

Assessing the Fidelity of the Malaria Vaccine Implementation in Malawi

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Abstract

Background:

Remarkable progress has been made in the fight against malaria over the last two decades. Despite the mounted response using preventive and treatment measures, the rate of malaria case incidence and mortality stalled from 2015 onwards. Mosquirix (RTS, S/AS01), a 4 dose malaria vaccine with an effectiveness of 39%, was piloted by the WHO in three countries including Malawi where the vaccine is integrated in the EPI as a regular schedule dose. The vaccine portrays a chance to enhance the globally stalled progress against the malaria epidemic. Fidelity, therefore should be assessed in order to correctly identify the adherence to the planned protocol for the rollout of the program and evaluate whether it is being undertaken as planned.

Methods:

This is a descriptive qualitative cross-sectional study that used the implementation fidelity framework (2007). 12 Healthcare workers were interviewed while 47 parents or guardians attended 2 focused group discussions, in two separate health centers serving as immunization clinics. A non-participatory checklist was also used to predetermine the status of the vaccine storage and the system of administration of the malaria vaccine. Data was analyzed using the framework analysis approach.

Results:

59 participants were interviewed in this study, 12 were HCWs and 47 were guardians. Out of the 12 health workers that were interviewed, 2 (17%) were female and 10 (83%) were male. While for the clients, all 47 (100%) were female. The average age of HCWs was 38 while for the guardians it was 29. The study observed that there was adherence to the protocols but to a lesser extent.

Conclusion:

It is evident that the Malaria vaccine programme has to some extent been implemented with fidelity and there is demonstrable adherence to the vaccine protocol. Nevertheless, gaps still exist and it is the role of the Ministry of Health through the respective departments to learn from such experiences and employ strategies that will even increase adherence to the vaccine protocol by health workers which ultimately will reduce the malaria burden in the country since adherence to the protocols may also lead to improved efficacy of the vaccine.

Background

Remarkable progress has been made in the past decade towards malaria control worldwide. According to the 2020 WHO World Malaria report, Malaria case incidence (i.e. cases per 1000 population at risk) reduced from 80 in 2000 to 58 in 2015 and 57 in 2019 globally. Between 2000 and 2015, global malaria case incidence declined by 27%, and between 2015 and 2019 it declined by less than 2%, indicating a

slowing of the rate of decline since 2015¹. Additionally, the report went further to indicate that globally, the malaria mortality rate (i.e. deaths per 100 000 populations at risk) reduced from about 25 in 2000 to 12 in 2015 and 10 in 2019, with the slowing of the rate of decline in the latter years¹.

It is apparent from the report that despite the progress made so far in the fight against malaria, there is more that needs to be done in terms of prevention and treatment. The most prevalent malarial parasite in sub-Saharan Africa, accounting for 99% of the estimated malaria cases is *Plasmodium falciparum*². Currently tools against the vector borne disease strain display only a partial effectiveness and in some cases increasingly threatened resistance².

There has been an increased need for a complimentary tool to drive down the disease burden and achieve a world free of malaria. In October 2015, the World Health Organization (WHO) jointly called for pilot implementation of the RTS, S/AS01 (Mosquirix™) vaccine in 3 to 5 settings in sub-Saharan Africa which include Ghana, Malawi and Kenya³. The Mosquirix™ vaccine, during the phase 3 trial, in children aged 5 to 17 months old, showed reduced malaria episodes by 39% (95% CI 34–43)⁴.

WHO established the malaria vaccine implementation program (MVIP) to support and coordinate the introduction of the vaccine in selected areas of Africa, characterized by medium-to-high malaria transmission, through country-led routine immunization programs and to evaluate the outstanding questions related to the public health use of the vaccine. A four dose schedule is required, at five, six, seven and twenty-two months of age. Mosquirix™ can also be administered with other vaccines in the national immunization program⁵.

Malawi, as one of the selected nation for the phased introduction and evaluation of the vaccine under the MVIP, has eleven districts participating in the program. The participation is based on high malaria burden, high extended program of immunization (EPI) coverage and high coverage of malaria interventions. The districts include: Karonga, Nkhata Bay, Ntchisi, Mchinji, Lilongwe, Balaka, Mangochi, Machinga, Phalombe, Chikwawa and Nsanje. Each of these eleven districts have been subdivided into clusters, each comprising two or more health facilities. These clusters are randomly grouped into two; half are malaria vaccine implementation areas and the others are serving as a comparison area (placebo). The comparison cluster sites will obtain the vaccination upon successful implementation of the MVIP⁶.

It is important to point out that for the vaccine to be effective and achieve the intended goal of offering protection against malaria in children, health workers must administer it or implement the pilot study on vaccine with fidelity. Implementation fidelity, sometimes called adherence or integrity, refers to the degree to which an intervention is delivered as planned⁷. Thus in this case implementation fidelity is likely to increase efficacy of the Malaria vaccine and on the contrary if not administered with fidelity it may not bring the desired results. Thus evaluating whether the Malawi vaccine trial was implemented with fidelity will contribute to the available literature in understanding some challenges that may arise in post vaccine or roll out phase. Such challenges may include side adverse side effects or indeed high failure rate of the vaccine.

Therefore problems with the fidelity of the vaccine implementation may diminish its chances of entering a worldwide implementation, depriving the world of a potentially successful tool that could eradicate one of the leading causes of child mortality in sub-Saharan African¹⁸. It is apparent that due to the high burden of Malaria within sub Saharan African and the high stakes invested in this evolutionary vaccine, it is evident that the chances of eliminating malaria are high if the vaccine works well or if the system in which the vaccine is used functions correctly.

Due to the high burden of Malaria within sub Saharan African and the high stakes invested in this evolutionary vaccine, it is evident that the chances of eliminating malaria are high if the vaccine works well or if the system in which the vaccine is used functions correctly²². Problems with the fidelity of the vaccine implementation would result in inadequate effect of the vaccine and thereby diminishing its chances of entering a worldwide implementation, depriving the world of a potentially successful tool that could eradicate one of the leading causes of child mortality in sub-Saharan African. Several studies on Malaria vaccine have been conducted in Malawi however the studies largely focused on safety and preventative effect of the vaccine against Malaria. This study therefore aims at contributing to the literature on fidelity of the Malaria Vaccine Implementation in Malawi which will be crucial in roll out of the Malaria vaccine in the country.

Vaccination Trends in Malawi

Vaccination has been practiced in Malawi since early 1900s which was later classified into the expanded program of immunization (EPI) in 1979⁸. EPI services extend across government and mission operated health centers as well as private hospitals in Malawi. There has also been a provision of outreach clinics with the aim to get vaccination services as close as possible to the clients in order to overcome the distance (geographical) barrier faced by them⁸. Despite the numerous efforts made to improve the uptake of immunization, there are several challenges to reach optimal uptake. According to the Malawi demographic and health survey (MDHS) 2015-16, 76% of children age 12–23 months had received all basic vaccinations⁹. The percentage of children 12–23 months in Malawi who have received all basic vaccinations declined from 82% in 1992 to 64% in 2004 before rebounding to 81% in 2010. Between 2010 and 2015-16, the percentage dropped slightly to 76%⁹. Studies have indicated multiple factors that affect the coverage of vaccinations. One of the factor that affects the coverage is the birth order⁸. Children born into larger families have a low vaccination coverage; and first born children are more immunized on time than second born children⁸. Residence of the child is another factor that affects the coverage of the vaccination. Children in urban Malawi are more likely to complete the immunization schedule successfully than those children in rural areas mostly due to problems relating to access to health facilities^{8, 9}. One of the most important determining factor for vaccination coverage remains the mother's education level. In the Malawian setting, taking children for vaccination remains the women's' responsibility (mother, aunt or grandmother) and rarely men step in to the task⁸. According to the MDHS, vaccination coverage generally increases with increasing mother's education (79% of children age 12–23

months whose mothers have a secondary education have received all basic vaccinations compared with 72% of children whose mothers have no education)⁹.

Overtime, one of the methods to address the shortfall of the vaccination program was to increase the workforce to meet the demands of the population coverage. In Malawi, health surveillance assistants (HSAs) have been instrumental in bringing immunization services, to remote areas amidst an acute shortage of professional healthcare workers¹⁰. HSAs work under adverse conditions with low remuneration, rare upward career mobility and inadequate equipment. Despite the challenges, HSA immunization services are generally considered satisfactory by supervisors as well as by caretakers/mothers among the local population¹⁰. HSA services have played a role in improving the knowledge and understanding of the vaccines for the mothers and thereby promoting the coverage of the vaccinations¹⁰.

Efficacy studies on Malaria Vaccine in Malawi

The efficacy and safety of the RTS, S/AS01 candidate malaria vaccine was conducted in Malawi from March 27, 2009, until Jan 31, 2011, children (age 5–17 months) and young infants (age 6–12 weeks) were enrolled at 11 health facilities. At the same time a similar study was being done in other countries, namely Ghana and Kenya³². The study found that RTS, S/AS01 prevented a substantial number of cases of clinical malaria over a 3–4-year period in young infants and children when administered with or without a booster dose. Efficacy was enhanced by the administration of a booster dose in both age categories. Thus, the vaccine has the potential to make a substantial contribution to malaria control when used in combination with other effective control measures, especially in areas of high transmission³². Thus based on the lessons learnt from this study, the next phase was to pilot the vaccine in the large population hence the decision by Malawi to integrate the Malaria Vaccine into the EPI.

Integration of Malaria Vaccine in EPI

In 2019, Malawi integrated the malaria vaccine in to the EPI as a regular schedule dose vaccine⁴. Alike every new vaccine introduced and integrated in to the EPI, there are challenges to its successful implementation and improving coverage. Similarly, Guignard, Praet, Jusot, Bakker and Baril argues that implementation and integration of new vaccines bring additional logistical complexity to delivery of existing immunization programs in LMICs²⁷. A range of factors may contribute to lower than desirable levels of vaccine introduction. Decision-making processes, economic and financial aspects of NVIs are critical ones²⁸. That's it is clear from available evidence that vaccine introduction in any setting is not an easy undertaking and needs careful consideration of the delivery strategy. Similarly, in a study on innovative vaccine delivery strategies in response to a cholera outbreak in the challenging context of Lake Chilwa. A rapid qualitative assessment, Heyerdahl et al add that participants perceived the strategies from which they benefitted to be better than the other strategies in the targeted area²⁹. Therefore, stressing the fact it is critical when implementing vaccine campaigns, for implementers to consider delivery strategies are acceptable and will likely increase vaccine coverage by a larger percentage. Thus

correctly established strategies eventually lead to positive implementation outcomes that can be measured to estimate the success of the new intervention⁷. It is therefore crucial that implementers must monitor and track how the vaccine is being delivered to ensure that any bottle necks are addressed and effectiveness is attained²¹. One such tool that may be used in monitoring vaccine delivery is the implementation fidelity framework. This study also utilized the implementation fidelity framework to understand whether the malaria vaccine program was being delivered as intended at Mangochi district health office.

Implementation Fidelity Frameworks

The implementation of Malawi vaccine program carries high hopes of eliminating and eradicating Malaria from the continent. In order for the program to succeed and be further expanded across other nations, it will require an effective implementation that will bridge the phase 3 trial earlier conducted into routine practice. Implementation research outcomes are used to measure the success or failure of an implementation activity and one of the components is Fidelity.

As previously defined implementation fidelity refers to the degree to which an intervention or programme is delivered as intended⁸. Only by understanding and measuring whether an intervention has been implemented with fidelity can researchers and practitioners gain a better understanding of how and why an intervention works, and the extent to which outcomes can be improved⁸. There are two types of implementation fidelity frameworks. A conceptual framework by Carol et al composed of 5 core elements and a modified implementation fidelity framework by Perez et al which that further incorporates adaptation components¹¹. The conceptual framework of implementation fidelity is composed of five elements which include: Adherence (extent to which the delivered intervention corresponds to the designed intervention); Dosage or Exposure (the amount of an intervention received by the participants); Quality of delivery (the manner in which a staff member delivers a program); Participant responsiveness (engagement of participants in activities of the intervention); and Program differentiation (the presence of unique and critical elements of the intervention)⁷. (Fig. 1 and Fig. 2 inserted below here)

The modified fidelity framework includes the components of the conceptual fidelity framework along with an addition of an adaptation component. This adaptation part focuses on the process of implementation in which users are bringing changes to the original design of the intervention due to contextual reasons and is mostly used for assessment of implementation fidelity adaptation balance requirements when implementing adaptive interventions¹¹. For the purpose of this study, the conceptual fidelity framework was used due to its greater suitability as the malaria vaccine program is novel and has little room or plans for changes due to adaptation. The 5 core components are the primary goals to assess the fidelity of the current program and identify the critical elements of the vaccine program.

Prior to this study, several studies have applied the conceptual implementation fidelity framework, most of them assessing adherence to respective protocols. These studies showed that the greater the adherence of implementation of an intervention, the better the intended outcome produced^{12, 13}. A

specific example study where this framework was utilized was in an evaluation of a program that was developed to improve school performance and student desired outcomes in Northern Florida: The Positive Action Program¹². This study demonstrated that the students in a cohort that adhered to the program's elements had improved their attitudes positively towards school as compared to the students in the cohort that did not adhere to the program. The study also showed that with greater adherence to the program, the students' behaviors also improved and there was a substantial reduction in substance abuse and violence. Studies that have examined the quality of delivery of an intervention and participant responsiveness indicate that interventions with high quality produce better outcomes as compared to those with poor quality¹⁴.

This study extensively determined the 5 core components of the framework in an applied manner to the program. Adherence included content, frequency, duration and coverage.⁶ Adherence relates to the amount of an intervention received by participants, the frequency, the duration and if it is delivered to the intended population¹⁵. An implemented intervention is likely to achieve its intended outcomes if it adheres completely to the content, frequency, duration and coverage as per the original design of the protocol¹⁶. As such, this study determined the performance of the vaccine providers in accordance to the designed adherence protocols.

Quality of delivery is the manner in which an intervention is delivered⁷. An intervention is more likely to be of high quality when facilitation strategies are put in place¹⁵. These strategies can include adequate trainings, provision of guidelines, simple and non-complex commands, adequate staff members, feedback to service providers, among other options¹⁶. This study assesses the availability of guidelines or manuals for service providers, trainings of staff members, monitoring and feedback provision mechanisms.

Participant responsiveness is the extent to which participants are engaged by and involved in the activities and content of the intervention⁷. It focuses on the thoughts of the service provider and the service recipient regarding the relevance of an intervention¹⁶. If participants therefore perceive the intervention as valuable, the implementation fidelity will be higher than compared to where participants have negative perceptions^{23, 24}. This study assessed the perceptions of both the service providers as well as the service recipients in order to evaluate their acceptance of the vaccine intervention.

Program differentiation is simply the identification of unique features of the intervention and elements which are essential to the intervention⁷. This study explored the essential components and evaluated the extent to which they are implemented. All the elements detailed above are interrelated. An effect on one element may positively or negatively affect another element^{15, 25}. The study employed multiple guides to enable the data collection of the required elements of the implementation fidelity framework.

While the MVIP portrays a chance to positively impact the stalled progress in the reduction of the case incidence of malaria, it was essential to evaluate and assess the progress the program embraced. The effectiveness and influencing factors of the vaccine with consideration of the coverage provided insight

and the current impact status and input to feasibility and further implementation plans of the vaccine program. Fidelity therefore is a crucial element that was assessed in order to correctly identify the adherence to the planned protocol for the rollout of the program and evaluation on whether it is being undertaken correctly as planned. This is the first study under the MVIP focusing on fidelity.

Methodology

Type of research study

This was a descriptive qualitative cross-sectional study in which implementation fidelity assessment was studied using the implementation fidelity framework. A cross sectional-sectional study design is a type of observational study design that measures the outcome and the exposures in the study participants at the same time²⁶. Thus the researcher only wanted to observe the health care workers practices in Malaria vaccine administration without any interference. Therefore, data was gathered to generate a picture of the implementation process of the malaria vaccine and its fidelity using non-participatory observations, process maps of accessing or delivering the vaccine, one on one interviews and focused group discussions.

Study Place

According to the 2019 vaccine performance data published by the WHO Malawi country office for the time period of January to October, of all the 11 districts currently enrolled in the MVIP, Mangochi district was shown to be the least well performing site for the program. With only a 34% coverage for the first scheduled dose, 19% coverage for the second scheduled dose and 12% for the third scheduled dose, its coverage was below the total average. Mangochi district is composed of 5 cluster sites for the vaccine and therefore evaluating the fidelity of the best performing cluster and least well performing cluster within the district aided in understanding the concrete issues impacting the program. The clusters (health centers) that were used for this study were Mangochi district hospital cluster and Chiponde health center. The services offered at Mangochi district hospital include inpatient and outpatient care, surgical and medical services, pediatric and adult wards, HIV and STI care, emergency care and outpatient clinic services. It is staffed with health workers ranging from specialist medical doctors to health technicians. The outreach clinics run daily for all the health facilities under the area where they serve. The services offered at Chiponde health center include OPD services and immunization services, it is staffed with 6 health surveillance assistants.

Study Population

The population of the study were the healthcare workers (HCWs) that are currently working in the malaria vaccine implementation program as well as the parents and guardians of the children that are eligible for the malaria vaccines.

Study Period

This study was conducted and finalized between the months of January 2020 to March 2022.

Sampling and Sample Size

Purposive extreme deviant case sampling method with maximum variation on sites (static and outreach) was administered and all the available stakeholders were approached for better data collection.

Purposive extreme deviant case sampling was used in this case to gain an understanding why participants in non-performing sites were not doing well in vaccine administration and which specific Malaria vaccine standard practices were they failing to adhere to. Similarly, palinkas et al argues that purposive extreme deviant case sampling is used to identify and expand the range of variation or differences, similar to the use of quantitative measures to describe the variability or dispersion of values for a particular variable or variables³⁰.

Studies have indicated that data saturation for most part occurs by the time twelve interviews are analyzed (92% coding created)¹⁷. We interviewed twelve individuals to reach a data saturation point (Table 2). For the focused group discussions, all the participants available were approached to participate to ensure a greater validity of the data and information available. Additionally, another criterion that guided the sampling was the experience, knowledge and practical skills in vaccine administration. That's participants to the study at least needed to have expert knowledge, experience in vaccines and practitioners who administer the malaria vaccine. Table 1 below shoes a distribution of the study participants

Table 1
Sample Size

Participant	Number	Rationale
District Environment Health Officer (DEHO)	1	The DEHO is the person in charge of the targeted disease prevention programs hence he is responsible for the vaccination programs
EPI Coordinator (EPIC)	1	The EPIC is the focal person in charge of all vaccinations as constituted by the expanded program of immunization
Malaria Vaccine Coordinator (MVC)	1	Every district has a MVC responsible for the planning and execution of the MVIP
Health Center 1 - Static Health Surveillance Assistant (HSA)	2	HSAs are the primary service providers at the village level of the districts. Their input to the study enhanced the understanding of the exact ground situation regarding the MVIP
Health Center 1 - Outreach Health Surveillance Assistant (HSA)	2	
Health Center 2 - Static Health Surveillance Assistant (HSA)	2	
Health Center 2 - Outreach Health Surveillance Assistant (HSA)	2	

Data Collection

Data was collected using a structured checklist that aimed at checking the following areas: Vaccine storage & usage, pre vaccination, vaccination, post vaccination, evidence of facilitation strategies and quality of delivery. This was done for the researcher to understand the routine practices by the health workers during vaccine administration, interview guide, focused group discussion guide and audio was recorded to capture all relevant details. A formal signed written consent was sought from all the participants prior to the start of the interview or the discussions.

Adherence included the subcategories of content, frequency, duration and coverage⁶. In-depth one-on-one interviews were employed to assess the service providers' (this included the HSAs as they were the ones responsible for the coordination of the activity) knowledge of the subcategories of adherence because an intervention is likely to achieve its intended outcome if it adheres to its designed subcategories. Quality of delivery related to the manner in which the intervention was delivered⁷. Facilitation strategies were supporting strategies that optimized and standardized the training and support provided to service providers, this included the provision of manuals, guidelines, trainings and feedback⁷.

Significant steps leading to receiving the vaccine were documented which led to formation of the process map for the vaccine. Heher and Chen defines process map as a diagrammatic representation of a sequence of actions for a given activity³¹. Thus in the case of Malaria vaccine the process map will provide an explanation and visualize the steps a guardian will have to take at a health facility for child to be fully vaccinated. The process map data was collected from observation of 6 parents/guardians and children on the steps involved for them from entering the health facility to receiving the vaccine to exiting the health facility. This process map details all the steps and instructions as well as processes required at each step in the cycle of program.

Non-participatory observations were used to assess for the quality of delivery and facilitation strategies. This checklist was developed (by the author) from the training manual for the introduction of the malaria vaccine. The checklist entails sections on vaccine storage and usage, pre vaccination phase, vaccination phase, post vaccination phase, evidence of facilitation strategies and quality of delivery. Participant responsiveness refers to the extent to which participants were engaged and involved in the program⁷. Since this category entails both the service recipients and the providers, a focused group discussion was used to ascertain the engagement of the service recipients and the service providers were engaged within in depth one on one interviews. Essentially, the study identified the critical elements that are pertinent for the intervention to have its intended effect, thereby addressing the program differentiation category⁷. A process map was also generated from the observations that were detailed in the pathway to getting the malaria vaccine for the children.

The focus group discussion was conducted by the investigator at the health center where the EPI services were provided. The investigator appointed was medical personnel with experience in qualitative data collection. A one-day training was conducted for the investigator in which he was oriented to the data collection tools and the data collection process. Mock interview and training for the focused group discussion was conducted so as to ensure a timely process is conducted. The investigator also conducted the observations according to the checklist. As there was no existing checklist that ensured the entire process of the MVIP, the checklist was developed by the principal investigator using the training manual for healthcare workers, the vaccine storage and handling guidelines, as well as information gathered from sources from the WHO and Ministry of Health EPI officials. Participation was open to all parents and guardians of children receiving the vaccine. A total of two focused group discussions were conducted, one from each site of vaccine delivery so as to compare the views of the parents and guardians from both the sites.

Table 2

below shows how the study participants were segregated based on the study design:

Method	Type of Participant	Rationale
Non-participatory observation	Healthcare workers	HCWs are the primary service providers for the program therefore to observe their routine practice
In-depth interviews	Healthcare workers	HCWs are the primary service providers for the program therefore assess their understanding and perceptions of the program
Focus group discussions	Guardians of the children	To consolidate the findings regarding the vaccine and its delivery process
Process maps		To establish the pathway to getting a vaccine

To ensure data quality was maintained, the right participants were recruited for the study, thus those only those who had expert knowledge in vaccine administration, practitioners who provide vaccines and guardians who had children eligible for vaccines and who brought their children to hospital to receive vaccines were free to share their experiences. Further to this, the data collection tool was piloted at Mangochi DHO and this provided the researcher an opportunity to refine any questions that were not clear. Further to this, participants were asked all questions in the data collection tool and in the same manner which ensured completeness and consistency of the data thereby increasing validity, reliability and generalizability of the study. Leung defines validity in qualitative research as “appropriateness” of the tools, processes, and data. And he went to define reliability as exact replicability of the processes and the results. Lastly he defines generalizability as the extent to which the findings in one study can be generalized to another under similar theoretical, and the proximal similarity model³³.

Data Management

Unique identification number was assigned to each recorded interview and focused group discussion as well as each checklist which was used for non-participatory observations. Data were stored securely with the investigator within their office based in Blantyre and accessible by only the investigator and supervisors.

Data Analysis

The data collected was then manually transcribed (and translated where required) and analyzed using the framework analysis approach. The steps of the framework analysis that were conducted included transcription where the audio recordings were transcribed word-for-word without dialogue transcription. Transcripts had large margins and adequate line spacing for later coding and making notes. This was followed by familiarization with the interview audio recordings and transcripts and all contextual or reflective notes. Coding was conducted with careful reading of the transcript line by line and applying a paraphrase or label (code) that described what was interpreted as important in the passage. After coding, a working analytical framework was developed after analyzing first few transcripts and discussed upon

and eventually applied by indexing the subsequent transcripts using the existing categories and coding. A spreadsheet was then used to generate a matrix and the data was charted into the matrix. The charting involved summarizing the data by category from each transcript. A separate file was used to note down the impressions, ideas and early interpretations of the data. If an interesting idea or concept showed up, a breakaway session was employed to explore the concept further as the data is being completely interpreted. Lastly, a write-up describing and interpreting the themes in relation to the research question was developed.

The non-participatory observations were compared and evaluated against the checklist that was developed by the author through the training manual used for training of HCWs.

Results

Demographics Characteristics of the study participants

This section details the results from the data collection exercise. It should be noted that the data presentation has been split into two since the study interviewed two groups of people, namely health care workers and clients. 59 participants participated in this study and out of the 59 study participants 12 were HCWs and 47 were guardians. Thus 12 health care workers were interviewed and 47 guardians took part in focus group discussions.

Gender Distribution of the study participants

12 health workers were interviewed, from which 2 (17%) were female and 10 (83%) were male. While for the clients, all 47 (100%) were female.

Age Distribution of the study participants

Age of the study participants was categorized into a 4 class variable as follows: 18–19, 20–29, 30–39, 40+. The average age of HCWs was 38 while for the guardians it was 29. Table 3 is a representation of age distribution amongst the health care workers and guardians.

Table 3
Age distribution for Health Workers and Guardians

Age	Frequency (HCWs)	Frequency (Guardians)
18–19	0	9
20–29	3	27
30–39	5	10
40+	4	1

Education Level of the study participants

All the 12 HCWs had completed secondary education. While for the guardians 35 had completed primary school, 11 had completed secondary education and 1 tertiary education. Additionally, 38 of the guardians were able to read and write and 9 were not able to do so.

Occupation status of the study participants

The average years of experience for the HCWs was 16. Additionally, 4 out of the 10 HWCs were senior HSAs and the others were just HSAs. While, for the guardians, 26 of them were house wives, 20 of them were doing businesses and 1 was on formal employment.

Content and Adherence

Adherence refers to the extent to which the delivered intervention corresponds to the designed intervention. As a general finding, from observations, it was noted that there was adherence to the protocols but to a lesser extent. The reasons for this vary from programmatic challenges to personnel. From observation it was noted that trainings and orientations were not extensive, this was later queried further where it was discovered that the HSAs had only 1 orientation session in which they were required to understand the entire protocol. This led to some parts of the protocol being adhered to and while others which are also crucial to the study being left out by the implementers on the ground. Some of the part of the protocols that were not adhered were pre-vaccination phase where guardians were not giving an opportunity to ask questions about the vaccine, during vaccination the vaccination points didn't have first aid kits for management of side effects, in some instances guardians were not informed of management of post vaccine side effects and supervision of vaccine providers was not done by supervisors. Health care workers during the interviews expressed to know the study protocol however further discussions and responses showed that they did not fully understand the protocols.

Almost all respondents, both HWCs and parents/guardians were able to describe what the vaccine is and the aims of the vaccines in the children. Parents/guardians in the FGDs from both performing and struggling facilities expressed satisfaction in the effectiveness of the vaccine in preventing Malaria. Parents/guardians also said that they did not experience any problems with the vaccine.

Most of the HCWs, especially from the performing facility, in agreement also expressed satisfaction in malaria case reduction at the facility. This is what some HCWs and guardians had to say:

"We are seeing the number of malaria in children to be reduced if we compare to before. The reason is maybe the malaria vaccine" - (HCW, 53, Male, Facility 1).

"I have children, and previously all used to have regular malaria sickness in turns as if it was contagious. But now after the malaria vaccine programme it seems as if this has changed" - (Parent/Guardian, 18, Single, Female, Primary, facility 2)

"None. Ever since my child got vaccinated there weren't any problems and even after the followed us up they found no problems with my child. We are very grateful and happy because the doctors are always available to us at all times" - (Parent/Guardian, 30, Married, Female, Primary, facility 2)

“The vaccine is being received well. Parents of children are happy to bring their children to get the vaccine” - (HCW, 35, Male, Facility 2).

Uptake

All the HCWs expressed that there was generally a positive uptake of the vaccine by parents/guardians. All HCWS argued that almost parents/guardians accepted that their children receive the vaccine, with only one declining within the study period. HCWs expressed that the positive uptake can be attributed to the fact that parents have been hopeful of children free of Malaria which is a common disease in the district. Few other HCWs expressed that the positive uptake is as a result of good counselling they provide to the guardians/ parents. The HCWs went on to say the following:

“The vaccine is being received well. Parents of children are happy to bring their children to get the vaccines” - (HCW, 35, Male, Facility 2).

“Although implementing this has been challenging, almost all women whom we felt were eligible did not decline to take part in the study. I can only recall one woman and that’s it” - (HCW, 38, Male, Facility 2).

“I have seen other women come up to me and say I have a child and I want him to receive the vaccine, these are women with toddlers who are outside the eligible age, so it shows that the reception is generally positive. (HCW, 30-F, Facility 1)

All parents/guardians displayed a liking of the vaccine, stressing that the vaccine has reduced the number of cases they observed. The guardians had this to say:

“I’m just grateful that with the malaria disease that has been problematic, those of us in this vaccination program are able to see some change with it.....” - (Parent/Guardian, 27, Married, Female, Primary, facility 2)

“I had a child who died because of malaria, so when they said malaria kills I agreed, for me that is even why I received this vaccine. If we had this when we had our first babies as women we would have saved many children in the village”. - (Parent/Guardian, 30, Married, Female, Primary, facility 1)

On actual uptake, not all HCWs expressed that there was positive uptake. Some HCWs argued that just like many health care interventions, there were few challenges on uptake in the Malaria vaccine program, particularly attributed to low literacy levels and misinformation by the public.

On low literacy, some of the HCWs said the following:

“One problem I would think of is probably low literacy level of the population here in Mangochi. We can counsel women regularly and use appropriate routes through chiefs to reach out to them but comes of surprise to us that some people claim to not know anything about the vaccine, this shows that some have a problem with understanding this program” - (HCW, 29, Male, Facility 2)

While on misinformation some HCWs said the following:

"I think the vaccine has been accepted very well however there are some people who speak negative about it that discourages people from getting the vaccines" (HCW, 40, Male, Facility 1).

While HCWs argued uptake was good, from observations and discussions with the DHO, facilities were still struggling to enroll targeted numbers in the program. As a program the DHO argued that district has struggled in enrolling more numbers, however, among those approached the decline rates have been lower. The DHO argued:

"I don't think we can say we are happy as a district. We have had campaigns well received than this one. One facility is doing better, while others are struggling with the numbers. And this is not just a district level problem, we are seeing the same across the country in the districts implementing this program".

One HCW in agreement attributed the struggle in uptake to the rollout of the program. The HCW argued that the rollout should have considered counter-information that may affect the uptake of the vaccine. He argued that the inability to deal with such things at the beginning caused challenges in terms of uptake:

"I know we have struggled but I think before we blame the people in the villages we should accept our part. This program was not well introduced. There are too many messages being shared nowadays, make fake news like the covid news. So on this vaccine, we have struggled to deal with that problems too" - (HCW, 34, Male, Facility 2)

Coverage, Dosage and vaccine administration

Study participants were also interviewed on coverage, dosage and vaccine administration. All parents/guardians, from both the facilities performing well and underperforming facility were able to describe who was eligible for the vaccine. Their understanding was as prescribed in the study guidelines.

On Coverage some parents/guardians had this to say:

"Children at the age of 5 months. If they are late for their initial vaccination, can still be started at 12 months' age" - (Parent/Guardian, 33, Married, Female, Secondary, facility 2)

"All of our children are between what they said, 5 months and 22 months. So that's where we know this from, even in the villages we can tell others that it's from 5 months" - (Parent/Guardian, 33, Married, Female, Secondary, facility 1)

Additionally, all HWCs were also equally able to describe the guidelines, including the guidelines for enrolling a child who present late to the facility for their first dose. Some health workers HWC reported:

"It is a vaccine given to children aged 5 to 22 months, to prevent them getting malaria" - (HCW, 52, Male, Facility 1)

“There are 4 doses. 1st dose at 5 months, then 6 months, then 7 months and finally at 22 months” (HCW, 38, Male, Facility 2)

One particular HCW candidly explained these guidelines. To an extent the explanation highlighted the depth of understanding of the guidelines by this particular HCW:

“You simply start them with the first dose if they are late and presented at age where dose 2 is due. From then on you proceed with same intervals. For example, if a child first presents at the age when dose 2 is due then we give the 1st dose right away then 2nd dose after 4 weeks, after 4 weeks the next dose, and the final dose at 22 months’ age still” (HCW, 52, Male, Facility 2)

The high knowledge observed in the HCWs from the performing facility was also observed in the FGDs with parents/guardians, this however was not the case with FGD participants from the struggling facility. All parents/guardians from the performing facilities were able to describe why their children were enrolled into the vaccine program.

HCWs from underperforming facility attributed this low level of knowledge among parents/guardians to low literacy levels. One parent/guardian from the underperforming facility said that:

“I cannot manage to explain what it is. We could go to the hospital and meet advisors who advocate for malaria vaccine” - (Parent/Guardian, 19, Married, Female, Primary, facility 2)

From the Non-participant observation, it was noted that although, the parents and guardians are further informed and encouraged to use INTs and other standard preventive measures of malaria along with the vaccine. It was observed that parents and guardians aren't given an opportunity to ask questions they could have regarding the vaccine. When asked why they (parents/guardians) could not ask the HCWs, some parents/guardians argued that the vaccines are offered in group set-up that does not allow one to express themselves fully. One respondents reported:

“Most times we are in a group and some are rushing to get back home since we stay in far places. So for me to keep on asking questions, I feel that I am making others go home late. If we had meetings with the doctors in person, I would ask where I was not sure.” – (Parent/Guardian, 21, married, female, primary, facility 1)

From observations it was also noted that the inferiority complex that clients from rural villages have towards HCWs could also be the reason why they do not ask question. One older respondent argued that she had full trust of the doctors, and that the information provided by HCWs was enough. She reported:

“I trust the doctors fully. Since my first child they have been helpful and they know what they are doing. I feel I should not ask any questions since the doctors know their jobs”. - (Parent/Guardian, 38, Female, Facility 1)

"I think my friends have said a lot about what it is, the other past wanted to know where we can get information, so most of our information we get here at the hospital from the doctors and nurses at the clinic, and we know they know what is good for our children". - (Parent/Guardian, 39, Female, Facility 2)

From observations, on actual vaccine administration, a poor adherence to the protocol was reflected in this phase. Neither centers had a first aid kit available. The ages of the children were verified prior to administration of the vaccine however, crucial information regarding hypersensitivity reactions to previous vaccines were not obtained. The performing facility had ruled out contraindications to administration of the vaccine by asking mothers if their child has ever reacted to any medicine before. However, at facility 2, the contraindications were not ruled out, like their counterparts in the performing facility, by just getting the child's history. Some guardians commented as follows:

"After being educated, the doctors here administer the vaccines. Also, there are researchers who follow us up in our house holds to check up on our children who have received malaria vaccine for any adverse effects. If there were any there are able to take us to the hospital" - (Parent/Guardian, 18, Single, Female, Primary, Facility 1)

"I don't remember being asked on the reactions my child has had to other medications. They just offer counselling and start the vaccinations. We are told that if any happens we should come back to the hospital" - (Parent/Guardian, 32, Married, Female, Primary, Facility 2).

Despite most of the guardians expressing knowledge and understanding of the vaccine, it was observed that some parents were still struggling with some details about the vaccine such as the schedule or frequency of administration. One guardian had this to say:

"I'm not sure which one exactly because some vaccines are given on the side of the shoulder and others on the thigh" - (Parent/Guardian, 24, Single, Female, Secondary, Facility 1)

On coverage, from the interviews with HCWs, it was noted that all facilities in the district were not doing well. HCWs agreed that the low performance observed in the national aggregations were true but were quick to argue that the result was not entirely HCWs fault. Some HCWs argued that amongst those reached at the facility, the uptake was good, but in general there was still a problem in having the wider community accept the vaccine. Superstition and poor program implementation were the common factors mentioned by HCWs.

"Of course our facility is doing better when compared to the other facilities in the district. We are at 44% which is about 10% high than the district scores. So it's good. But the way the program was started is the main problem. It's difficult for me to convince people when I don't have the backing of the chiefs. So those we convince are people who were already going to get the vaccine, either after being referred by their friends or they just follow medical advice". - (HCW, 38, Male, Facility 1).

"Honestly, we are struggling. I mean when we compare other vaccine campaigns this one is not as good as the others. Maybe it's also because it is new, people are used to measles and other vaccines, but the

malaria one is new. The coming of the covid has also made things very difficult. We started gaining more numbers but after covid things became static. I don't know how it will end" - (HCW, 34, Male, Facility 2)

"I wouldn't say we are doing good. But here at this facility we are doing better as compared to other facilities, I am saying this because I talk with other HSAs from other facilities and they are complaining, both on materials and also just people making a decision to have the vaccine- (HCW, 30-F, Facility 1)

Despite providers being able to articulate the duration of the vaccine, parents/guardians had mixed responses as to how the vaccine was administered. Most participants from the study (more from the underperforming facility) were unable to describe how the vaccine was administered.

"I'm not sure how exactly the vaccine is given to the children and what is in that liquid they give" - (Parent/Guardian, 24, Single, Female, Secondary, Facility 2)

Storage, Transport and cold chain

From observation, it was observed that the guidelines for vaccine storage were well adhered to. The temperature was within the recommended range of 2 to 8 Degree Celsius and vials stored away from all cold air vents. There were no other food items in the fridge. Vaccines were placed in plastic trays within the racks. During transportation, vials were placed in cold boxes with adequate ice packs. Prior to the start of the clinic, vaccine expiry dates were checked and the vaccine vial monitor was checked to ensure viability of the vaccine. The diluent and antigen was reconstituted appropriately and used well within 6 hours of reconstitution with dedicated syringes. Some health workers commented as follows:

"Vaccines are placed on flex foam in the open after reconstitution of the vials. We do this preventing placing vaccines on the ground so as to not compromise desired temperature for the vaccines" - (HCW, 45, Male, Facility 1)

"We store it in vaccine carriers during transport and specialized refrigerators in the labs. We put ice packs in the vaccine carriers together with vaccines. In addition, Fridge cards (cold chain monitor cards) are also in there to be able to tell if the vaccines have been successfully transported without compromise". - (HCW, 29, Male, Facility 2)

"We store it in Styrofoam carriers during transport and specialized refrigerators in the labs. We put ice packs in the carriers together with vials. - (HCW, 40, Male, Facility 1)

All HCWs demonstrated a wide base of knowledge on how to dilute and transport the vaccine. Almost all HCWs were able to explain in detail the processes and detailing out the technical aspects of reconstitution and transportation.

"The vaccine comes in a form of powder with its diluent. These two items are mixed by shaking the mixture, and then 0.5 (cc's) is drawn and administered"- (HCW, 38, Male, Facility 2)

Management of Side effects

Further deficiencies were observed at both sites, reflecting poor knowledge on side effects as seen in both parents/guardians and HCWs. Parents and guardians were not informed of the signs and symptoms of adverse reactions to look out for; they are not informed about the possible side effects. In an observed session, the HCWs did not explain about side effects. The HCWs were just quick to say if the child falls sick, the parents/guardians should rush with the child to a health facility. One FGD responded argued that:

“In most sessions that I have attended we are just encouraged to come to the hospital. We don’t know if the child’s sickness has been caused by the vaccine or not. That is why it is not possible for me to say what problems the vaccine causes. These children get sick all times. They are just babies, so I don’t know.”- (24, female, married, facility 2)

Data Management

From the observation, it was noted that the immunization tally sheet, which counts the number of doses provided, is not completed following the clinic. However, the HCWs will complete it at later day, usually more than two days later, which may lead to errors of documentation. This can perhaps be attributed to lack of consistent supervision noted in the study period. When asked, some HCWs argued that in some cases they run out of tally sheets while in the field, as such it was hard to document.

“I will be honest that in some cases I don’t have enough materials. We sometimes have to photocopy the documents on own and in such cases when I don’t have money, and more people show up, some will not have their details document. In some cases, we write in the hard cover but we still don’t have enough time to go back and transfer the details on the actual tally sheets”- HCW, 38, Married facility 2)

Assess the magnitude of the moderators of the implementation with reference to the implementation fidelity framework.

Strategies and feedback mechanisms

All HCWs reported that the program had no official feedback structures. They argued that they knew their supervisor, but the supervisor had never visited them in relation to the vaccine program. Thus, they relied on the knowledge they had received during training and had to ask other HSAs for clarification in cases where they were not sure. This was more prevalent in the underperforming facility, perhaps because of the location and distance to the district hospital. HCWs argued that in some cases their supervisors were not part of the team to be briefed about the program which made it difficult to have proper supervision. HCWs from the performing facilities cited that in cases of doubt they had human resources nearby to seek guidance from.

“Supervision /monitoring is lacking and this is because of lack of resources such as fuel and transportation means” - (HCW, 35, Male, Facility 2)

“On the vaccine we don’t have supervisors. That is a challenge because we need someone with more knowledge than ours to help us when we don’t do things right. But lucky for us sometimes we have other

HCW who we can go to, but that doesn't make all of work of good quality" -(HCW, 36, Male facility 1)

P: Senior HSAs are in a way supervisors, but are however excluded from any important meetings or briefings involving the EPI program" - (HCW, 38, Male, Facility 2)

In addition to HCW feedback and reporting mechanism, all HCWs reported that they had no feedback mechanisms with parents/guardians. They said that the only opportune time they had with parents/guardians is during a vaccination meeting, where most of them took initiative to ask parents/guardians if they had noted side-effects or other challenges with the vaccine. Some of the HCWs from the underperforming facilities argued that they believed that for parents/guardians who are shy to ask for clarification and stay further from the facility, seeking further help when they experience side-effects and problems was low. They argued that this would negatively affect adherence to the vaccine in cases where the side effects were severe. The HCWs argued as follows:

"Not exactly. We have only ever gotten one complaint from the people, and on that occasion the message was relayed by the village volunteers. We have no official feedback system". - (HCW, 27, Male, Facility 2)

"Our work has no supervision; we usually try to make sure we are doing the best we can" - (HCW, 45, Male, Facility 1)

HCW and parent/guardian client challenges

Although at facilities, both the uptake and adherence seems good, there were number of challenges that are programmatic and also on individual level. The programmatic challenges, listed by HCWs, increased workload with no incentives, stock out of resources/supplies, erratic power supply, lack of proper trainings and refresher trainings and lack of sensitization and support from stakeholders.

Increased workload and no incentives

Another challenge was expressed by health care workers was the increased the workload. They argued that although the program was incorporated to the normal EPI programs, the work in the vaccine program was demanding and this made their overall work tiresome. This was heavily tied to lack of incentives for HCW participation in the program. All HCWs argued that allowances during the vaccine period would motivate most of them, as compensation to their increased workload. These sentiments were shared by HCWs from both facilities, with HCWs from the underperforming facility vocal and emotional on the topic. One of the HCW had this to say:

"I think yes. We are supposed to do our job regularly but with this vaccine added it can increase the workload that's why some incentive would encourage a lot" -(HCW, 45, Male, Facility 1) P: "some allowance to help us do the extra work that has been brought by the vaccine would help many HSAs work harder. We do it now since it's our job but we also know that there is now more work"- (HCW, 36, Male facility 1)

Stock out of resources/supplies

Stock-outs of resources to be used in the program was also mostly mentioned by the HCWs. All HCWs reported a stock-out of materials like syringes during their vaccination campaigns. HCWs argued that stock-out were problematic as they discouraged parents/guardians who were adherent. They argued that some parents/guardians have to travel long distances and when they experience a stock-out whilst at the vaccination station, such parents/guardians were not likely to return on the next suggested date. The HCWs argued as follows:

“During delivery of vaccines there is need for a corresponding ratio between syringes for delivery and actual vaccine vials. Syringes are usually low supply so sometimes we run out of syringes but still have the vaccines” -(HCW, 52, Male, Facility 1)

“Amount of malaria vaccine supply is not being tailored to suit the actual population of a catchment area. We are always finding ourselves to have run out of the vaccine midway when more vaccine supply should have been considered for areas with larger populations. This becomes a problem for other children who were scheduled and, in this case, fail get their due malaria vaccines” - (HCW, 27, Male, Facility 2)

“We usually see a lot of people and sometimes do not have enough stocks of vaccines to give them to all” - (HCW, 35, Male, Facility 2)

From observations it was noted that some stock outs were as a result of poor planning. For example, most HCWs had no tally sheets and resorted into writing vaccination details on papers. This was more common in the poor performing facility, HCWs argued that they depended on supplies from the district hospital, which were not supplied at the required intervals. In the program, tally sheets were introduced for planning purposes, and without them HCWs struggled to plan for the next vaccination activity. One HCW argued:

“Because we stay far from town we have to ask our friends to bring us the tally sheets. We use our own airtime to do that. And if they don't bring the tally sheets there is nothing we can do about it. Sometimes when we visit we get those available so that we can use here”- (HCW, 27, Male, Facility 2)

Furthermore, from observations, the deficiency in required additional IEC materials (flyers, pamphlets) also raised several red flags. Neither of the sites had the IEC materials available, nor did they have a table or chairs to operate from. They did however, have a provision of water and soap as well as a safe disposal box. Medications to counter allergic / adverse drug reactions were not available in either of the centers. Each facility had a vaccine register and child health profile with inadequate malaria vaccine stickers and no calendar. From the observation notes, we noted that child health passports were available in both centers, however, neither of the centers had none of the following: under 2-year-old registers; vaccine tally sheets; adequate malaria vaccine stickers; calendars; guide books for HSAs; reference manuals; nor a vaccine vial monitoring poster. Specifically, on guide books which supports the correct implementation of the SOPs, the HCWs added the following:

“No. the guidelines we use are those provided by the health facility” - (HCW, 52, Male, Facility 1)

“None, we use the guidelines provided by the health centers” - (HCW, 45, Male, Facility 1)

“We aren’t given any guidelines for our reference so it can be difficult to recall from trainings - (HCW, 27, Male, Facility 2)

“Guidelines for the schedules are available. Also, posters are available mostly in the offices that assist for easy remembrance - (HCW, 40, Male, Facility 1)

Erratic power supply

Erratic supply of electricity was also commonly mentioned. Some HCWs argued that electricity challenges do affect their effectiveness. HCWs argued that it would be a challenge if the malaria vaccine study were to be a national program before addressing the challenges that have been experienced so far. One of the HCWs had this to say:

“Erratic electricity availability at the health facility is a worry as they go off almost every day. This might put the vaccines at risk of being compromised due to failure to maintain constant refrigeration” - (HCW, 45, Male, Facility 1)

Lack of proper trainings and refresher trainings

Lack of extensive knowledge on the vaccine that is compounded with absence of refresher courses for HCWs was also a challenge. Training period for all HSAs was for 8 weeks, but an individual HSA would only be trained within 2 days. Most HCWs agreed that the training period was short and that there was supposed to be additional training or updated SOP shared to ensure the messaging going out is the same from all HSAs. Such an approach will equip the HSAs on how to deal with challenges from the field like traditional beliefs. Some HSAs had this to say:

“We did not cover extensive information about the vaccines. As such it is difficult to know how the vaccine works” - (HCW, 45, Male, Facility 1)

“I think it is good vaccine. However just as any program set up, a review meeting (to review the introduction of the vaccine) is needed, and this has not happened at all as an EPI unit. These would have been essential for us to have a platform to voice any concerns”. - (HCW, 38, Male, Facility 2)

“The challenge in the training is that the program provided just vaccination basics. I see this is a challenge as vaccination in general has a lot of science involved and was not taught extensively, as such hoped that more education be provided” - (HCW, 35, Male, Facility 2)

Lack of sensitization and support from stakeholders

Another challenge mentioned by HCWs was lack of proper sensitization, specifically, lack of support from chiefs. HCWs argued that unlike many vaccine campaigns where chiefs were trained and tasked to sensitize locals, the vaccine program excluded chief’s involvement. HCWs argued that it was a challenge to convince parents/guardians who look up to chiefs for guidance.

The HCWs had this to say:

"We don't have support from chiefs really. Other campaigns involved chiefs, they went and had trainings so that when the villagers go to them they [chiefs] can help remove misconceptions. So for this one we are struggling to get people whose neighbors have not accepted the vaccine before". – (HCW, 38, Male, Facility 2)

"In the time of covid-19, we are facing many challenges. It's difficult because we are dealing with many challenges, including covid-19. And without chiefs' help, it's double the problems we face. It would have been helpful if chiefs had cleared the path for us" - (HCW, 45, Male, Facility 1)

"Look, some campaigns have chitenjes, t-shirts, some sort of campaigns that help people to easily accept. In some cases, we hear songs and dramas on the radio, those things seem simple but they do help to change the mind set of people. See Mangochi is the lowest in the country on this vaccine and I think we can say some of the causes is lack of proper awareness" - (HCW, 52, Male, Facility 1)

Covid-19

Although not mostly mentioned, Covid-19 was also one of the reasons mentioned to have challenged HCWs. The extent of how covid-19 was a problem would only be extensively explored later, as during data collection field activities had just been suspended.

"We usually run out of syringes and vaccines. COVID-19 has also reduced the number of people coming for the vaccines - (HCW, 45, Male, Facility 1)

"So it's mixed, like for me I had few women ask me if they should still be coming, some were saying there is covid at the hospital. Yet some are still coming. But I cannot say they have stopped coming due to covid. Had it been a covid related service maybe they could have stopped, I know people have a lot of wrong facts about covid- (HCW, 30-F, Facility 1)

Participants of the FGDs however seemed to have embraced Covid-19 and did not report it as a challenge. Most respondents argued that the hospital knows the rules that must be followed to protect them from the virus.

"As the lady has already explained, I would just like to add that with these days of the corona virus pandemic, they make sure they (HSAs) bring a bucket of water with soap to wash hands and say if we do not wear masks we will not be assisted. Also, they advise us to stay in a distanced line although other mothers do not follow this stubbornly" - (Parent/Guardian, 32, Married, Female, Primary, Facility 1)

We are fine, as of now I think we are used that this virus is here to stay. When we come to the hospital, they make sure that we are following the rules, so it has not affected our ability to come here- (Parent/Guardian, 33, Married, Female, Primary, Facility 2)

“As you can see most of them have masks and gloves on, since covid started, we have seen that all doctors wear those, so we know they are also protecting us- (Parent/Guardian, 22, Married, Female, Primary, Facility 1)

Discussion

The findings of the study have demonstrated that there is adherence to the malaria vaccine protocol which was evidenced by some health workers being able to explain the necessary steps that are taken before vaccine administration, during vaccine administration and post vaccine administration. Again, comments by some guardians expressing knowledge of the vaccine, its purpose and even the schedule is a testimony of the same. Further to this, it is also evident that health workers are knowledgeable about the essential components that play a role in the determination of the fidelity of the program such as scheduling and counselling. It was also evident from the study that there is an established pathway that both health workers and guardians are aware of, that aids in the smooth administration of the vaccine and this was evident from the comments of both health workers and guardians who were able to explain the steps taken on entry into the facility by a guardian up to vaccine administration and exiting of the facility.

As presented in the findings, it is evident that health workers are to some extent adhering to the malaria Vaccine protocol. Similarly, a study by fatiregun et al on Missed opportunities for vaccination among children aged 0–23 months visiting health facilities in a southwest State of Nigeria found that 59% had sufficient knowledge about vaccination³⁴. Thus despite some personnel and programmatic challenges the health workers make an effort to follow the recommended protocol for the vaccine. Again, parents expressed knowledge of the aim of the vaccine, the target group and even indicated that the vaccine has led to reduction of malaria episodes amongst their children. The perception by caregivers that the malaria vaccine has led to reduction in malaria episodes among children, parents are in agreement with other studies on vaccines that have shown that vaccines play a crucial role in reducing diseases. And in agreement with this, a Nigerian study on Immunization Utilization in Nigeria revealed that majority (95.7%) of the respondents (caregivers) stated that immunization prevents diseases, with polio and measles being the vaccine preventable diseases that they were most aware of³⁵. Again, as noted in other studies, vaccination has greatly decreased the burden of infectious diseases globally and has dramatically decreased the threat of diseases that were once wide spread and often times fatal¹⁷. Again, all these are an indication that health care workers are able to explain to parents what the vaccine is all about, the dosage, the route of administration and side effects which suggests that the health workers were to some extent able to adhere to the vaccine implementation protocol. Additionally, the experience acquired from administering other vaccines and Integration of the malaria vaccine protocol assisted the health care workers to properly administer the malaria vaccine.

However, on the contrary it was also apparent that there were challenges with adherence to implementation protocol evidenced by some health workers not providing adequate and correct information to parents which may have an impact on the vaccine uptake and efficacy of the vaccines. In

agreement, a study on missed opportunities and barriers for vaccination in four African countries found reluctance by health workers to open a ten-dose measles vaccine vial for a few children despite policy guidelines allowing the health workers to open the vial even for one child³⁶. And this led to missed opportunities for children to be vaccinated, and in the case of Malaria vaccination it may lead to the same challenges when caregivers are not provided with correct and adequate information regarding the vaccine. Additionally, all facilities did not have first Aid kit which are critical in management of any adverse effects of the vaccine. The study findings have shown that there was minimal exploration of side effects by health workers across all facilities and minimal information given to caregivers regarding side effects which is similar to findings from other studies. Thus health workers commonly communicate little and poorly with mothers, so that some mothers leave not knowing when to return and what to do about side effects³⁷. Again, the study findings have demonstrated that in all sites health workers had poor knowledge of the vaccine side effects. Similarly, in a study by Nkwenkeu et al on Health workers perceptions and challenges in implementing meningococcal serogroup a conjugate vaccine in the routine childhood immunization schedule in Burkina Faso it was found that health workers were unable to engage in health education with care givers during immunizations sessions because they are overloaded with multiple responsibilities¹⁹. Despite this being the case, as part of the vaccine administration protocol health workers are supposed to properly explain to caregivers all the necessary information about the vaccine and unfortunately this indicates noncompliance to vaccine administration with fidelity as it is against recommended practice. Similarly, Xeuatvongsa et al argues that health-care workers should clearly provide information on vaccinations, including the vaccination schedule²⁰. Perhaps apart from documenting the next vaccine dates in the child's health passport, there is need for more proactive approaches by health workers in providing vaccine information to caregivers, such strategies could be playing prerecorded messages about vaccines at under 5 clinics, providing leaflets to caregivers and utilizing every opportunity a mother or care giver come to the clinic with the child, by providing information about vaccines.

Conclusion And Recommendations

Conclusions

It is evident that the Malaria vaccine programme has to some extent been implemented with fidelity and there is demonstrable adherence to the vaccine protocol. Nevertheless, some gaps still exist and it is the role of the Ministry of Health through the respective health offices to learn from such experiences and employ strategies that will even increase adherence to the vaccine protocol by health workers which ultimately will reduce the malaria burden in the country since adherence to the protocols may also lead to improved efficacy of the vaccine

Recommendations

Based on the study findings, the following recommendations have been made:

- Area of Further Research: The following areas must be explored further

- Exploring the behavioral aspects influencing acceptability of Malaria vaccine

- Training of health workers: As alluded in the findings, health workers expressed lack of refresher trainings which ultimately affected their competence in vaccine administration. Therefore, to improve implementation of the malaria vaccine programme it is important that deliberate initiatives be put in place for health workers to undergo refresher training after a certain determined period post training. This will provide them an opportunity to learn skills and experiences from colleagues, reflect on their competence and consequently an improvement in their skills and adherence to recommended vaccine guidelines

- Supervision: Again routine and consistent supervision by supervisors will provide an opportunity for feedback to the health workers which may also motivate them to even since presence of the supervisor indicates that their efforts are being recognized despite of any existing challenges

- Health education: Health education plays a critical role as it provides an opportunity for the health care workers to engage with parents. Consequently, any existing misconceptions about the vaccine are cleared. Further to this it helps to improve the health workers understanding of the vaccine as they have to prepare by reading, consulting from colleagues about the vaccine prior to giving such information to care givers

- Availability of Equipment: It is important that equipment such as refrigerators be readily available and in working condition to ensure that cold chain is maintained thereby improving adherence to vaccine protocol while at the same access of the vaccine

Declarations

Ethics Approval & Consent to Participate:

This study possessed a low overall risk for ethical issues. College of Medicine Research Ethic Committee (COMREC, certificate number: P.03/20/2970) approval was obtained prior to conducting the study. Informed consent and option of opt out was administered to all participants for the qualitative data collection prior to any questions asked. The names of the participants were replaced with identification number to protect the privacy of the participant. The data collected was password protected and all documents were stored in a lockable cabinet which only the researcher had access to. There was no use of human tissue or other biological materials in research published by the WHO. All information was confidentially stored and accessible only to the investigator and supervisors of the study.

Consent for Publication:

Not applicable.

Availability of Data and Materials:

A spreadsheet was then used to generate a matrix and the data was charted into the matrix (<https://docs.google.com/document/d/1-GJo0COdHDS3ulcruDewJ4V8RPTvZIE/edit?usp=sharing&oid=109806019965036199772&rtpof=true&sd=true>).

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The authors declare that they have no competing interests

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Authors Contribution:

Parth K Patel had developed the background, methodology, wrote the results, conclusion and discussion section.

Alinane Linda Nyondo-Mipando guided the proposal development and co-wrote the conclusion and discussion sections.

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Figures

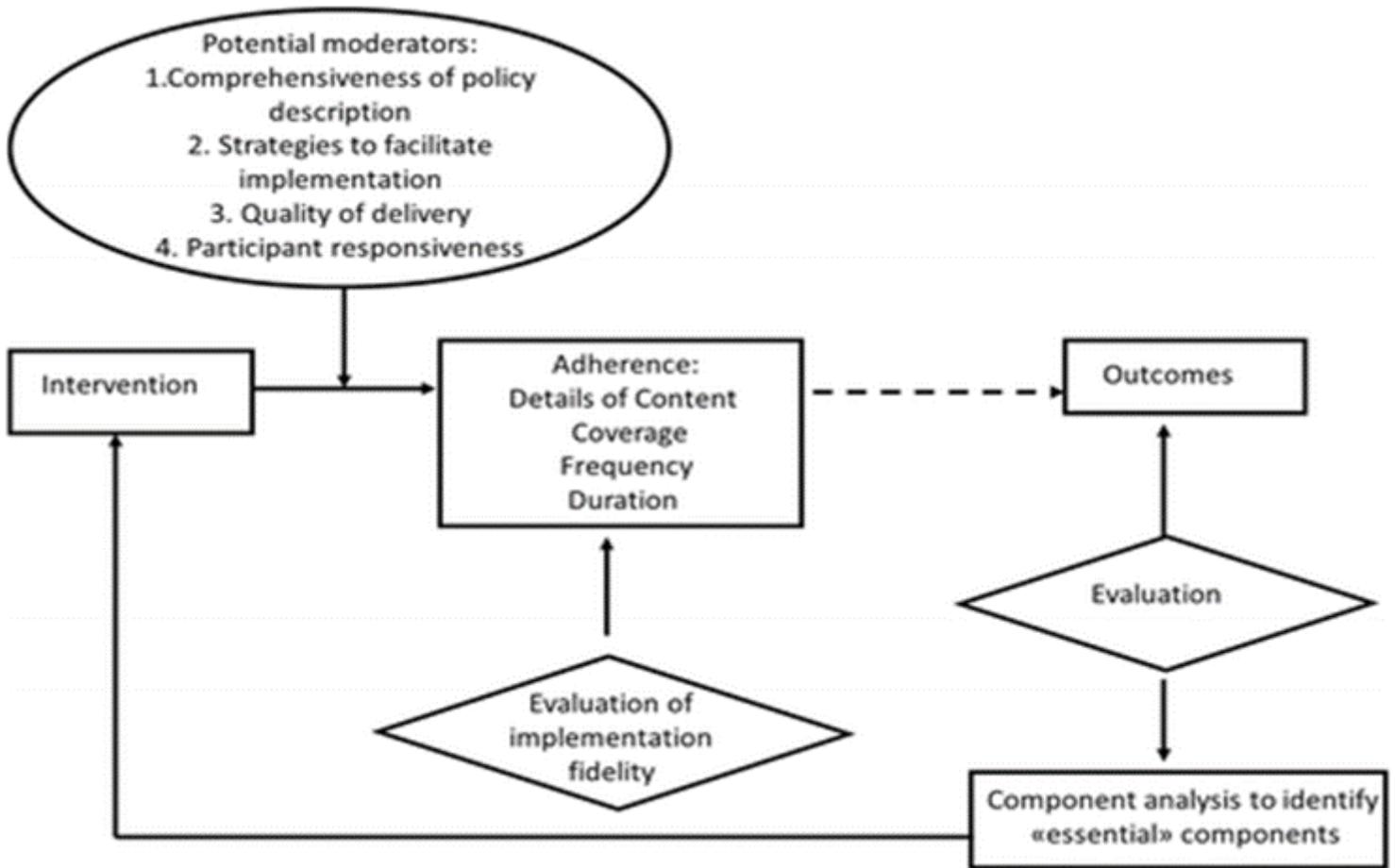


Figure 1

Conceptual Implementation Fidelity Framework

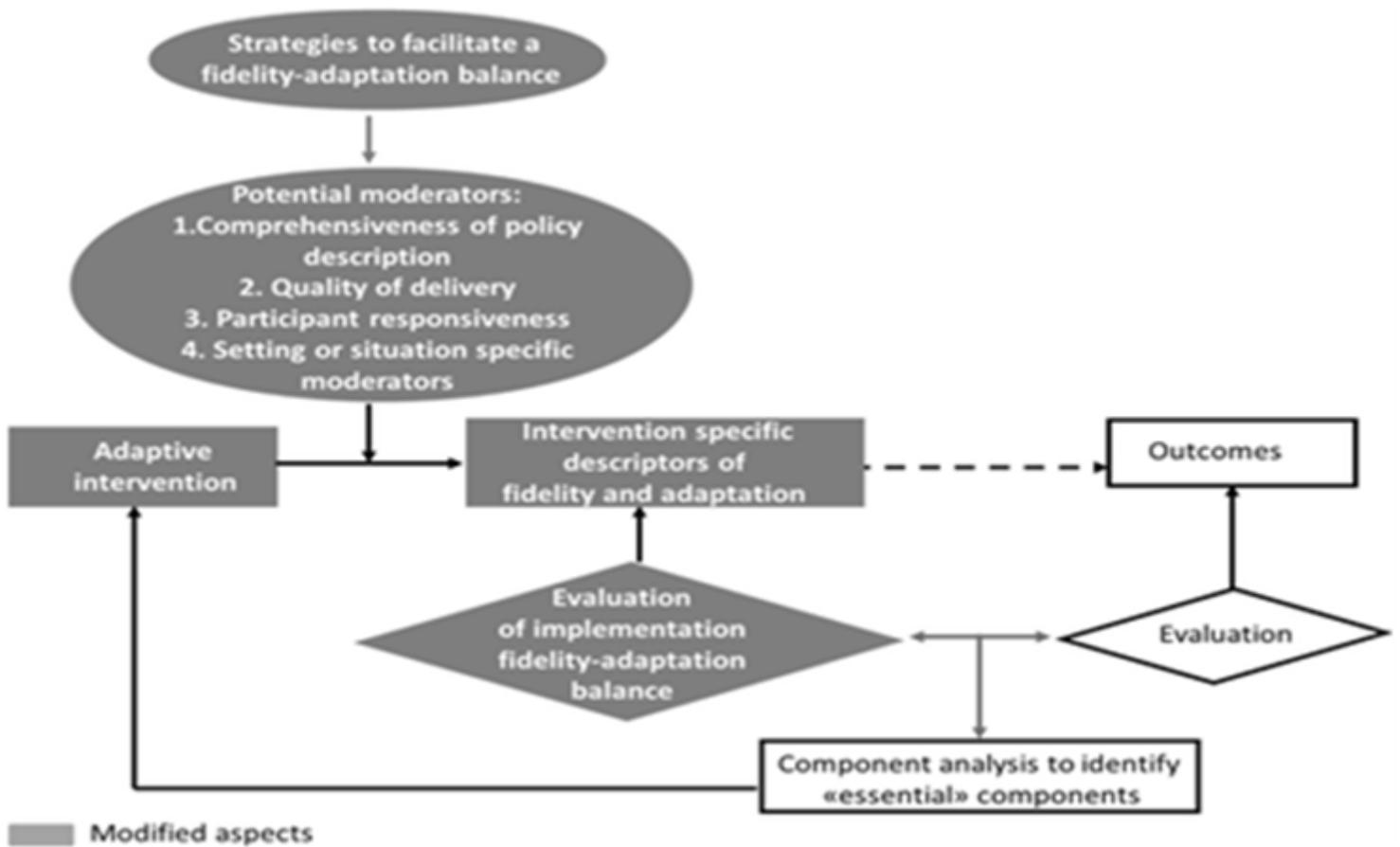


Figure 2

Modified Implementation Fidelity Framework