaria Lake Endemic zone, specifically reviewing uptake of malaria vaccine, RTS, S 1 to 4 doses, malaria vaccine RTS, S drop-out rates and proportion of children unimmunized in Kenya between 2019 and 2022. The main findings showed increased uptake of malaria vaccination (RTS, S) 1 to 4 from 2019 to 2022. However, in Vihiga County, the uptake in the initial rollout was notably lower than in other counties. There is a notable low uptake of malaria vaccine (RTS, S) 4 at 50% of the desired regional coverage of 80% (7). The dropout rate progressively declined between malaria vaccination doses 1 to 3 in conforming with the national threshold of 10%. However, malaria vaccination dose four dropout showed an unsatisfactory level of 57%.

Malaria vaccination (RTS, S) is a preventive strategy for eliminating malaria. The initiation of this program commenced in September 2019 and occurred in tandem with similar programs in Ghana and Malawi. Trends noted in Malawi showed that with social mobilization and community engagement, the annualized coverage for the first dose increased to 88% in 2020, and this has steadily been sustained at an average of 90% for the first dose, 85% for the second dose, and 80% for the third dose in 2021. In Ghana, the vaccination started in May 2019 with a community-led launch. The coverage in 2021 for the dose 1 was 74%, 72% for the dose 2, and 74% for dose 3 (8). Variances seen in the initiation of vaccination programs in Vihiga County were addressed through the scale-up launch pivoted from this county. Furthermore, there is a need for public health education, advocacy campaigns, and address to demographics, vaccine profiles of safety and efficacy, vaccine hesitancy, and attention to anti-vaccine movements (9). The general pattern of low coverage of the fourth dose could be attributed to the vaccination schedule variance from the routine childhood KEPI program. There is a need for continuous public awareness, outreach campaigns for demand generation, and socio-behavioral change communication.

In 2021 Malawi, the dropout rate was initially high at 20%, but this reduced to 12% by the third dose. However, drop out of RTS, S4 from RTS, S3 stood at 19% even after nine months of giving the fourth dose. Ghana had low dropout rates of 3% and 1% for the second and third doses, respectively, but still had a high fourth-dose dropout rate of 30% (8). Possible ways to address this include the importance of relaying knowledge on completing the schedule. This can be done through scheduled dates for return, reminders, and defaulter tracing mechanisms, including leveraging on community health promoters (CHP) household visits.

There has been a sustained downward trend in the proportion of unimmunized children less than 1yr, from 63% in 2019 to a low of 17% in 2022. However, the Division of National Program (DNMP) needs to strategically trace and immunize children who are yet to be reached despite the excellent coverage. This is to achieve optimal immunization coverage in line with the WHO's Global Vaccine Action Plan, which proposed that countries attain about 90% and districts or administrative units attain about 80% fully immunized children by the year 2020 (7). The Kenya demographic health survey (KDHS 2022) reports coverage of 80% in 2022, with Vihiga county having the highest percentage of children aged 12-23 months fully vaccinated for basic antigens (96%) (10). This is noted even in malaria

vaccination, where the county has the lowest proportion of unimmunized children.

Strengths of the Study:

The study used age-eligible populations to estimate vaccine coverage and drop-out rates, providing a more comprehensive picture of the vaccine's reach.

Study Limitations:

There are limitations to this study. Firstly, data analysis was undertaken on only 26 selected sub-counties with high parasite prevalence, proximity to a main hospital, and the ability to provide a sufficient number of children for showing impact. There could be children under one year who crossed from comparator sites to vaccination sites whose data were analyzed. Secondly, the vaccination was launched late into the first year, and as such, it was not feasible to determine considerable uptake and dropout rates for the fourth dose vaccination in 2019.

Implication for Policy

There are health policy implications for the health system in Kenya. The coverage of malaria vaccine (RTS, S) 4 among the children by age two declined, which is an indication of a high dropout, which needs community advocacy for socio-behavioral change. Further, it calls for research on predictors associated with vaccine hesitancy among caregivers.

CONCLUSION

The study confirms that the vaccination coverage for children aged 6-24 months during the malaria vaccine pilot implementation in the Lake Malaria endemic zone in Kenya is significantly below the target coverage rates for the later vaccines. There is a dropout between doses 3 and 4 at 50%, way above the desired threshold. Further, the data collected showed a substantive percentage (17%) of children not immunized in the later year (2022) of the malaria vaccination implementation. Strategies that aim to strengthen integration of malaria vaccination in the second year of life are recommended. Further, targeted communications and community engagements on the importance of completing malaria vaccination for adequate protection through outreaches, campaigns, community sessions, male involvement, and advocacy by political/opinion and gatekeepers need to be enhanced.

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Supplementary Files:

Supplementary File S1:

		2019		2020		2021		2022	
County	**Malaria vaccine**	**n%**			**n%**		**n%**		**n%**
Bungoma	Total population (under 1 yr.)	7556		7282		7519		7880	
	RTS, S 1	2984	39	5569	76	6340	84	6572	83
	RTS, S 2	1814	24	4864	67	5703	76	6073	77
	RTS, S 3	589	8	4302	59	5061	67	5776	73
	RTS, S 4		*	77	1	2403	33	2798	37
Busia	Total population (under 1 yr.)	13453		10852		11170		11509	
	RTS, S 1	5069	38	9242	85	9633	86	10047	87
	RTS, S 2	3534	26	8692	80	8653	77	9603	83
	RTS, S 3	1290	10	8264	76	7441	67	8643	75
	RTS, S 4		*	123	1	3473	32	3912	35
Homabay	Total population (under 1 yr.)	17762		15205		15695		16167	
	RTS, S 1	7062	40	11925	78	11925	76	13125	81
	RTS, S 2	4179	24	10673	70	10376	66	11809	73
	RTS, S 3	1114	6	9348	61	9032	58	11002	68
	RTS, S 4	2	*	113	1	2935	19	4570	29
Kakamega	Total population (under 1 yr.)	34205		28267		29120		30176	
	RTS, S 1	12257	36	22446	79	23720	81	25779	85
	RTS, S 2	8048	24	21201	75	21964	75	23987	79
	RTS, S 3	2900	8	20486	72	19991	69	22616	75
	RTS, S 4		*	608	2	9462	33	11642	40
Kisumu	Total population (under 1 yr.)	30459		27924		27395		29860	
	RTS, S 1	11302	37	22150	79	24690	90	24628	82
	RTS, S 2	6996	23	21500	77	22704	83	22572	76
	RTS, S 3	1047	3	20105	72	20706	76	21269	71
	RTS, S 4	16	*	558	2	9044	32	10552	39
Migori	Total population (under 1 yr.)	13274		11726		12176		12657	
	RTS, S 1	5039	38	9758	83	9786	80	9993	79

	RTS, S 2	2941	22	8871	76	8812	72	9325	93
	RTS, S 3	564	4	8318	71	7830	64	8666	68
	RTS, S 4		*	191	1	2741	23	4269	35
Siaya	Total population (under 1 yr.)	17438		13910		14313		14740	
	RTS, S 1	6540	38	11214	81	11877	83	12354	84
	RTS, S 2	4082	23	10400	75	10574	74	11256	76
	RTS, S 3	1385	8	9732	70	9459	66	10497	71
	RTS, S 4		*	388	2	3729	27	5190	36
Vihiga	Total population (under 1 yr.)	11855		8208		9269		9588	
	RTS, S 1	4321	36	6383	78	6988	75	7331	76
	RTS, S 2	2891	24	6074	74	6439	69	6982	73
	RTS, S 3	1233	10	5848	71	5923	64	6808	71
	RTS, S 4		*	383	3	3504	43	4341	47

Supplementary File S2:

Malaria vaccine RTS, S between the doses in Malaria Lake endemic zone, Kenya 2019-2022

Malaria vaccine (RTS, S)	**2019** **n (%)**	**2020** **n (%)**	**2021** **n (%)**	**2022** **n (%)**
RTS, S 1	54574	98687	104959	109829
RTS, S 1 &2 drop out	20089 (37)	6412 (6)	9734 (9)	8222 (7)
RTS, S 2 &3 drop out	24363 (71)	5872 (6)	9782 (10)	6330 (6)
RTS, S 3 &4 drop out	10104 (99)	83962 (97)	48152 (56)	48003 (50)