

Rectal Artesunate Information Education & Communication (RASIEC) Study Report

A cohort study in Malawi assessing the role that targeted Information Education and Communication (IEC) tools play in health seeking and the delivery of care.



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Executive Summary

Background

In communities located several hours from a health facility where intravenous treatment for severe malaria would be administered, the World Health Organization (WHO) recommends rectal artesunate (RAS) also known as artesunate rectal capsules (ARC) be used as a community-based pre-referral intervention for children, to rapidly reduce parasitaemia and allow for transit time to reach treatment. This pre-referral intervention, administered by a community health worker or health surveillance assistant (HSA) in the case of Malawi, can only be of benefit if the continuum of care is uninterrupted. In other words: the patient presents early enough to benefit from the intervention; the pre-referral intervention is administered promptly and correctly and the patient is urgently referred to a health facility where intramuscular or intravenous treatment is administered correctly, over the correct period and followed up with oral ACT.

This study intended to inform future programming in relation to the role that Information – Education – Communication (IEC) could play in enhancing this continuum of care. This study used a tailor-crafted IEC RAS toolkit (<https://www.mmv.org/access/tool-kits/rectal-artesunate-tool-kit>), developed by Medicines for Malaria Venture (MMV), and field tested for comprehension and appropriateness in Malawi and Senegal in 2015. The study hypothesized that community exposure to targeted IEC would increase early presentation by the caregiver at the village health clinic (VHC) for Rectal Artesunate (RAS) and the caregiver acceptance of RAS; and that community health worker (CHW/HSA) exposure to a targeted toolkit would increase appropriate assessment, administration of RAS and referral, and in turn enhance prompt compliance with referral instructions among caregivers.

Methodology

Malaria is the leading cause of death in Malawi among children age 5 and under. The selection of the study areas within Malawi was guided by several scientific and operational considerations, including the eligibility criteria for a hard-to-reach VHC and a resident/on-call HSA. Based on these considerations, Salima and Ntchisi Districts were selected. Salima and Ntchisi are both moderate – to – high transmission settings in the Central Region of Malawi and have a high burden of severe malaria in children 5 years of age and under as compared to the other shortlisted Districts.

Since rectal artesunate has the most significant positive effect for those living the furthest from care, only hard-to-reach communities with VHCs located greater than 5 kilometres from a referral health facility/health centre were included. The study population was entirely rural and represented the hardest to reach village health clinics in the sampled arms. Malaria transmission in these areas is high throughout the year. The study was initiated toward the end of the malaria season 2018/2019 and continued for 12 months until end of March 2020.

The study was designed as a single country, two-arm study with an exposed (intervention) arm receiving the RASIEC toolkit and the unexposed (control) arm receiving no IEC intervention which comprised a community component and a village health clinic component. The community poster emphasized the importance of early treatment of danger signs, eligible ages, signs and symptoms, rectal administration, and the importance of compliance with referral. Two hundred posters in Chichewa were mounted throughout the catchment areas in the exposed arm. Posters were mounted in areas identified and recommended by respondents at baseline.

The HSAs working in the enrolled VHCs in the exposed arm were issued the IEC toolkit – jobaid, reference booklet, flipchart to be used during sessions with community members and two refresher sessions to familiarize them with the toolkit.

The two arms of the study were investigated at baseline and then observed, to determine the caregiver and HSAs attitudes, behaviour and practices in response to an event of suspected severe malaria either at the household or VHC respectively, with or without possible exposure (community intervention) and confirmed exposure (HSA/Village Clinic) to the RASIEC toolkit. The two groups interviewed using structured questionnaires included: i) All 23 HSAs from all the eligible Village Health Clinics and ii) 173 (Salima) and 55 (Ntchisi) caregivers of children <5 years of age in the target catchment areas at the baseline/endline and all (89) reported cases of danger signs presenting at the target VHCs throughout the intervention.

Key Findings

The key results of the study are presented alongside the 5 research questions:

1. ***What is the reality on the ground of community case management of severe febrile illness in a country promoting RAS pre-referral?***

All health surveillance assistants met the basic requirements to operate in their role of community health worker. A minority of the VHCs experienced significant infrastructural challenges that interfered with smooth RAS administration in the minority of VHCs – specifically access to running water, power for nighttime lighting and dry storage facilities for keeping drug supplies. The minority of HSAs received clinical supervision and additional continuing education to support clinical practice during the study period.

2. ***Does caregiver exposure to the RAS IEC intervention increase the likelihood that s/he identifies danger signs and seeks treatment for danger signs from the Village Health Clinic?***

Over 80% of community respondents in the household survey had seen the project IEC posters frequently and recently, and were able to recall the information and communicate a level of understanding. The majority of caregiver respondents, who were unable to read, responded positively to the pictorial posters despite their lack of literacy. Knowledge of the symptoms of malaria and recognition of danger signs among caregivers increased in both study arms during the study. However, the increase from baseline to endline was significantly larger in the unexposed arm. Confounders including the ongoing Malaria Vaccine Trial were considered. All caregivers recognised severe illness and the importance of seeking care – exposure to the IEC (posters) during the course of the study did not influence health seeking in response to danger signs.

3. ***Does Health Surveillance Assistant (HSA) exposure to the RAS IEC intervention increase the likelihood of an HSA correctly identifying the danger signs in < 5-year-old child?***

RAS was acceptable to the surveyed HSAs and the community at baseline and acceptability increased during the course of the study. The IEC intervention had a positive impact on correct response and administration of RAS among exposed HSAs. Exposed HSAs demonstrated more capacity to recognise danger signs, respond and administer RAS than those in the control arm. There was strong evidence that the odds of the child receiving the correct HSA measures at the VHC were higher in the exposed arm.

4. Does HSA exposure to the RAS IEC intervention increase the likelihood of an HSA formally referring a caregiver post –RAS administration?

100% of the 89 tracked danger sign cases who received RAS in the study VHCs were issued a study referral slip, therefore, no difference in HSA capacity to refer post-RAS was observed between the exposed and unexposed HSAs.

5. Does caregiver exposure to the RAS IEC intervention increase the likelihood of a caregiver complying with a referral made by an HSA?

Compliance with referral was extremely high and equal in both study arms. Whether or not the HSA making the referral had been exposed to the IEC toolkit did not make any significant difference to the caregiver's compliance with referral post-RAS. The role of the referral slip in these high levels of compliance was not measured. Caregivers in both arms perceived the referral slips as valuable and reported that it had positively influenced the reception (not the quality of care) they received at the referral facility. The medical care received at the referral centre (as reported by caregivers) revealed that 30% of the tracked cases (who had received RAS and complied with referral) received the required parenteral care of injectable artesunate or quinine. Of those who complied with referral, 24% were admitted, while 86% were managed as outpatients.

Conclusions

Despite over 80% coverage and associated poster visualization and information recall, the IEC in the form of posters did not significantly influence knowledge and VHC health seeking practice among the communities in the exposed arm. It emerged that in general, caregivers in both study arms do not delay seeking care when their child has severe danger signs. Any delay that occurred, occurred when the disease was still uncomplicated – in other words - prior the presentation of the danger signs which were perceived as an emergency. This highlights the need for IEC materials that alert caregivers to the more subtle signs and symptoms of deteriorating uncomplicated malaria (for example - a persistent fever) and emphasize that danger signs are a consequence of delayed care seeking. In addition, posters proved not to be the most effective mode of message delivery, with a large number of the posters replaced after having been removed during the course of the 9-month intervention. Other forms of messaging such as radio broadcasting were preferred by this community group.

The introduction of regular supplies of 100 mg RAS to all the village health clinics in the study sites resulted in a consistent supply of a commodity where it had previously not been reliably at hand. This appears to have had a significant influence on health seeking practices that may in part account for an increase in prompt presentation at the village health clinic in the exposed arm. The HSAs who were exposed to the IEC toolkit showed higher levels of knowledge and their practice was positively influenced, and overall they offered a higher quality of care as compared to the HSAs in the unexposed arm. The IEC toolkit targeting HSAs had a significant positive impact on practice, however the introduction of the referral slip introduced a bias that interfered with the study's capacity to measure the influence of the toolkit itself on referral success.

Despite not being part of the formal intervention, the referral slip was very well-received by both HSAs and caregivers. It played a key role in closing the gap between VHC and the referral centre. Introducing referral slips to enhance the continuum of care should be considered alongside consistent supplies of RAS in the VHC. In addition, HSA refresher trainings, more frequent supervision, improvement of the VHC infrastructure and HSA remuneration to encourage them to remain living in the hard-to-reach communities should be seriously considered.

Although the care received within the referral centre was outside the remit of the study which reviewed the continuum of care from household to referral centre, the inconsistent response to the referral slips and the treatment received at the referral facility highlighted challenges around comprehensive care after a child receives the RAS pre-referral intervention. This is an important conclusion. Further investigation would be necessary to better understand the disconnect between what the HSAs observed at the village health clinic (danger signs) and what the referral facility staff observed (no danger signs anymore) due to the strong effect of the rectal artesunate in reducing parasitaemia. This finding highlights more than ever the important role of the referral slip in communicating the need for treatment despite the absence of danger signs.

This study draws attention to five *Continuum Criteria* (CCs) that should be considered as part of any attempt to enhance the continuum of care for children in remote areas suffering from danger signs, that are suggestive of severe malaria: *Care Transitions* for the patient; *Connectivity of Care* between providers; *Consistency of supplies* in delivery sites; *Comprehensiveness of the Care* received by the patient at the VHC and at referral health centre and *Communication* between all parties, including community residents to know that the service and commodity is available, as well as targeted IEC for all providers at all points of care that builds capacity and confidence to offer the service, ensuring that the benefits of any one intervention are not lost due to lack of information, education or communication up or downstream.

In summary, the IEC toolkit for the HSAs alongside a referral slip protocol that formally links the levels of care enhanced the continuum of care. IEC interventions in the community must be adapted to better meet the health seeking behaviours and care practices, in response to febrile illness in young children.

Acronyms

ANC	Antenatal Care	MMV	Medicines for Malaria Venture
ARC	Artesunate Rectal Capsule	MOH	Ministry of Health
CHW	Community Health Worker	mRDT	Malaria Rapid Diagnostic Test
HBM	Health Belief Model	MVT	Malaria Vaccine Trial
HHS	Household Survey	NMCP	National Malaria Control Programme
HSA	Health Surveillance Assistant	RAS	Rectal Artesunate
HSAS	Health Surveillance Assistant Survey	RASIEC	Rectal Artesunate Information Education and Communication Study
iCCM	Integrated Community Case Management	SFI	Severe Febrile Illness
IEC	Information Education Communication	TBA	Traditional Birth Attendant
IM	Intramuscular	VHC	Village Health Clinic
IMCI	Integrated Management of Childhood Illness	WHO	World Health Organization
IV	Intravenous		
MCH	Maternal Child Care		

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Introduction

The risk of death from severe malaria is highest within the first 24 hours of onset of danger signs, but the risks can be reduced substantially by immediate and effective parenteral antimalarial treatment and specialized facility care (Dondorp A 2005, Dondorp AM 2007, Dondorp AM 2010). In communities located several hours from a health facility where intravenous treatment for severe malaria can be given, the World Health Organization (WHO) recommends rectal artesunate/artesunate rectal capsules (RAS/ARC) be used as a pre-referral intervention for children under 6 years of age, to rapidly reduce parasitaemia and allow for transit time to reach treatment. This pre-referral intervention can only be of benefit if:

- The patient presents early enough to benefit from the intervention.
- The intervention is administered promptly and correctly.
- The patient is urgently referred to a health facility where intramuscular or intravenous treatment is available and is correctly and completely administered followed by oral ACT treatment.

Most often for caregivers of young children who live in a remote hard-to-reach community, the village health clinic is the first port of call for a sick child. Management of severe malaria however requires a two-step process: the caregiver must first seek care from the village health clinic, as soon as danger signs of severe malaria (inability to eat, drink, or suck, and/or repeated vomiting; recent convulsions; lethargy; or altered/lost consciousness) are recognized. Then, assuming RAS is available and has been administered at the village health clinic, the caregiver must then travel further out of the catchment area to seek post-referral treatment at the referral facility, where the child should in theory receive parenteral care upon admission.

Living far from a health facility, malaria knowledge, local perception of illness, misconceptions about severe malaria progression, perceived susceptibility to malaria and perceived barriers to seeking treatment (costs and logistics) have been known to influence how soon and if caregivers seek biomedical health care for their child's severe febrile illness (Mitiku and Assefa 2017). Assuming the caregiver overcomes some or all of these barriers and reaches the village health clinic (VHC), the expectation is then that the community health worker is able to recognize the signs and symptoms, administer pre-referral RAS and refer the caregiver. The outcome of the RAS intervention will then rely heavily on the caregiver's compliance with advice from the community health worker (CHW/HSA) to proceed to the referral health facility without delay. Data on the effectiveness of referral systems is limited – the literature shows varying levels of compliance with CHW referral (Chanda, P et al, 2011) (Thomson A et al, 2011) (Warsame, Gyapong et al. 2016) (Gomes MF 2009) (Lal, Ndyomugenyi et al. 2018). Compliance with RAS has been independently associated with factors such as referral health centre distance (the further the referring health centre the lower the compliance), the day or season of referral by a CHW (compliance decreased if referral occurred on a weekend or in the wet season), time of presentation (compliance decreased if child presents 24 hours after onset of fever and not sooner) and severity of illness at the time of referral (the more severe the condition of the child, the more likely the caregiver was to comply) (Lal, Ndyomugenyi et al. 2018). In fact, the lack of a clarity on referral has been highlighted as a priority research area by the international taskforce on iCCM (Wazny K, 2014). Once the caregiver finally reaches the referral centre the onus is then on the health facility to administer the correct care for severe malaria post-RAS: IV/IM artesunate followed by ACT.

A community health worker or a health surveillance assistant in the Malawian context, is typically a member of a community with little or no medical experience who is trained over a few months to diagnose and treat a very small number of specific conditions – including malaria (Olaniran, A 2017). A key part of their task is to identify and refer children who require higher level care, assuming that the health centres are equipped and staff trained and ready to recognise and manage these appropriately referred children. Intensifying the sensitization of CHWs – those administering integrated community case management (iCCM), through refresher training and supervision that emphasizes referral and discourages monotherapy has shown to improve compliance with referral advice among primary caregivers (Siribié, Ajayi et al. 2016) (Warsame, Gyapong et al. 2016).

In Malawi, RAS is indicated in both the malaria treatment guidelines and in the iCCM guides. The RAS policy was adopted in 2013 and was included in the guidelines before WHO recommendations were made in the region; and recently Malawi has been reviewing its guidelines and aligning them with the WHO policy, specifically in terms of age categories. RAS was rolled out in 2013 but due to various challenges with procuring RAS, the commodity has been available inconsistently and supervision infrequent. Currently the MOH does not have an IEC approach associated with RAS to make the residents aware of the availability of the service and steps to take post-administration.

The study intended to inform future programming in relation to IEC delivery for severe malaria by determining if and how IEC tools distributed within hard-to-reach communities, affect the continuum of care from the homestead to the referral health centre. Does it enhance health seeking and compliance with RAS referral advice? Does it improve assessment and administration of pre-referral RAS by the community health worker with access to a job-aid? What are the challenges and issues raised for caregivers seeking care at the VHC and at the referral facility for children suffering from danger signs suggestive of severe malaria? And what challenges and issues are raised by community health workers receiving these patients? This study used a tailor-crafted IEC RAS toolkit (<https://www.mmv.org/access/tool-kits/rectal-artesunate-tool-kit>, https://www.mmv.org/sites/default/files/uploads/docs/access/Rectal_artesunate_tool_kit/RAS_Field_Testing_Report_Malawi.pdf, https://www.mmv.org/sites/default/files/uploads/docs/access/Rectal_artesunate_tool_kit/RAS_Field_testing_report_Senegal.pdf), that was developed by MMV and field tested for comprehension in Malawi and Senegal in 2015.

The study focused on the role of IEC in enhancing the continuum of care from home to the referral centre for children with danger signs. With this came the opportunity to better understand the reality on the ground of community case management of severe febrile illness extending through to the post-referral experience, in a country promoting RAS pre-referral. The study hypothesized that exposure to IEC would increase early presentation at the HSA for pre-referral intervention with RAS, improving CHW/HSA diagnosis, administration of RAS and referral of danger signs, and in turn enhancing prompt compliance with referral instructions by caregivers.

This general report presents the first round of analysis, with results that target audiences interested in adapting programming and practice as they related to the continuum of care for severe malaria management in remote settings.

Study sites, Population & Timing/Season

The RASIEC toolkit was field tested in Senegal and Malawi in 2015. For operational reasons and due to the longstanding commitment and support of the Malawi National Malaria Control Programme, it was decided to run the study in Malawi.

The selection of the study areas within Malawi was guided by several scientific and operational considerations, including the eligibility criteria for a hard-to-reach VHC and resident HSAs. Based on these considerations, Salima and Ntchisi districts were selected. Salima and Ntchisi are both moderate – to – high transmission settings in the Central Region of Malawi, and have a high burden of severe malaria in children 5 years of age and under as compared to the other shortlisted districts.

RAS administration in village health clinics has been rolled out country-wide, including in these arms since 2014 – although access to the RAS commodity has been inconsistent.

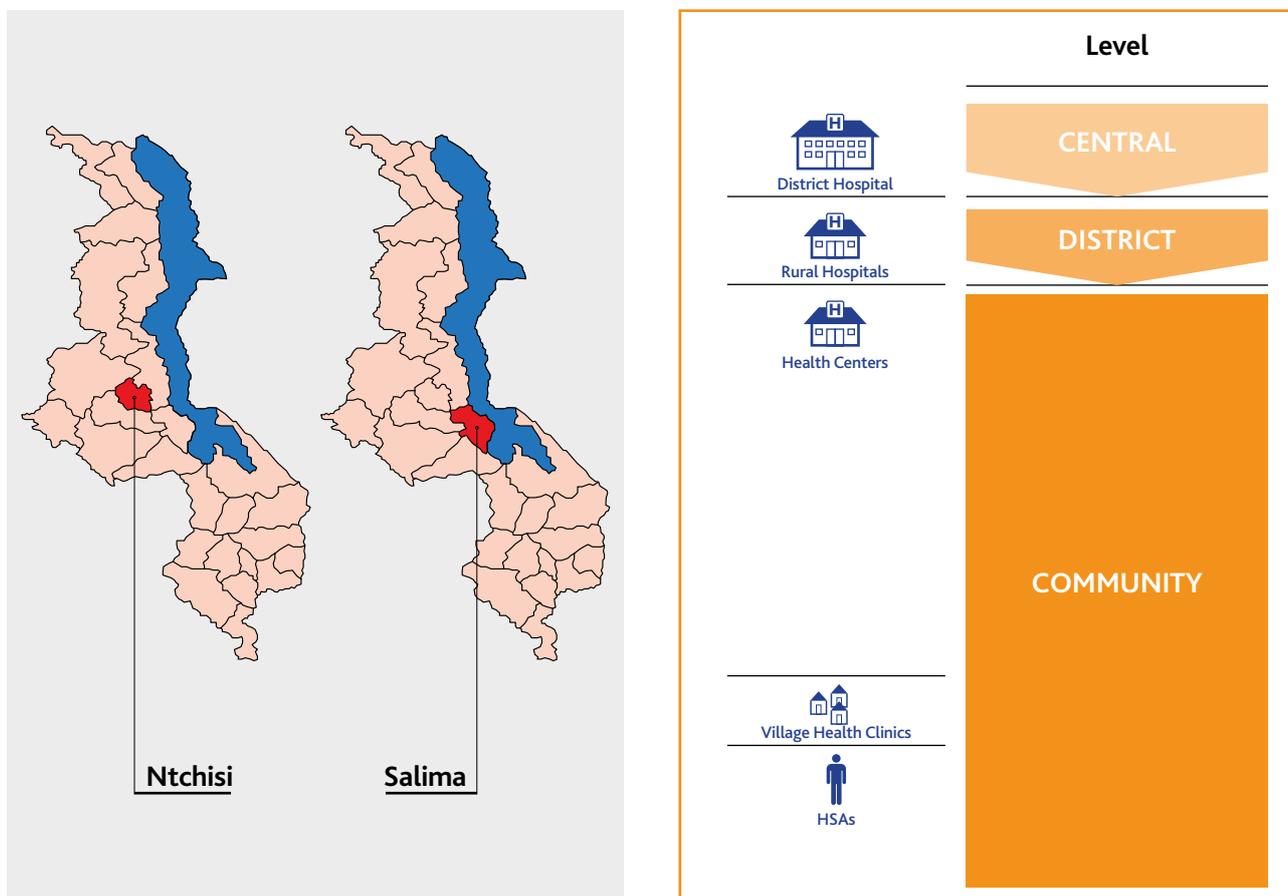


Figure 1: The health system relevant to the RASIEC study

Project Areas

Village Health Clinics, Catchment Areas & Households



Fourteen Village Health Clinic catchment areas based on Traditional Authority (TA) boundaries in Salima District and 9 in Ntchisi, met the eligibility criteria to be included in the study. These areas were considered distant enough to avoid cross contamination between districts. Recognizing that rectal artesunate has the most significant positive effect for those living the furthest from care (Gomes, MF et al, 2009), 'hard-to-reach' for this study was defined as VHCs located 5 km or more from a referral health facility/health centre – recognizing that caregivers that live in close proximity to the VHC would need to travel an equal distance to reach the referral facility.

The total catchment population of the RASIEC study is outlined in Table 1 below. The study population was entirely rural. The selected sites are scattered throughout the two arms and were the hardest to reach VHCs in the arms (see eligibility criteria). All HSAs declared themselves to be resident full time in the catchment areas. However, because HSAs are often splitting their time pursuing other income generation, they are sometimes not living in the village, particularly if it is located far from a trading centre.

Table 1: Catchment Populations – Salima and Ntchisi

SALIMA Arm						
No	Referral Health Facility (HF)	Name of village clinic (VHC)	KMs VHC to HF	Total Population	# of Households with children 5 years and under and registered with HSA/VHC	HSA resident
1	Chagunda	Mndola	12	1,558	62	YES
2	Chagunda	Mgaya	8	1,642	364	YES
3	Chipoka	Kamphinda	15	1,603	156	YES
4	Chipoka	Chazima	18	1,994	168	YES
5	Mchoka	Ntauchira	15	2,672	197	YES
6	Mchoka	Chidzanje	14	6,805	128	YES
7	Mchoka	Namajika	18	1,273	172	YES
8	Lifuwu	Ngalinje	17	1,681	86	YES
9	Lifuwu	Kentchentche	10	2,300	102	YES
10	Kaphatenga	Mvululu	24	1,090	241	YES
11	Thavite	Mgwere	12	3,750	210	YES
12	Khombedza	Chimphanga	18	1,340	143	YES
13	Khombedza	Seketeni	12	3,054	347	YES
14	Khombedza	Kapuzira	17	1,385	301	YES
NTCHISI Arm						
No	Referral Health Facility (HF)	Name of village clinic (VHC)	KMs VHC to HF	Total Population	# of Households with children 5 years and under and registered with HSA/VHC	HSA resident
15	Mzandu	Chafumbwa	10	1,213	84	YES
16	Malomo	Chamwazi	9	2,253	323	YES
17	Malomo	Chasolo	12	1,985	78	YES
18	Malomo	Ching'amba	10	2,007	240	YES
19	Mzandu	Chitawo	11	1,060	148	YES
20	Khuwi	Kachilandozi	8	1,571	140	YES
21	Ntchisi DH	Kantchere	8.5	1,631	254	YES
22	Malomo	Mankhaka	10.5	2,591	153	YES
23	Chinguluwe	Zambalero	158	1,058	160	YES

Intervention

Community Component

Community members and primary caregivers were exposed to the intervention via two avenues:

Target: Primary Caregiver & Community at large

The IEC poster - was the primary RAS sensitization tool. This poster emphasizes the importance of early treatment of suspected severe malaria, eligible ages, signs and symptoms, rectal administration, and the importance of compliance with referral.

Two hundred posters in Chichewa were mounted throughout the intervention arm catchment areas. Posters were mounted in areas identified by respondents at baseline as frequently passed places where s/he would be likely to look at the poster: these included water collection locations, churches, community halls, tea rooms, trading posts, homes of prominent people and at the health post/VHC. The location of the posters was recorded by GPS allowing the possibility of the study households to be plotted in relation to poster locations. The posters were checked regularly and status recorded, and damaged or lost ones replaced/relocated, if feasible, recording the reasons for loss/damage.



Flipchart - A tool to support the HSA while doing patient education or group discussions. Caregivers may have been exposed to the same information in the poster - but in the form of a flipchart at all routine Maternal Child Health (MCH) or antenatal care (ANC) encounters with the sensitized HSA.

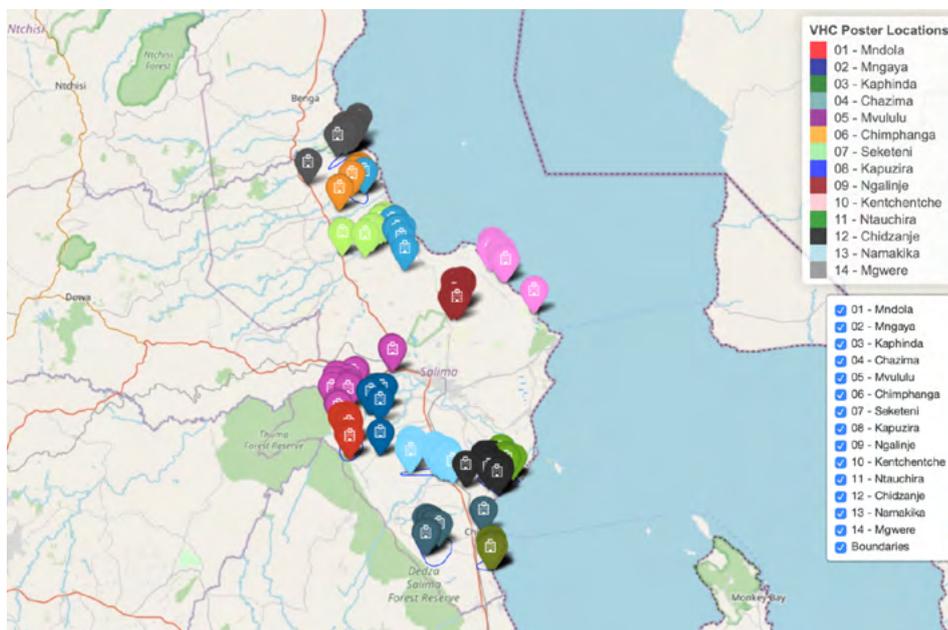


Figure 2: Distribution of Intervention Posters in Salima (intervention arm)

Village Health Clinic Component

Target: Health Surveillance Assistant - HSA

The Health Surveillance Assistants (HSAs) working in the enrolled VHCs in the intervention arm were exposed to the IEC toolkit:

Job-Aid & Information Reference Booklet - Each HSA in the intervention arm was given two laminated job-aids and an information booklet in the local language of Chichewa.

Kupereka mankhwala a artesunate oika ku njira yopangira ya mwana

Age
kwa ana onse opasala miyazi isanu ndi umodzi

Zizindikiro zozoya za malungo zomwe zingapangitse kufanika mankhwala a Artesunate oika ku njira yopangira chimbuzi ya mwana

Ngali kuzingizirapo kutentha thupi kapenoso mbiri ya kutentha thupi, kuzapanso zozoya zira zozoya za zindidiro za malungo, perekani mankhwala amalungo oika ku njira yopangira chimbuzi ya mwana.

KUPOOKAKULEFKA **KUSADYA/KUSAMWA**
KUKOKAKOKOMOKA **KUSANZANZA**

Hifundo yoyamba: Perekani mankhwala oika ku njira yopangira chimbuzi ya mwana

Gawo lachiwiri kutamiza kuchipatala
Atangira kutandira mankhwala oika mwanayo akuyenera kutumidwa kuchipatala chaphupi mofulumira kormwe mankhwala oyenera a malungo akulu akaperekedwe

Maperekedwe a mankhwala amalungo a Artesunate oika ku njira yopangira chimbuzi (rectal artesunate)

1 Kukonzekera
Duzani malungo wa mankhwala kuti ulingire ndi zaka zake kapena kutentha thupi

Zaka
Kuchokera miyedi isanu ndi umodzi mpaka zaka zilata
Kuchokera 14kg
Kuchokera pa 14kg mpaka 20kg

Kufanera
Kuchokera 0kg
Kuchokera pa 14kg mpaka 20kg

Malingi 10 mg/kg
Mthulu amodzi wa mankhwala oyika kamakha (1 x 100mg)

Mthulu lauri ya mankhwala oyika kamakha (2 x 100mg)

Sankani mwanja **Valeni mapangwi** **Mgoneni chumbi mwananga**

2 Perekani
Chokani mankhwala mu pakati kwa mankhwala

1-2 minutes

3 Tumizani
Kuchitatala chaphupi kormwe mwanayo akalandiro ngakhwala onse oyenera. Perekani mankhwala oika ku njira yopangira chimbuzi yopangirana.

4 Kalondolondo
Mwanayo amodzi wazozoya zira zozoya za malungo akalandiro ngakhwala onse oyenera. Atangira kutandira mankhwala oika mwanayo akuyenera kutumidwa kuchipatala chaphupi mofulumira kormwe mankhwala oyenera a malungo akulu akaperekedwe

Refresher Training - Each HSA in the intervention underwent two refresher trainings (month 1 of the intervention and month 6 of the intervention - using the toolkit booklet focused on key steps of assess, treat, refer and follow-up. The training was run by the study principal investigators (PIs), both medically qualified, alongside representatives from National Malaria Control Programme (NMCP) and Integrated Management of Childhood Illness (IMCI) programmes at the Ministry of Health using a set 3-hour programme. This included reviewing how to recognise and assess signs and symptoms that require RAS and referral to a health centre; how to administer RAS, including a practical simulated session on rectal capsule insertion, and how to officially refer a patient using the referral slip and the importance of follow-up.

The HSAs in the control arm received no training beyond what is offered by the NMCP/IMCI – iCCM routine programme of the Ministry of Health.

REMEMBER

<p>Less than 6 years</p> <p>6 months</p> <p>ASSESS AGE AND WEIGHT Between 6 months to less than 6 years.</p>	<p>RECOGNIZE THE DANGER SIGNS A febrile child or a child with recent history of fever with one or many danger signs: and/or → Unconscious or Lethargic and/or → Not able to drink or eat and/or → Vomits everything → Seizing or Convulsing</p>	<p>ADMINISTER RECTAL ARTESUNATE The community health worker prepares the child and administers rectal artesunate.</p>	<p>TRANSFER URGENTLY The child must be referred immediately to the nearest hospital or health care facility for a full course of antimalarial medicine by IV or IM.</p>
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Methodology

Study Design & Study Population

The study was designed as a single country, two-arm cohort study with an exposed (intervention) arm receiving the RASIEC toolkit and the unexposed (control) arm receiving no IEC intervention. The two arms of the study were investigated at baseline and then observed, to determine the caregiver and HSAs attitudes, behaviour and practices in response to an event of suspected severe malaria either at the household or VHC respectively, with or without possible exposure (community) and confirmed exposure (HSA/Village Clinic) to the RASIEC toolkit.

Study Populations

Two groups were studied: (i) The caregivers of children ≤ 5 years of age in the target catchment areas and (ii) the resident HSAs working out of hard-to-reach VHCs.

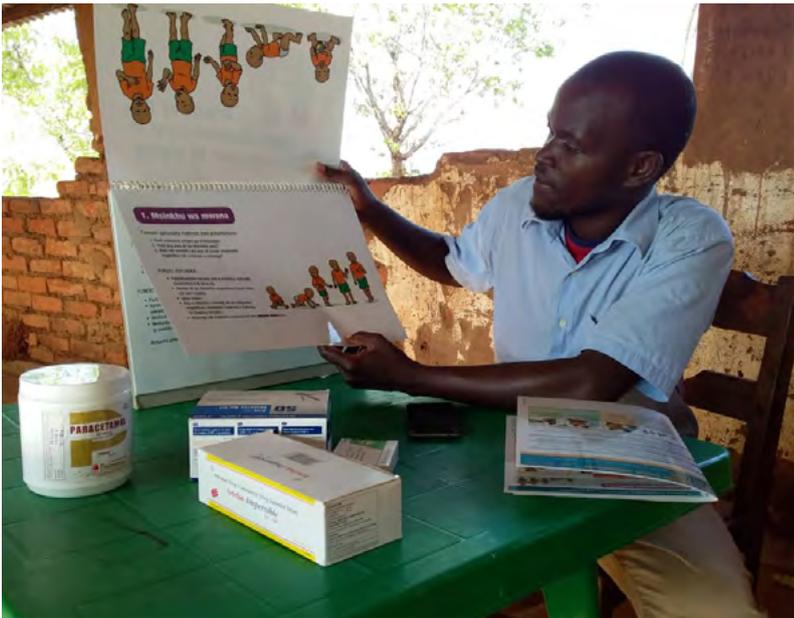
The **Baseline Assessment** was used to gather baseline data on knowledge, attitudes and practices and to guide the community component of the intervention exercise specifically identifying the location where the posters should be mounted; and the differences between the exposed and unexposed arms to be used in the investigation of being possible covariates in comparisons between the baseline and endline assessments.

The **Tracking Phase** assessed the response of caregivers who experienced an event of a child having severe febrile illness/danger signs during the tracking period - recognition of the severe malaria signs, seeking care from the VHC, and complying with referral; and the HSA activities of - assessing the sick child, confirming suspected severe malaria, administering RAS and formally using a referral slip.

The **Endline Assessment** was a re-assessment of caregivers' and HSAs knowledge, perceptions, and attitudes to severe malaria after the intervention phase. The baseline and endline assessments were compared for any differences in the caregiver and HSA perceptions and choices before and after the intervention and whether, in the case of the community, they were directly exposed to the intervention poster, and if it influenced choices/health seeking behaviour and in the case of the HSA if it affected knowledge and the delivery of care.

Intervention

- (1) The caregiver/household exposed group:** the posters were mounted throughout the intervention catchment areas in locations identified by the baseline respondents (HSAs and caregivers): community vetted/appropriate locations throughout the target communities - places where community members would easily be exposed/see the IEC posters.
 - (2) The HSA exposed group:** the 14 intervention arm HSAs were equipped with job aids, information booklets, flipcharts and posters at their VHCs and participated in two 3-hour participatory sensitization sessions (one at the start of the intervention and one half way through) with IMCI/NMCP trainers using the RASIEC toolkit (info booklet, flipchart and the job aids) developed by MMV. In the control site (unexposed), the community and the HSAs received no additional RAS-related IEC.
-



Additional Supporting Tools

Referral Slip - Each HSA in both control and intervention sites was supplied with a carbon triplicate referral slip booklet to be used for all cases of danger signs. Both sites were supplied with RAS 100mg at the start of the study and restocks were facilitated/encouraged by the field team. These stocks supplemented any 50mg RAS supplied by the MOH that may or may not have been ordered by the Village Clinic.

Artesunate
rectal capsules +
100mg



As a standard of care both control and intervention arms were supplied with RAS 100mg commodity and referral slip booklets for onward referral of patients post-RAS administration.

Only rectal artesunate formulations of proven quality should be used. The first rectal artesunate product was prequalified by WHO in February 2018. A second quality-assessed product is currently included in the Global Fund List of Malaria Pharmaceutical Products evaluated under the Expert Review Panel (ERP) mechanism. Both the WHO list of prequalified products and the Global Fund List of Malaria Pharmaceutical Products are updated on a regular basis and can be accessed from the latest information at the following links.

- WHO list of prequalified products:
<https://extranet.who.net/prequal/content/prequalified-lists/medicines>
- Global Fund List of Malaria Pharmaceuticals Products:
https://www.theglobalfund.org/media/4756/psm_productmalaria_list_en.pdf

Table 2: Summary Table – Activities, Study Design, Study Population & Procedures

Activities	Study Design	Study Population	Procedures
Activity 1: Household Survey (HHS)	To assess treatment seeking choices, caregivers' knowledge about danger signs and severe malaria and attitudes towards RAS at community level at baseline and endline after intervention – using the same households at both points.	Simple random sampling (see household sampling approach) of all caregivers of children 5 years of age and under residing in the 23 catchment areas eligible for inclusion in the study.	A field worker administered semi-structured questionnaire of caregivers at baseline/endline.
Activity 2: Health Surveillance Assistant Survey (HSAS)	To assess knowledge about severe malaria & dangers signs recognition & management, attitudes & beliefs in relation to RAS administration & practices among HSAs when presented with fever & danger signs including reported referral practices/ preferences at baseline and endline – after intervention – interviewing same HSAs.	Included all consenting HSAs operating in the 23 eligible VHCs enrolled in the study.	A field worker administered semi-structured questionnaire of HSAs in the 23 village health clinics at baseline/endline. Collected demographics, education/training, work experience & supervision, knowledge, attitudes & reported practices relevant to febrile illness, implementation of pre-referral RAS, referral choices/actions & knowledge of post-referral treatment.
Activity 3: HSA-Phone Tracking	To identify any cases of danger signs in children 5 years & under presenting at one of the 23 HSAs enrolled in the study & document HSA practice in response to the case.	Included all consenting HSAs operating in the 23 eligible VHCs enrolled in the study.	A phone or WhatsApp-based field worker administered structured 'inquiry' of 23 HSAs, daily after initiation of the intervention. Inquiring on cases of danger signs or severe febrile illness and any actions taken.
Activity 4: HSA Follow-up at the VHC	To follow-up the case reported in HSA phone tracking and liaise with a health volunteer to arrange a follow-up visit to the household of child who presented with danger signs – no sooner than 7 days after original visit to the VHC.	Included all consenting HSAs operating in the 23 eligible VHCs enrolled in the study.	The field worker visits VHC after detection of a ≤ 5 -year-old child presentation with severe febrile illness/danger signs to collect details of case for Activity 5 in collaboration with the health volunteer to arrange a follow-up visit.
Activity 5: Household - VHC-Track	To assess experience post-VHC visit & treatment seeking choices, actions and experiences of the caregiver, and perceived health status of child no sooner than 7 days after the recorded visit to the VHC.	Included all consenting caregivers of children ≤ 5 years of age who had sought care for severe febrile illness/danger sign episode presenting at one of the 23 VHCs enrolled in the study. Caregivers were followed up no sooner than 7 days after VHC visit.	Household questionnaire conducted with consenting households of caregivers who presented at the VHC with a child with severe febrile illness no less than 7 days before. Questionnaires addressed health seeking choices/ actions, time frames, care received at VHC, referral experience & care received at referral centre & current perceived health status of the child.
Activity 6: Routine Monitoring (RM)	To record severe febrile illness/ suspected severe malaria incidence in children under 6 years & ongoing interventions in the study areas, infrastructures, drug stocks, ongoing training, and supervisions as well as the progress of the intervention.	Included gathering data from the VHC records and the Referral Health Centre records and conduct observation/audit in the VHC.	Ongoing routine data monitoring using 2 checklist forms completed by the field workers auditing the facility or reviewing secondary data in the form of clinic records or District records monthly: including total cases of danger signs, total confirmed cases, total deaths, clean water, lighting, dry storage, supervision visits, number of doses of RAS used in a month.

Sample Sizes

Activity 1: Household Survey (HHS)

The sample size of households was calculated relative to the event of danger signs/severe febrile illness reported at the health facilities within the catchment areas of the study during 2018. These incidences were adjusted for prevalence of caregiver medical service seeking practices. This provided a sample of the households that were expected to have an incident of severe malaria in the subsequent malaria seasons relative to the approximate number of households within the catchment area of each VHC. The same households were interviewed at baseline as at endline.

The households included in the baseline/endline met the following criteria:

- ✓ Household within catchment population of selected hard-to-reach VHC
- ✓ Household is home to at least one child 5 years and under
- ✓ A primary caregiver is available and consents to be interviewed

Due to low migration rates, we did not anticipate significant replacement of households at endline due to non-response, however a response rate was still included in the calculation of the sample size to account for any selected households that refused to participate, withdrew from the study or that were lost to follow-up after consent and baseline assessment as well as unavailability at endline.

For each VHC, the sample size of household is calculated with the formula below:

$$n = \left\{ \frac{N \times Z_{1-\alpha/2}^2 \times p \times (1-p)}{\left((d^2 \times (N-1)) + \left(Z_{1-\alpha/2}^2 \times p \times (1-p) \right) \right)} \times \text{contingency} \times DE \right\} / r$$

Where:

- **n**: is the sample size of households
- **N**: Number of children in the VHC catchment area
- **r**: number of children per household (Number of children/Number of households in the VHC catchment area)
- **p**: the prevalence of severe malaria reported at the VHC referral health facility during the last malaria period relative to the study period of reference (Feb - July 2018) divided by the facility health seeking rate of 74.6%
- **α**: Confidence level of 95%, standard value ($Z_{1-\alpha/2}$) of 1.96
- **d**: Precision/margin of error of 5%
- **contingency**: the non-response error that encompass the aspects of refusal to participate, the unavailability at the household on household visits and migration after the selection of the household. This is assumed to be 10% (Contingency=1.1)
- **DE**: Design effect to adjust for VHC effect since the households are clustered under the VHCs. The design effect is computed based on the computation of the 'actual' and 'expected variance': Design effect = Actual variance/ Expected variance. These can be computed at the District level to adjust for the differences in the prevalence in the different health facilities selected for the study using the formula:

$$\text{Actual Variance} = \frac{\sum_{i=1}^c (\text{Prev} - \text{mean prev})^2}{(c-1)}; \text{Expected Variance} = \frac{\text{Mean Prev} \times (1 - \text{Mean Prev})}{(\text{Sample size} - 1)}$$

This resulted in a design effect of 1 for Salima District and a design effect of 1 for Ntchisi District and a sample of 173 households in Salima and 55 in Ntchisi. The sample of households were selected randomly from the arms categorized into quarters to ensure a geographical representation of the households (see example in Figure 4). The sample of the households in the quarters was determined proportional to the number of the households in the quarters and the sample within the quarter selected randomly. The final sample of households were distributed as illustrated in Table 3.

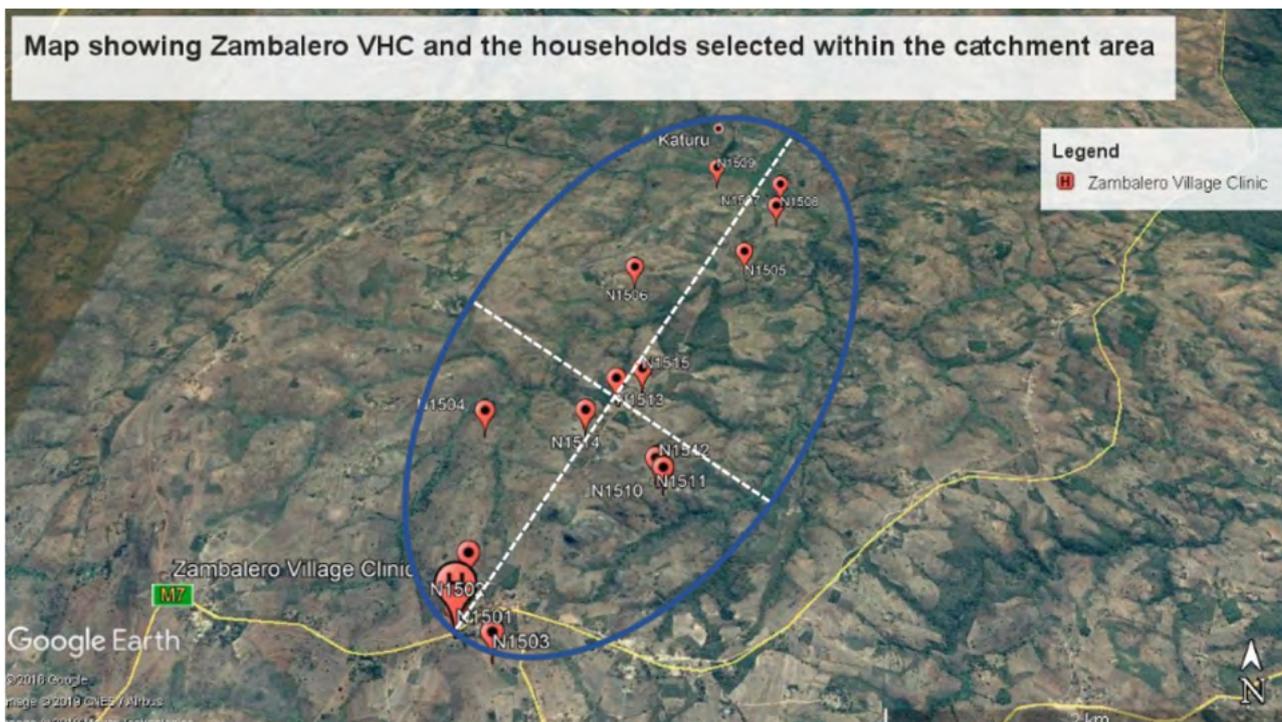


Figure 3: Geographical representation of quarters in the catchment area and corresponding households

Table 3: Household Sampling

District	Health Centre	VHC	# households w/ child 5 & under sampled for Baseline & Endline	District	Health Centre	VHC	# households w/ child 5 & under sampled for Baseline & Endline
Salima	Chagunda	Mndola	13	Ntchisi	Chinguluwe	Zambalero	15
Salima	Chagunda	Mngaya	16	Ntchisi	Khuwi	Kachilandozi	6
Salima	Chipoka	Kamphinda	6	Ntchisi	Malambo	Chamwazi	6
Salima	Chipoka	Chazima	6	Ntchisi	Malambo	Chasolo	5
Salima	Kaphatenga	Mvululu	12	Ntchisi	Malambo	Ching'amba	6
Salima	Khombedza	Chimphanga	7	Ntchisi	Malambo	Mankhaka	6
Salima	Khombedza	Seketeni	8	Ntchisi	Mzandu	Chafumbwa	4
Salima	Khombedza	Kapuzira	5	Ntchisi	Mzandu	Chitawo	3
Salima	Lifuwu	Ngalinje	6	Ntchisi	Ntchisi DH	Kantchere	4
Salima	Lifuwu	Kentchentche	6				
Salima	Mchoka	Ntauchira	25				
Salima	Mchoka	Chidzanje	30				
Salima	Mchoka	Namajika	25				
Salima	Thavite	Mgwere	8				

Activity 2: Health Surveillance Assistant Survey (HSAS)

The 23 HSAs in charge of the 23 eligible VHCs in the two arms were interviewed at baseline and endline in their village health clinics/health posts.

Activity 3: HSA-Phone Tracking (VHC Track 1) & Activity 4: HSA-VHC Tracking (VHC Track 2) & Activity 5: Household - VHC-Track (HH VHC Track)

In Activity 3 and 4 all HSA activities in relation to every case of severe febrile illness presenting at the VHC for a caregiver presenting with a child 5 years and under, were recorded. This was followed up by a caregiver tracking visit no less than 7 days after the reported VHC visit in Activity 5 to interview the primary caregiver in relation to the most recent episode of febrile illness. The actions taken by the HSA during the visit were extracted from the HSA self-report as gathered during phone tracking, and triangulated with the referral tracking slips and the caregiver report during the follow-up home visit. All 23 HSAs were contacted every day throughout the tracking phase of the study (9 months) to identify and track severe febrile illness patients.

The study identified a target number of Severe Febrile Illness (SFI)/danger sign cases for the VHC Household tracking component using the reality captured during the first months of the study, since the original sampling frame proved unreachable and was based on HMIS data that could not be verified. The sampling computations for the tracking are summarized in the last 2 columns below.

Table 4: Sampling computations for tracking component

Study period	Sampling frame study period	Sample calculation		Incidences reported at the VHCs in May to August, projected based on rates of increase in incidences at the hospitals in the past year	
		Salima	Ntchisi	Salima	Ntchisi
May - Aug 2019	May - Aug 2018	28	15	13	8
May - Sept 2019	May - Sept 2018	91	16	19	11
May - Oct 2019	May - Oct 2018	104	18	21	13
May - Nov 2019	May - Nov 2018	124	19	27	16
May - Dec 2019	May - Dec 2018	134	19	29	17
May 2019 - Jan 2020	May 2018 - Jan 2019	4,348	20		
May 2019 - Feb 2020	May 2018 - Feb 2019	4,649	20	HMIS data disregard & too unstable	
May 2019 - Mar 2020	May 2018 - Mar 2019	4,839	20		
May 2019 - Jan 2020	Jan, May - Dec 2018	152	24	34	29
May 2019 - Feb 2020	Jan-Feb, May - Dec 2018	172	25	38	40
May 2019 - Mar 2020	Jan-Mar, May - Dec 2018	194	40	43	74

The computations were based on the number of incidences of SFI that were reported at the referral centres in the study catchment areas and the rate of increase of reported incidences at the referral centres in 2018-2019, using the monthly increments noted above. We applied the same rate of change, using the number of actual cases between May and end of August 2019, in order to predict how many cases could exist for the study to track over the subsequent months.

For tracking there was therefore not a sample, but a projected population of all incidences reported. The study tracked all incidences of SFI/danger signs reporting to the VHC from June 2019 to February 2020. The tracking study population was the entire 'population' of caregivers seeking care for pediatric SFI and danger signs at the study VHCs and reported by the HSA during the daily phone contact, for the selected period. The predefined target of a minimum of 30 cases in each arm was determined, regardless of the number of cases per VHC - enabling more interesting parametric analysis if needed.

Selection of the study participants

Recruitment

HSAs: All the Health Surveillance Assistants (HSAs) from all the eligible Village Health Clinics in the project areas in the two study arms were recruited into the study.

Severe Febrile Illness at VHC: All cases of severe febrile illness with danger signs that visited and reported the enrolled VHCs were listed and details attained for enrollment in the Tracking component of the study. A caregiver who presented more than once at the VHC for new episodes of severe febrile illness were repeatedly part of the study. The enrollment in the Tracking phase was done at the point the case was reported during the daily phone contact with the HSA.

Caregiver recruitment for Baseline/Endline survey: A random sample of households based on the prevalence of the last malaria season, with at least one child 5 years or under, based on a household listing of all 23 catchment areas linked to the geographic characteristic - village name. The exact location of the household was known to the health volunteers who were responsible for recording the number of children 5 years and younger in each household in their jurisdiction within the catchment area.

Inclusion criteria

Household survey (HHS):

- Household parent / primary caregiver of children 5 years and under
- Signed consent form from parent / guardian
- Household within catchment population of selected VHC

Health Surveillance Assistant Survey (HSAS):

Health Surveillance Assistant at the eligible village health clinic at enrollment:

- The HSA must report to be resident in the catchment area of the VHC and be available day and night and cannot reside outside of the VHC catchment area.
- VHC must be > 5 kilometres from the referral health facility
- VHC must be operational – as indicated by current up to date records of children 5 years and under.
- HSA must have signed the consent form.

Tracking:

- Caregiver of child 5 years and under
 - History of fever plus danger signs indicative of severe febrile illness / suspected severe malaria, according to local iCCM guidelines
 - Signed full consent form from parent / guardian at household visit
-

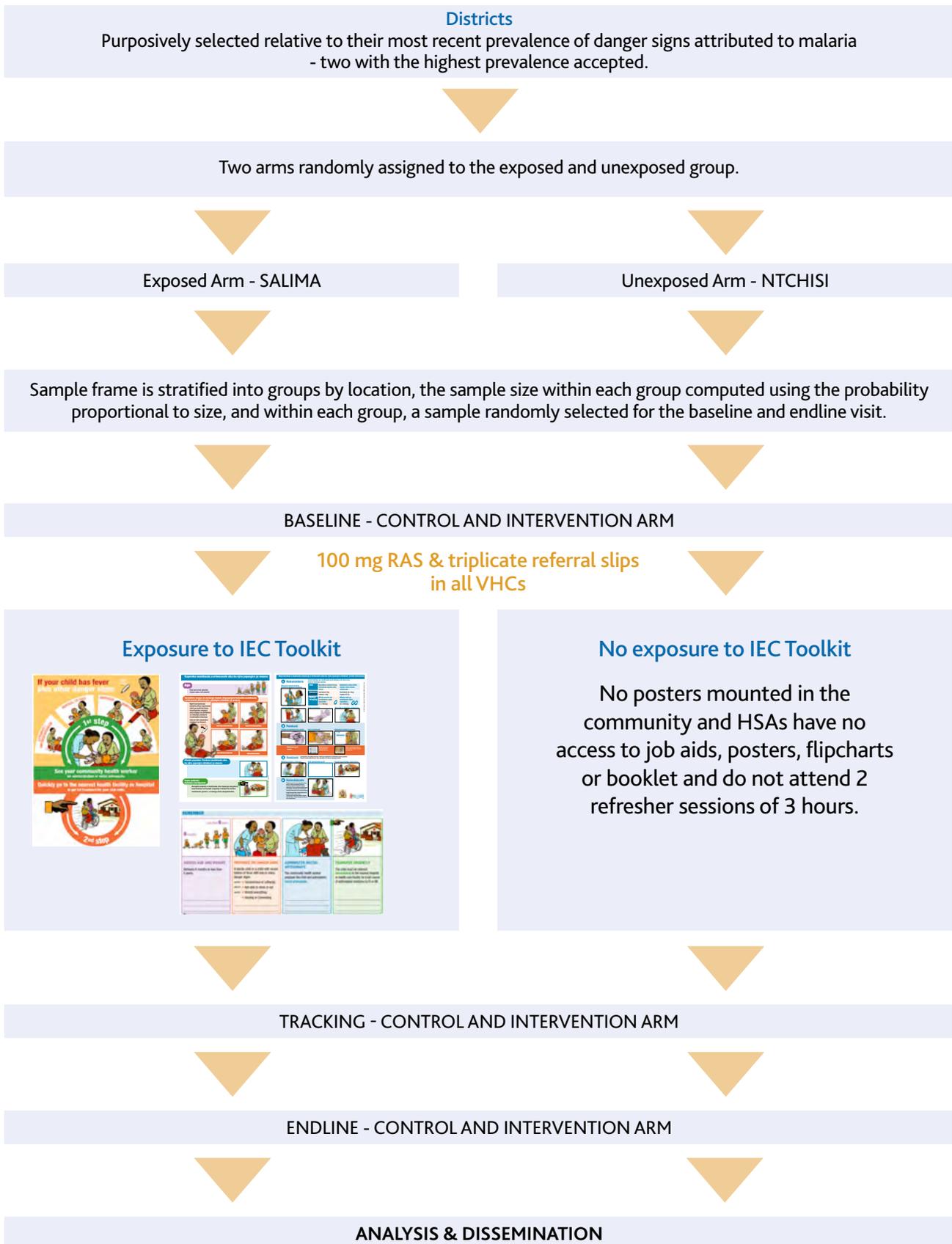


Figure 4: Study Design

Ethical Approval

Before study initiation, the protocol was submitted to the responsible IEC/IRB for opinion/approval. This included the WHO Research Ethics Review Committee (ERC) and the College of Medicine at the University of Malawi (COMREC). COMREC is authorized by the Ministry of Health to review public health research done in collaboration with the College of Medicine, issued ethical clearance for this study.

This study was primarily operational and introduced an information – education – communication intervention only. There was a low/minimal risk arising from the study for participants. Since no treatments or tests were involved in this study, no additional regulatory approvals were required in Malawi for a non-clinical intervention of this nature apart from regular review by COMREC.

The research project was carried out in accordance with the approved research protocol and with principles enunciated in the current version of the Declaration of Helsinki, International Conference on Harmonization ICH Topic E6: 'Guideline for Good Clinical Practice'.1996 (CPMP/ICH/135/95), Essentials of Good Epidemiological Practice issued by Public Health Switzerland (EGEP) as well as all national legal and regulatory requirements as applicable.

All necessary measures were taken to ensure gender equality throughout the conduct of this research project. We do not foresee any risk of gender bias regarding the treatment of patients and survey participants enrolled in this study.

For both the control and the intervention arms, consent was sought to administer a baseline and endline questionnaire to the primary caregiver responsible for the child <5 years old.

For both the control and the intervention arms, consent was sought to administer a baseline and endline questionnaire to all the eligible resident HSAs operating in the hard-to-reach village health clinics.

Inclusion occurred only if the participant gave written informed consent. Written informed consent was obtained prior to any data collection being carried out by field workers only. All these individuals underwent adequate training. During this training, theoretical and practical sessions were devoted to research ethics and obtaining informed consent.

Analysis

The study database was developed as a web-based application using .NET Core MVC/C# and SQL Server 2016. The study Statistician used the data export functionality of the database to export both the data dictionary and the study datasets in excel format. The data dictionary described the metadata for each of the questions, namely variable name, question text, data type, list values (where applicable for coded responses) and also whether the question was mandatory or not. The data manager used R for data management and cleaning before the data was availed to the study Statistician for analysis.

During the analysis phase, data cleaning, management and analyses was performed in STATA (StataCorp LP, College Station, TX, USA) and STATA for the analysis. Excel was used for some of the data management and result presentation.

Descriptive analysis

Descriptive analyses of specific indicators were performed once after Baseline Assessment (pre-RASIEC), once during Tracking phase, and once at Endline, 9 months after the intervention components described above were initiated. Mostly tables and some graphics of indicators were generated. Most variables in this general report are presented as proportions, except for numbers of events recorded as part of routine monitoring. Measures of the indicators were clearly defined in the analysis plan and the results in this report are presented in line with the indicators referenced in the Indicator table in the Appendix A.

Investigations and Comparisons

The investigation can be summarized as follows:

At Baseline Assessment

For the households:

- General investigation of the demographic's household SES (graded high and low), access to media forms, knowledge, attitudes and practices (graded poor and good) to health care services, malaria, prevention and treatment of malaria, identification of severe malaria, HSA services, and acceptability of RAS.
- The investigations were done separately for the households in the exposed and unexposed arms; then compared to identify any differences between the two arms. Since the study was dealing with categorical variables, a chi-squared test was undertaken and presented when relevant or useful.
- Identification of the preferred location for posters at baseline and those seen after the intervention, preferred location versus locations where posters were seen.

For the HSAs:

- General investigation of the HSA demographics, training and financial status, HSA challenges, VHC services, HSA malaria and RAS knowledge, community utilization of VHC services, community RAS attitudes, community compliance to HSA referral, and community knowledge of a child severe malaria in the community.
 - The investigations were done separately for the HSAs in the exposed and unexposed arms; then compared to identify any differences between the two arms.

At Endline Assessment:

For the exposed (intervention) and for the unexposed (control) households:

- Levels of caregiver knowledge, attitudes, practice, and acceptability of the HSA services at baseline and endline were compared. This was done to determine if there was a change in the levels at endline relative to baseline and if there is evidence that this change is significant by looking at the proportions (improved, deteriorated, or remained the same) and the chi-squared test result.
 - Descriptive comparison of the HSA challenges, malaria/RAS knowledge, and community attitudes to the VHC services. This was done to determine if there was a change in the levels at endline relative to baseline by looking at the proportions.
-

Baseline and Endline Assessment:

A comparison of the baseline and endline levels of caregiver knowledge, attitudes, practices and acceptability of the HSA services at endline was undertaken to create a variable that defined whether the level improved, deteriorated, or remained the same. The exposed and unexposed were compared by this variable to observe if there was evidence of a significant difference, then adjusted for the potential covariates identified at baseline, undertaking a logistic regression. A comparison of the baseline and endline levels of HSA knowledge, attitudes, practices and perceptions of community attitudes, was undertaken to create a variable that defines whether the level improved, deteriorated, or remained the same. The exposed and unexposed are compared by this variable to observe the differences in the proportions.



During the Tracking Phase:

- Included in this phase are the households that were reported to have a child with danger signs during the Tracking phase. The Tracking Assessments included the caregiver's severe malaria and RAS knowledge, the source of the knowledge, caregiver's severe malaria diagnosis abilities, the response to the diagnosis (whether a VHC was visited), experience at the VHC (whether RAS is administered, response to treatment), caregiver compliance to HSA referral and response to any treatment received at the health facility. Also attained were the caregiver characteristics (age, sex, relationship to the sick child and the number of children cared for), child's age, and child's severity of illness. Investigated was whether the level of the danger sign recognition, appropriate response to the danger signs, RAS knowledge, compliance with the HSA referral were compared for the households in the exposed and unexposed arms. This comparison was adjusted for the caregiver characteristics, child's age, and perceived severity of the child's illness. With the variables in the comparison grouped to categorical variables, logistic regression was undertaken, to explore factors associated with compliance, assuming that some would not comply.
- The HSAs were also assessed for their activities during the caregivers visit to the VHC and the proportion of caregivers that received care in-line with the guidelines in the exposed arm was compared, relative to those in the unexposed arm.

Handling of data

During the questionnaire design phase, questions where a response would always be expected were identified, as well as those questions that were mandatory in the database. In addition, we also identified the questions where skip logic would be required and added help text on the questionnaires to guide the field staff when completing the questionnaires. The skip logic was programmed into the database.

Missing data checks were carried out on variables that were to be used in the analysis. The missing data checks were done in both R (by the data manager) as well as in STATA (by the statistician). A list of data queries was produced and given to the data team to resolve the queries. The corrections were made to the electronic database and the data cleaning program was re-run to verify that the queries had been resolved.

Inconsistency data checks were also done to identify missing data where a response was required based on a previous question having a certain value. An example of this is where a narrative has been provided for a question, but the corresponding postcode is missing (postcode refers to coded response). Data checks across various database forms were also done, to verify that tracking identifiers for Phone Tracking, VHC Tracking and Household tracking could be matched, where a match was not found, a data query was raised.

Results - Section 1

The results of the study are presented in 5 sections guided by the principal indicators identified by MMV at the outset of the study (Appendix A):

- **Section 1: Illness status and study area infrastructure**
- **Section 2: HSA danger sign recognition, response, and management**
- **Section 3: HSA referral of a child post-RAS intervention**
- **Section 4: Caregiver characteristics/resources, knowledge, attitudes, response (health seeking) and poster exposure**
- **Section 5: Caregiver referral compliance & patient outcome**

Section 1: Illness status and study area infrastructure

This section of the report presents data relating to the reality on the ground of integrated community case management (iCCM) of severe febrile illness and the infrastructural context in the study sites as it relates to rectal artesunate and its use. This section includes data collected through routine monitoring and the health surveillance assistant surveys (HSAS): HMIS data of SFI cases, staff capacity, supervision and training, RAS acceptability and usage and HSA knowledge of malaria, preferred IEC channels and infrastructure at the VHCs, and any possible confounding events in the study arms.

Challenges with HMIS data in relation to RAS

During routine monitoring data was gathered from the HMIS registers of the 12 referral facilities to which the VHCs in the study referred patients and data was extracted from the DHIS for April 2019 to April 2020. Upon review of this data certain challenges became apparent. First, the number of positive mRDTs done at the referral health facility may well not capture the post-RAS referral cases because often patients who were given RAS may test negative at the referral centre because RAS reduces parasitaemia completely.

Second, records of danger signs raise issues of whether more than one danger sign is recorded per case and how this data from the VHC is captured and collated when received by the health facility. Third, we recorded 2 deaths among the children tracked, 1 in each arm of the study during the course of the study and none of these were captured in the referral site data reviewed. Rates of confirmed malaria diagnosis based on the mRDT done at the Village Health Clinic did not capture the children who presented with danger signs because in most cases these children are not tested prior to administering RAS. Having raised these limitations, the tables below use HMIS data but may not be a true representation of the situation in light of issues raised above.

What is iCCM?

Integrated Community Case Management (iCCM) is a strategy to train, support, and supply community health workers (CHW or HSAs) to provide diagnostics and treatment for multiple illnesses specifically pneumonia, diarrhoea, and malaria for sick children of families with difficult access to case management at health facilities.

As part of iCCM, front-line workers at the community level should be trained, supplied and supervised to diagnose and treat children for malaria, pneumonia and diarrhoea, using artemisinin-based combination therapies, oral antibiotics, oral rehydration salts and zinc.

All patients are assessed/screened for the 3 diseases and treatment is administered based on the results of the examination and diagnostic testing that includes malaria RDTs, disease history and respiratory rate. The inclusion of pre-referral treatment with rectal artesunate and RDTs is recommended, where feasible.

https://www.who.int/malaria/areas/community_case_management/overview/en/

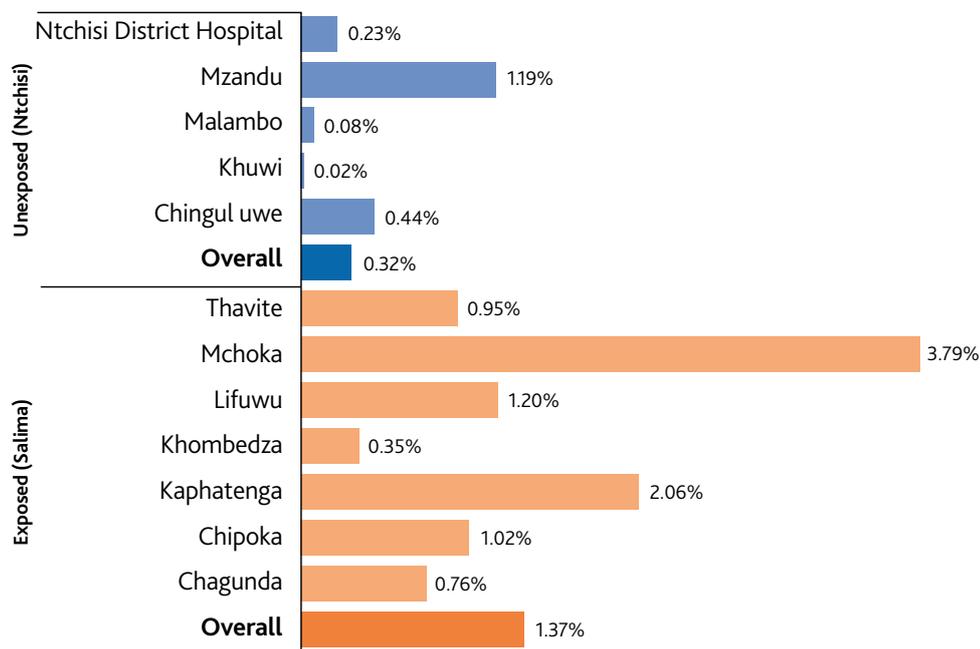


Figure 5: Danger sign prevalence in ≤5 years 2019-2020 in RASIEC study referral health centres

Table 5: Confirmed Malaria, Severe Malaria, Danger Signs & Malaria Deaths reported at Study Referral Health Facilities during the study period

District	Referral Health Facility enrolled in study	Confirmed Malaria mRDT	Danger Signs reported	Malaria Deaths reported
SALIMA	01 - Chagunda	2,936	4,611	0
SALIMA	02 - Chipoka	1,952	5,734	0
SALIMA	03 - Kaphatenga	533	1,206	0
SALIMA	04 - Khombedza	4,179	10,701	0
SALIMA	05 - Lifuwu	1,059	2,705	0
SALIMA	06 - Mchoka	3,087	14,277	0
SALIMA	07 - Thavite	727	2,855	0
Sub-TOTAL		14,473	42,089	0
NTCHISI	08 - Chinguluwe	2,287	5,294	0
NTCHISI	09 - Khuwi	536	1,249	0
NTCHISI	10 - Malambo	5,397	11,843	0
NTCHISI	11 - Mzandu	625	2,154	0
NTCHISI	12 - Ntchisi District Hospital	4,378	18,579	17
TOTAL		13,223	39,119	17

(Source: HMIS registers)

Routine Monitoring: Other interventions in study arms

Routine monitoring took place every month in each of the 23 catchment areas. No events or outreach activities specifically related to RAS and management of severe malaria or danger signs were observed or reported by the District Health Management Team or at the referral health facilities. The District Health Management Teams are responsible for overseeing all health services provided in their catchment, including planning, implementation and monitoring of all child health services and interventions underway.

After the study was initiated, routine monitoring revealed that the Malaria Vaccine Trial (MVT) had been initiated in Ntchisi District (<https://www.who.int/news-room/detail/23-04-2019-malaria-vaccine-pilot-launched-in-malawi>). As a district with moderate to high levels of Malaria, Ntchisi (unexposed arm in RASIEC) was also chosen by WHO in partnership with the MOH and PATH as a site for the Malaria Vaccine Trial (MVT). Malawi is the first country trialling the first malaria vaccine recommended by WHO through phased introduction in routine settings. The District Health Management Team (DHMT) did not inform us of this activity prior to launch of RASIEC - they did not anticipate that this could present any confounding issues for this small IEC study. However, upon reviewing the data, it could be of value to explore further the influence that the heightened IEC around malaria and its dangers disseminated by MVT may have had on the study results in relation to knowledge and health seeking actions for danger signs. With the MVT timeline crosscutting the RASIEC intervention period – there is a possibility of some bias to the unexposed areas where the MVT is being undertaken. One way to see if the trial had an impact on the study outcome would be to separate the unexposed data at endline for those that were covered in the MVT and those that were not, and then investigate any differences in the aspects covered in both the study and the MVT. However, it emerged that of the 9 catchment areas in the RASIEC study's unexposed arm all were in the MVT's focus areas: 5 catchment areas, including the VHCs and referral health facilities were within the MVT's vaccine intervention arm and 3 catchment areas, including VHCs and referral health facilities were in the MVT's control arm (Table 6). Therefore, the RASIEC unexposed sites were exposed to MVT-related activities (either intervention or control activities) throughout the RASIEC study period. None of the catchment areas in the RASIEC study's exposed arm were in the MVT. Details of the MVT activities are described below.



Some preliminary analyses were done looking at only two knowledge indicators, aspects that were relevant to the RASIEC study and potentially the MVT too. The superficial analysis revealed that the MVT led to some increase in the knowledge of the caregivers in the RASIEC study's unexposed arm, however this increase was slight and preliminary analysis suggests no evidence of a significant increase. More analysis should be considered to investigate other indicators to confirm no significant effect.

Table 6: Malaria Vaccine Trial cross over sites in Ntchisi

Health Centres involved in Vaccine Trial & RASIEC	VHC Catchment Areas involved in Vaccine Trial & RASIEC	Trial Activities **
Malaria Trial Intervention Sites		
Chinguluwe Health Centre	Zambalero VHC	<ul style="list-style-type: none"> • Training of all health workers (HSAs, Clinicians & Nurses) • Health talks in at health centres and under-five growth monitoring clinics • Letters to religious institutions • Community health talks • IEC materials (posters and leaflets) • Peer education using peer educators
Malomo Health Centre	Chamwazi Chasolo Ching'amba Mankhaka	
Malaria Trial Control Sites		
Ntchisi District Hospital	Kantchere	<ul style="list-style-type: none"> • Routine DHO IEC & Supervision
Khuwi Health Centre	Kachilandozi VHC	
Mzandu Health Centre	Chafumbwa Malindi	

**Source: District Health Management Team Communication only – could be further confirmed with the trial when necessary.

Demographics of practicing HSAs

Malawi launched a national community health strategy in 2017 (2017–2022), which provides a national framework founded on a team-based approach for harmonising multiple health initiatives at the community level, and for strengthening delivery of primary health services. The core community health team (CHT) consists of health surveillance assistants (HSAs), clinicians, environmental health officers and community health volunteers (CHVs). The government of Malawi has a target of one health surveillance assistant for every 1,000 people. HSAs, constitute the formal link between communities and health facilities and the task of administering RAS is assigned to them. HSAs must have some secondary school level education and must receive approximately 12 weeks training. They also supervise all community-based health initiatives and the village health committee volunteers within their communities.

The HSAs enrolled in this study are described in the tables below and meet the criteria above. Of the 23 HSAs, only 2 were female, aged 39 to 45 years and all had the government recommended secondary education.

Origins of HSAs

An important feature of the Village Health Clinic is that the HSA is available to help manage childhood illness anytime of the day or night – this was a criterion for selection of the VHCs for the study. Although none of the HSAs were born in the village where they worked, they had spent between 5 and 12 years in the village where they were posted for work; with half having lived in the village for more than 10 years.

HSA availability & other work

HSA typically complement their HSA wages with other work – which in this case was either farming or clerical work, none of the HSAs reported being a labourer or small business owner. Ideally, their choice of complementary work does not interfere with their HSA commitments, and availability for emergency care. Five (at baseline) and 7 (at endline) of the 23 HSAs relied solely on their Ministry of Health income and the remainder topped-up their income with other work in the community – this seemed to fluctuate, with changes occurring during the course of the study. For example, a HSA in the exposed arm, who had also been a farmer at baseline got a clerical job; while in the unexposed, two HSAs that had a clerical job at baseline to complement their income at baseline, reported relying on their HSA MOH wage only at endline.

Table 7: Demographics of practicing HSAs

Demographics of Study HSAs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
		#	%	#	%
HSA gender					
	Male	12	85.7%	9	100.0
	Female	2	14.3%	0	0.0
HSA age					
	Median (IQR)	43	(39 - 45)	39	(37 - 41)
Age grouped					
	30 - 40	4	28.6	6	66.7
	41 - 53	10	71.4	3	33.3
Primary source of income					
	Farming/Agriculture/Fishing	1	7.1	0	0
	Office/Clerical	8	57.1	9	100
	Health worker/HSA	5	35.7	0	0
	HSA Primary source of income (Yes)	5	35.7	0	0
Employed by Ministry					
	Transport - HSA a mode of transport to reach patients (Yes)	13	92.9	5	56
HSA Seniority					
	HSA	11	78.6	9	100.0
	Senior HSA (permitted to supervise an HSA)	3	21.4	0	0.0

Table 8: Origins and residency of HSAs serving the study catchment areas

Origins & Residency	Baseline				
	Exposed n=14 VHCs		Unexposed n=9 VHCs		
	#	%	#	%	
Number of years as resident in the village					
	Median (IQR)	10	(5 - 12)	9	(7 - 11)
	Lived in the village for > 10 years (Yes)	8	57.1	4	44.4

Level of experience and training as HSA

The HSAs serving the catchment areas had a median of 12 years of experience working as HSAs. The HSAs also received a median 3 months of basic training with 74% having received 3 or more months of training - falling within the government specifications. There was no significant difference between the exposed and unexposed HSAs.

Table 9: Experience and length of training among HSAs serving the study catchment areas

HSA Experience & Length of Training	Baseline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%
Years of being an HSA				
Median (IQR)	12	(12 - 17)	12	(12 - 12)
Length of training received				
Median (IQR)	3	(2 - 3)	3	(3 - 3)
Received 3 or more months of HSA training (Yes)	9	64.3	8	88.9

Level of English comprehension

This indicator was generated from the combined scores of a self-assessment of ability to read in English and an objective assessment of reading an excerpt of text from the toolkit in Chichewa. Table 10 below shows that only one third of the HSAs in both arms reported and demonstrated capacity to read with slightly more capability to read in the unexposed arm. The field-testing exercise confirmed that with sensitization, HSAs were able to understand the job aid, but this finding reconfirms the value of images embedded within the job aids to support understanding and the need for refresher training to review new toolkits and ensuring comprehension. At endline, there was some improvement across both arms, most likely due to familiarity with the content.

Table 10: Ability to read among HSAs

Ability to read among HSAs	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Combined score: Ability to read & comprehend text from Job aid	5	35.7	3	33.3	7	50.0	7	77.8

RAS Training and Supervision

Recent RAS training was only reported in the exposed arm, however perceived confidence in administering RAS increased from baseline to endline among those in the exposed and in the unexposed arm, increasing from 64% to 86% in the exposed and 44% to 77% in the unexposed. This highlights a theme that runs throughout the results – that the presence of the RAS commodity and a referral slip booklet may have attributed to the increase in confidence. Having regular supplies of the RAS commodity to hand increased the opportunity to manage severe malaria and in turn increased confidence through practice.

Table 11: RAS Training and perceived confidence to administer RAS among HSAs (HSAS)

RAS training & perceived confidence	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Last RAS training less than 2 years ago (Yes)	4	28.6	0	0.0	14	100	0.0	0.0
Strong confidence in administering RAS (Yes)	9	64.3	4	44.4	12	85.7	7	77

Based on the data gathered during the 276 routine monitoring monthly visits during the 12-month study, the minority of HSAs reported receiving regular RAS related supervision (iCCM – IMCI – NMCP) during the 12-month study period (Figure 6). More supervision took place in the unexposed arm with the source of the supervisions originating from the IMCI programme.

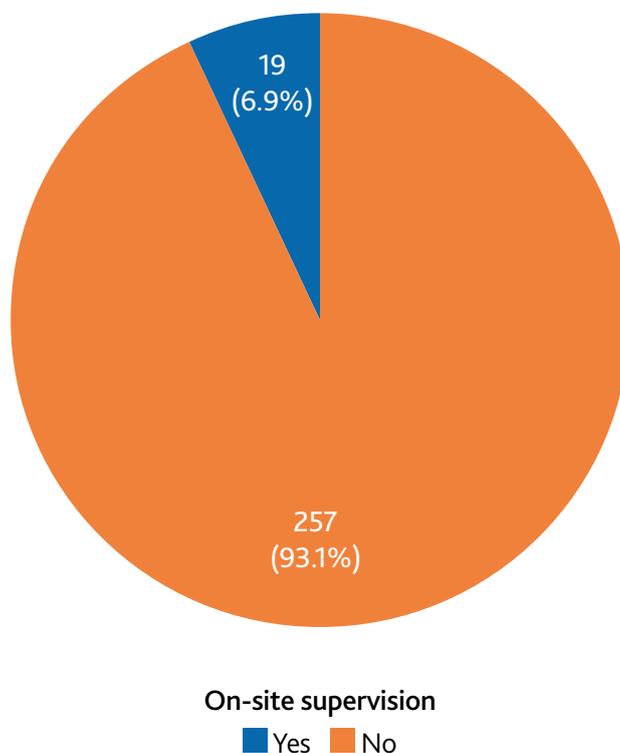


Figure 6: Supervision of HSAs

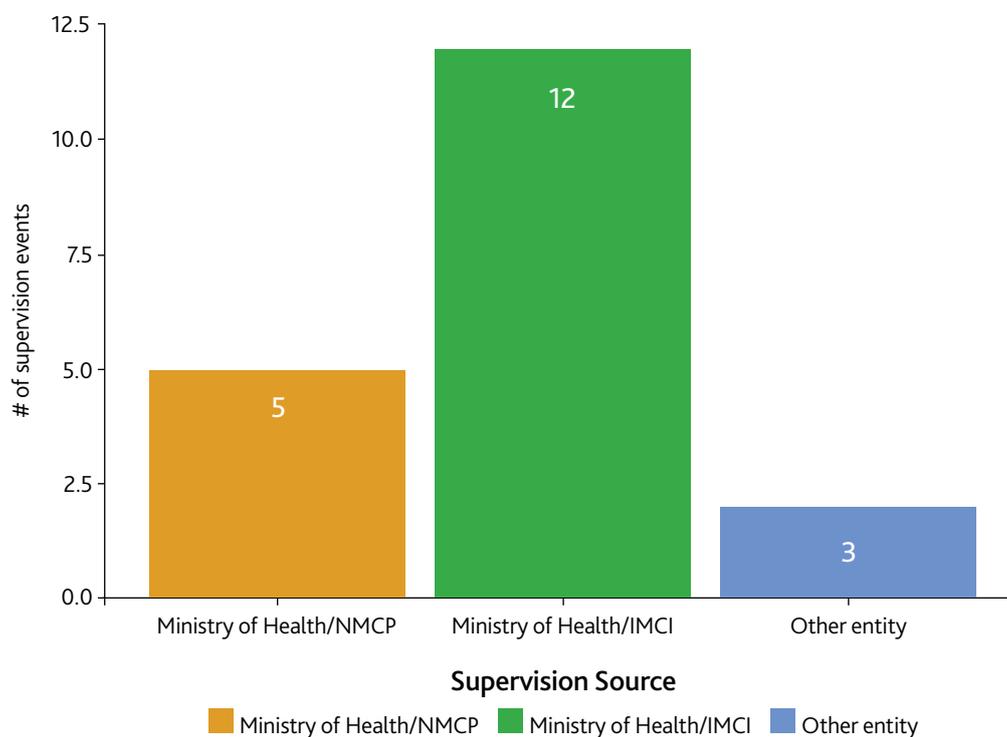


Figure 7: Source of the supervision (n=19 events)

At endline, HSAs from both arms had a strong belief that regular (minimum of every 2 months) supervision was essential to keep them updated on malaria (complicated/uncomplicated) management of children 5 years and under. As illustrated in the table below, frequency of supervision related to malaria management and severe malaria was very low. There was also a strong belief in both study arms at endline that the availability of job reminders/job aid did help/encourage HSAs with severe malaria management. The HSAs in the exposed arm identified this need more strongly at endline than baseline – noting that they had operated without job aid. This may have attributed to the errors in dosing observed more frequently in the unexposed arm.

Table 12: Attitude to supervision

Attitude to regular supervision	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Regular supervision essential to keep the HSA current on malaria management (Strong Belief)	13	92.9	3	33.3	14	100.0	8	88.9
Availability of job aids important to support HSA with Severe Malaria management (Strong belief)	10	71.4	2	22.2	14	100.0	9	100.0

HSA Capacity Building and Training

The RASIEC study conducted sensitization refresher training on two occasions during the 12-month study for the intervention arm HSAs, accounting for 28 training reports or 87.5% of the training experiences reported over 12 months among the 23 study HSAs. The majority of HSAs reported receiving no other training, refresher training or continuing education during the 12 months.

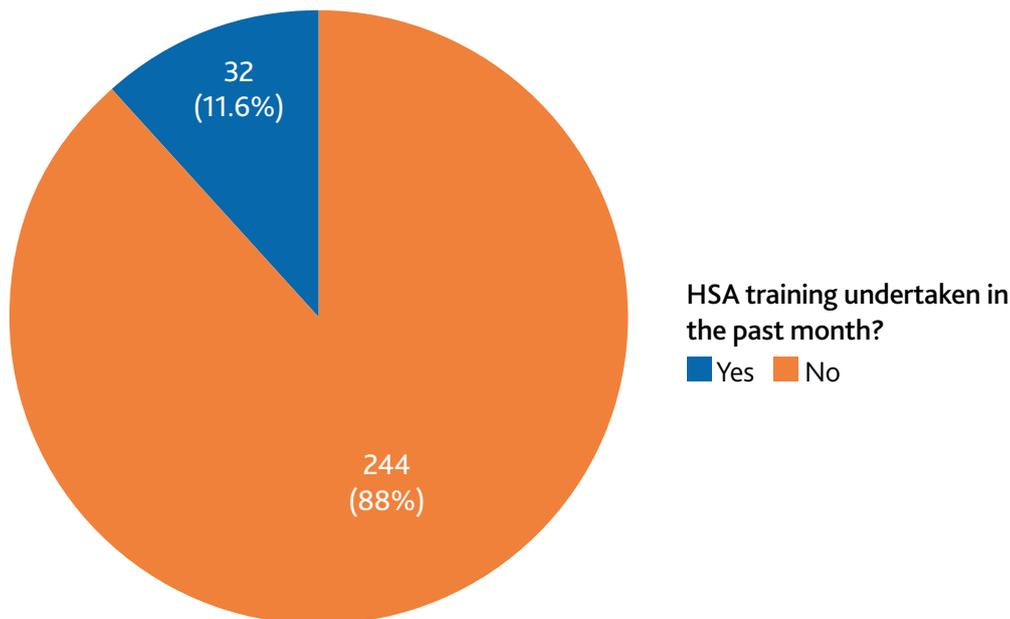


Figure 8: Continuing education among the study HSAs

VHC Readiness - Functionality & Conduciveness to RAS Delivery

Various features of the VHC health delivery system were assessed during the 276 routine monthly monitoring visits to determine readiness for RAS delivery. VHCs with access to clean water, power and lighting for night-time care and a dry safe space for storing drugs were recorded at the end of each month throughout the study.

Some Village Health Clinics were housed in a permanent structure, in other cases in temporary or shared structures (e.g.: a school or church) while others had no structure at all, operating out in the open. The structural status of the VHC could change from month to month, for example in some cases structures were destroyed by the rain and funds raised to rebuild, in this case the VHC would become a temporary health post until the structure was complete. In Salima 58% and in Ntchisi 56% of the monitoring visits revealed VHCs with impermanent floors of either earth, mud, or sand, 41% of the visits in Salima and 43% in Ntchisi, revealed permanent floors of cement. The majority had a tin/iron roof, the remainder a straw roof. During 5 monitoring visits, the clinic was operating in the outdoors. The permanence of the VHC structure was not considered critical to effective RAS administration, since the majority of respondents knew where to find the HSA at their home when they required care.



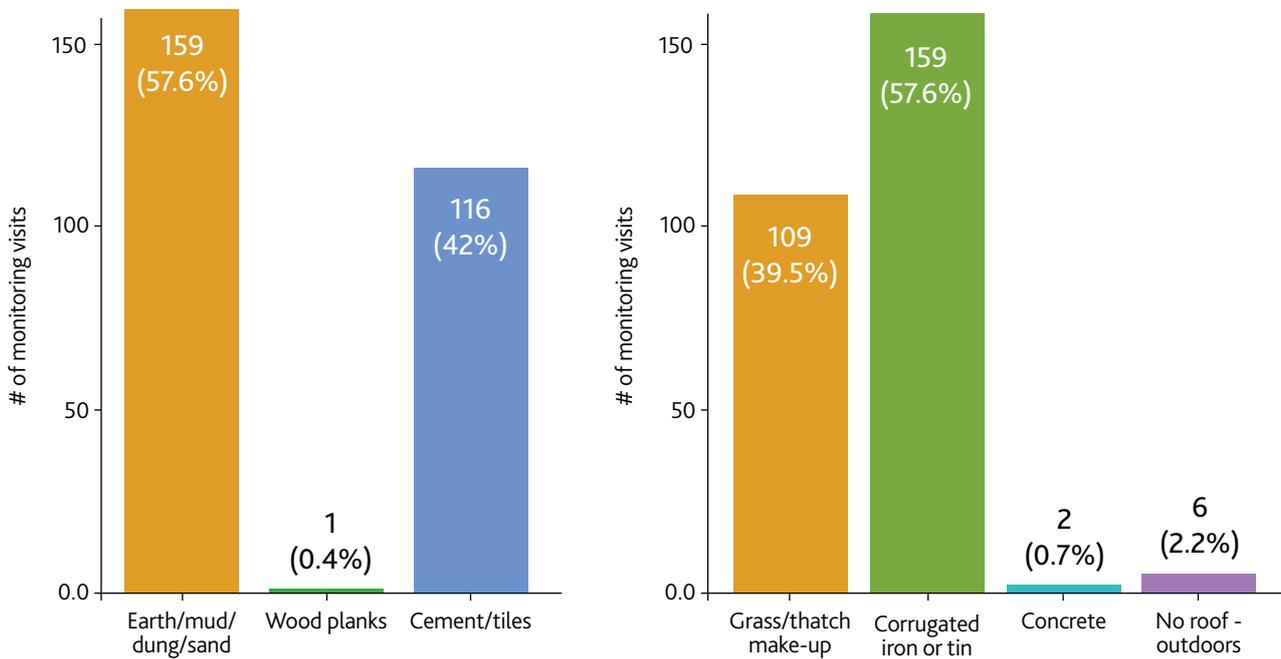


Figure 9: Floor and roof material at study VHCs



On the other hand, access to water for handwashing would be considered a priority in a village health clinic when administering RAS. Seventy percent of the monthly monitoring checks ($n=276$) revealed that the VHCs had no running water. On these occasions water was stored in a closed container, usually a bucket with a tap, carried to the site by the HSA for essential hand washing. During 27% of the monitoring visits there was no water on site at all. Sixty six percent of the monthly routine monitoring visits revealed clinics had at least a one-month supply of gloves available, 25% of the visits revealed inadequate supplies of gloves (insufficient for 1 month) and 9% of visits revealed no gloves at all.

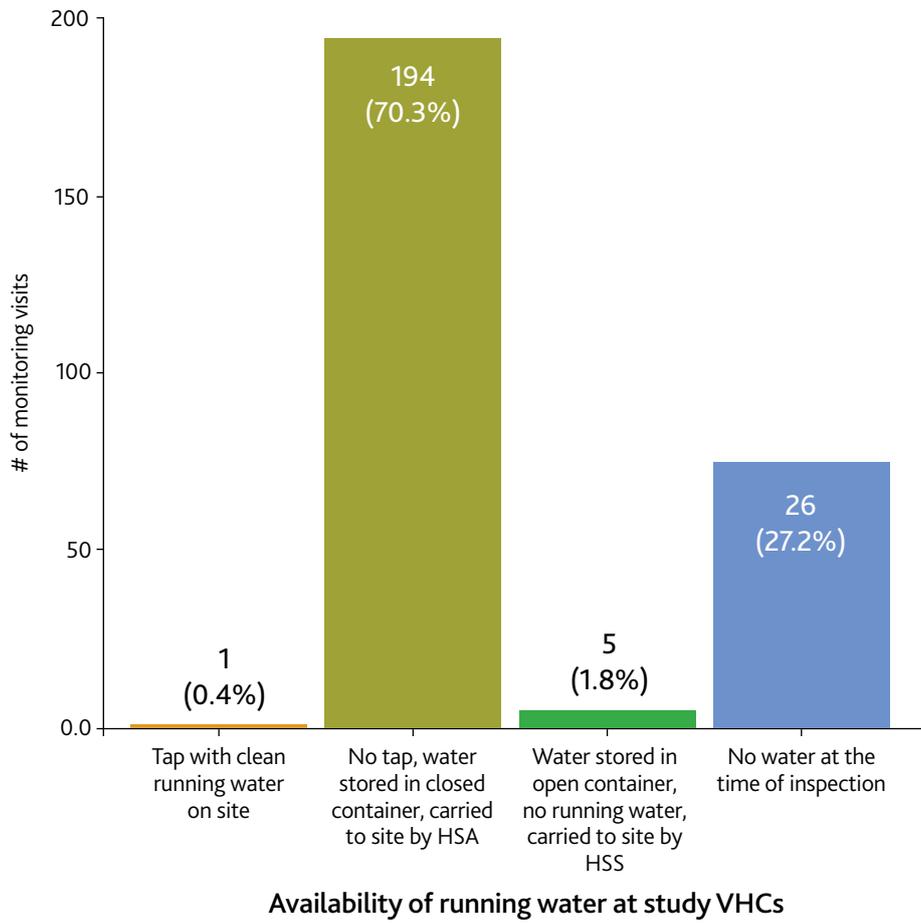


Figure 10: Availability of running water at study VHCs

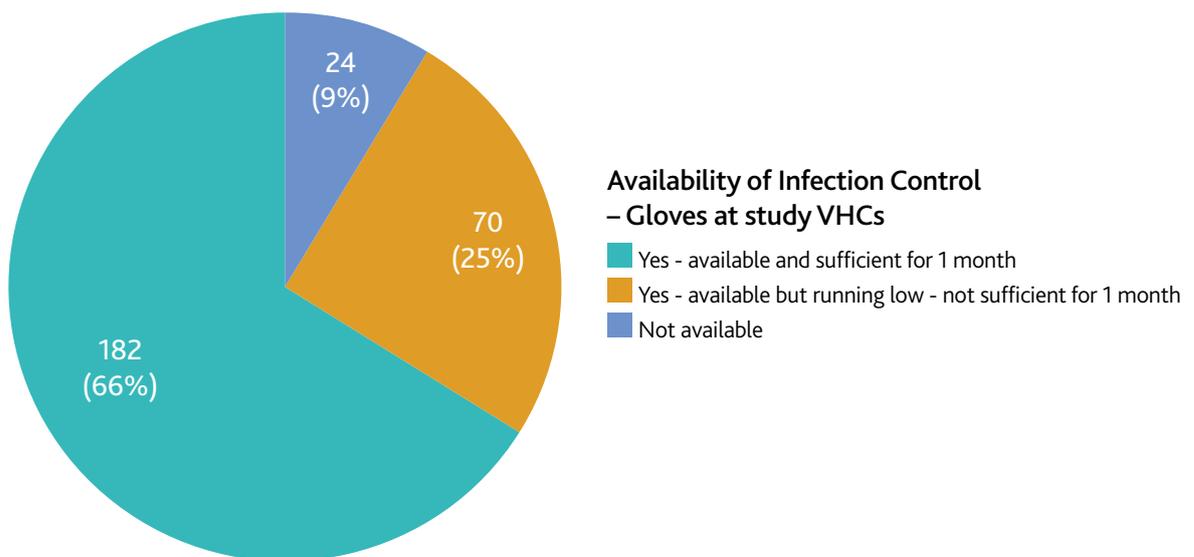


Figure 11: Availability of Infection Control – Gloves at study VHCs

Availability of HSAs 'after hours' is considered a key benefit of the Village Health Clinic system with HSAs resident in a catchment area to treat childhood illness at any time of day or night. The graphs below illustrate that most of the VHCs monitored during the course of the study had no reliable source of power and lighting, with a few exceptional cases having access to functional solar power. Table 13 confirms that when HSAs reflect on the previous season, they confirm that they are seeing malaria patients at night.

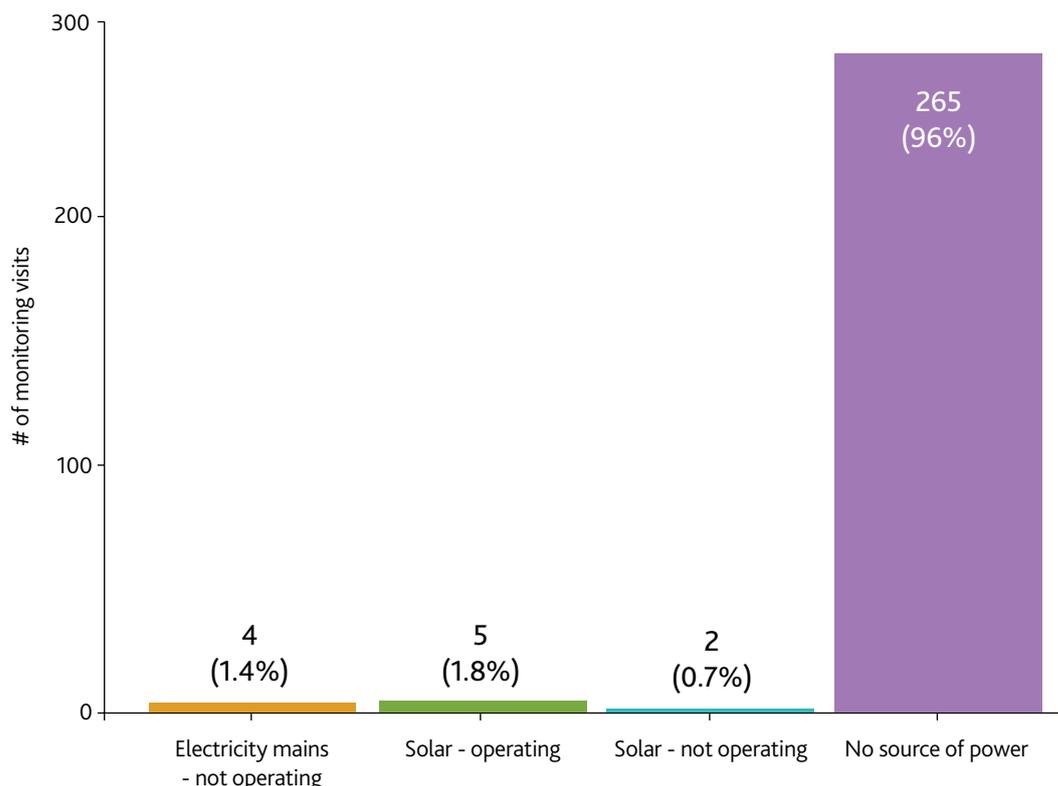


Figure 12: Presence of power lighting and power at study VHCs

Table 13: Frequency of night-time patients - reported by HSAs (HSAS)

HSA VHC patient load	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Ever receive malaria patients at night in last season (Yes)	13	92.9	7	77.8	13	92.9	8	88.9

In terms of storage facilities for the drugs, including the RAS commodity, 68% of the visits revealed the drugs stored in a sealed and locked storage container, 17% in an open container (cardboard box or bucket) and 15% stored free on a table or stool, without a container or box. These storage boxes were stored either in the Village Clinic if it was a permanent lockable building or in the HSAs home if the clinic structure was impermanent.

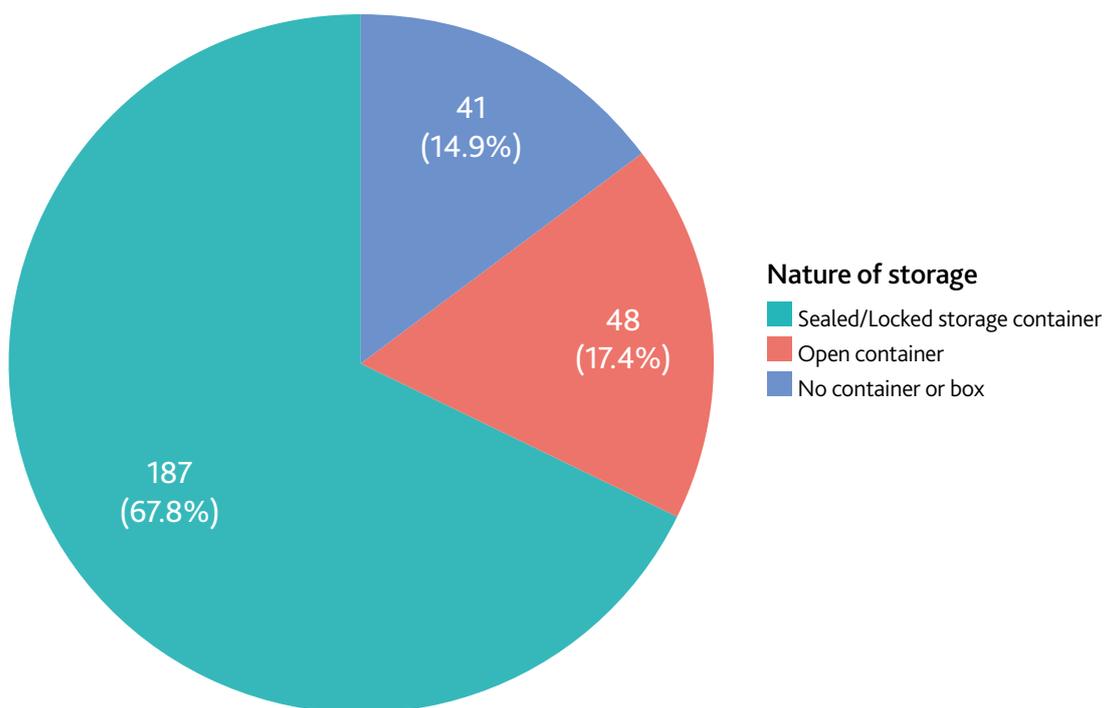


Figure 13: Medication storage facilities at study VHCs

Attitudes to RAS & HSA impression of community attitude to RAS

The study shows an increase in perceived confidence when administering RAS among HSAs in both study arms at endline. This indicator was based on *Ever administered RAS (Yes)* and *Perceived highly confident in administering RAS (Yes)*, noting that all sites had access to RAS and referral notes but not job aids and training materials. The HSAs impression of RAS acceptability in the broader community revealed already high acceptability in the exposed arm at baseline and endline, with one HSA changing his/her opinion during the course of the study, while in the unexposed arm, perception of community acceptability increased.

Table 14: Acceptability of RAS (HSAs)

Acceptability & Attitude to RAS	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
HSA impression of community attitude to RAS: community acceptability (Highly acceptable)	13	92.9	3	33.3	14	100.0	8	88.9
HSA confidence in administering RAS (Strong confidence)	9	64.3	4	44.4	12	85.7	7	77.8

RAS Usage

The NMCP was in support of this study to encourage uptake/use of RAS through IEC, however, it was keen to ensure that uptake/use of RAS was encouraged regardless of the RAS strength. The MOH continued to ensure that doses of 50 mg RAS procured by their partner PMI with confirmation that the commodity has undergone rigorous quality assurance (regardless of WHO prequalification). The MOH – NMCP confirmed that the 100 mg could be used but that the NMCP was not replacing the 50 mg with 100 mg and that HSAs should be encouraged to use both strengths as appropriate.

Throughout the study the HSAs continue to procure the 50 mg as per their routine drug requisitions. The RASIEC study team ensured that rectal artesunate 100 mg supplied to the referral centres on behalf of the MOH via USAID Global Health Supply Chain Program (GHSC-PSM) was made available to all the enrolled VHCs whenever supplies of 100 mg were required.

Figure 14 below illustrates the number of doses of RAS used monthly by the VHCs from May 2019 to March 2020 – 92 doses were used in the intervention sites versus 51 doses in the control site. Figure 11 shows the patterns of usage across sites and how some sites were entirely inactive – administering no RAS throughout the malaria season.

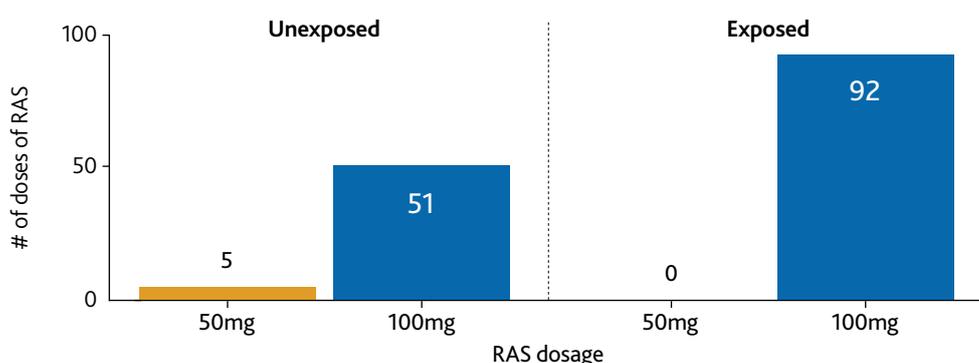


Figure 14: Number of doses of 100 mg & 50 mg RAS used by VHCs throughout the study period by study arm

Severe Malaria Knowledge & Severe Malaria Experience

The data below relates to severe malaria knowledge and experience managing danger signs – distinguishing between what people know (actual knowledge) and what people think they know (perceived knowledge). Perceived knowledge is thinking one knows a lot, which can lead to greater feelings of self-efficacy. That can be positive or negative, depending if the self-efficacy is based on weak, insubstantial actual knowledge or strong well-founded knowledge. By the end of the study all HSAs stated that they had had experience managing danger signs in the past month.

Table 15: HSA response: Experience managing danger signs

Experience managing danger signs	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Recent Experience of child patient with danger signs								
Had the experience in the past	14	100.0	9	100.0	14	100.0	9	100.0
Recent experience within past month	13	92.9	9	100.0	14	100.0	9	100.0

Perceived correct knowledge of the severity of malaria was high at baseline in the exposed arm and improved from 64% to 86% from baseline to endline, however the improvement in the unexposed arm, from 11% to 100% was more significant (Table 16). The bias created by the intensified IEC efforts in the vaccine trial sites would need to be considered as a potential cause of this accentuated change - more analysis in this regard is required. Meanwhile, the appropriate/correct perception of the symptoms of severe malaria and danger sign recognition improved significantly among the exposed HSAs from 42.9% to 85.7% and deteriorated among the unexposed HSAs. This could be directly attributed to the intervention which emphasised these aspects of care.

Perceptions of the severity of malaria – defined as CORRECT in the analysis

- Severe malaria cannot improve by itself without treatment
- A strong healthy child can get severe malaria
- A HSA cannot manage severe malaria on his or her own without referral
- Severe malaria can cause death and permanent brain damage in children
- Risk of dying from malaria is higher in children compared to adults

Perceptions of the Severe Malaria Danger Signs – defined as CORRECT in the analysis

- Fever
- Loss of consciousness
- Lethargy
- Cannot eat or drink
- Vomiting/cannot hold food down
- Convulsions

Table 16: HSA response: perceived knowledge of malaria severity & signs of severe malaria

HSA Perceived Knowledge – severity of malaria & symptoms of severe malaria	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Correct perceived knowledge - severity of malaria	9	64.3	1	11.1	12	85.7	9	100.0
Correct perceived knowledge - signs of severe malaria/ danger signs	6	42.9	5	55.6	11	85.7	4	44.4

At baseline and endline all HSAs reported knowing about RAS and at endline almost all had understood that RAS was an emergency pre-referral intervention, however very few understood that the child was being referred for onward treatment of injectable artesunate or quinine (Table 17), highlighting the need to teach HSAs about the care the caregiver could expect upon arrival at the referral facility and that admission should be expected.

Table 17: HSA Responses: RAS purpose as pre-referral intervention

HSA Knowledge about RAS & RAS purpose	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Knowledge of RAS	14	100.0	9	100.0	14	100.0	9	100.0
Knowledge of RAS as a pre-referral intervention	12	85.7	9	100.0	14	100.0	9	100.0
Specifically, as an:	11	78.6	6	66.7	14	100.0	8	88.9
<i>Emergency pre-referral action to save a life</i>								
<i>Intervention when a child can't swallow ACT</i>	3	21.4	2	22.2	0	0.0	1	11.1
<i>Pre-referral intervention</i>	4	28.6	2	22.2	5	35.7	0	0.0
Knowledge of post-referral treatment as artesunate IV/ injection/Quinine (Yes)	0	0.0	2	22.2	4	28.6	3	33.3

The summary is presented in Table 18 that shows an improvement in the perceived knowledge of the severity of malaria more among the unexposed; perceived knowledge of severe malaria danger signs more among the exposed; HSA correctly responding to cases of severe malaria danger signs more among the exposed; and HSA confidence when administering RAS more among the exposed. Overall HSA exposure to the IEC intervention increased their knowledge of severe malaria danger signs, capacity to respond to danger signs and confidence in administering RAS.

Table 18: Comparisons in changes in the HSA reports of the Exposed & Unexposed at endline relative to the baseline

Outcome change in HSAs (Crude)	Exposed n=14 HSA		Unexposed n=9 HSA		Comment Improvement > among:
	#	%	#	%	
Perceived Knowledge of the severity of malaria					
Remained poor	1	7.1	0	0.0	
Remained good	8	57.1	1	11.1	
Improved	4	28.6	8	88.9	Unexposed
Deteriorated	1	7.1	0	0.0	
<u>Improvement 1:</u> No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)					
Yes (Remained good/Improved)	12	85.7	9	100.0	
<u>Improvement 2:</u> No (Remained poor) vs Yes (Improved)					
Yes (Improved)	4	80.0	8	100.0	Unexposed
<u>Improvement 3:</u> No (Remained poor/Deteriorated) vs Yes (Improved)					
Yes (Improved)	4	66.7	8	100.0	Unexposed
Perceived Knowledge of severe malaria danger signs					
Remained incorrect	1	7.1	2	22.2	
Remained correct	4	28.6	2	22.2	
Improved	7	50.0	2	22.2	Exposed
Deteriorated	2	14.3	3	33.3	
<u>Improvement 1:</u> No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)					
Yes (Remained good/Improved)	11	78.6	4	44.4	
<u>Improvement 2:</u> No (Remained poor) vs Yes (Improved)					
Yes (Improved)	7	87.5	2	50.0	Exposed
<u>Improvement 3:</u> No (Remained poor/Deteriorated) vs Yes (Improved)					
Yes (Improved)	7	70.0	2	28.6	Exposed

Outcome change in HSAs (Crude)	Exposed n=14 HSA		Unexposed n=9 HSA		Comment Improvement > among:
	#	%	#	%	
HSA Reported actions for severe malaria danger signs					
Remained incorrect	1	7.1	1	11.1	
Remained correct	4	28.6	2	22.2	
Improved	7	50.0	2	22.2	Exposed
Deteriorated	2	14.3	4	44.4	
<u>Improvement 1: No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)</u>					
Yes (Remained good/Improved)	11	78.6	4	44.4	
<u>Improvement 2: No (Remained poor) vs Yes (Improved)</u>					
Yes (Improved)	7	87.5	2	66.7	Exposed
<u>Improvement 3: No (Remained poor/Deteriorated) vs Yes (Improved)</u>					
Yes (Improved)	7	70.0	2	28.6	Exposed
HSA Confidence (perceived self-efficacy) when administering RAS					
Remained incorrect	1	7.1	2	22.2	
Remained correct	8	57.1	4	44.4	
Improved	4	28.6	3	33.3	Fairly the same
Deteriorated	1	7.1	0	0.0	
<u>Improvement 1: No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)</u>					
Yes (Remained good/Improved)	12	85.7	7	77.8	
<u>Improvement 2: No (Remained poor) vs Yes (Improved)</u>					
Yes (Improved)	4	80.0	3	60.0	Exposed
<u>Improvement 3: No (Remained poor/Deteriorated) vs Yes (Improved)</u>					
Yes (Improved)	4	66.7	3	60.0	Exposed

Key Findings – Section 1

VHC characteristics – did they meet the minimum standards for delivery of RAS?

- 27.2% of the village clinic monthly visits revealed no water whatsoever on site for handwashing and for 9% of the visits no gloves were available on site – further complicating administration of the RAS intervention. During 96% of the visits there was no source of power for late night consultations – requiring kerosene lamps with fuel supplied by the HSA. Clean, dry secured medicine storage facilities were unavailable during 15% of the visits. These infrastructural factors could constrain or discourage RAS administration.

HSA characteristics and qualifications – did they meet the MOH guidelines?

- At baseline all HSAs met the criteria of the study and the MOH: completed secondary education and residing in the village. All had many years of experience. However, severe malaria-related supervision was very low throughout the study period.

RAS acceptability

- RAS acceptability increased at endline.

Impact of the intervention/exposure on HSA knowledge, actions and confidence (positive impact of intervention)

- Revealed positive impact of the exposure on the HSA knowledge of severe danger signs, correct response and confidence in the administration of RAS.
- Knowledge of severe malaria danger signs and actions to take when confronted with severe danger signs improved among the exposed HSAs as did perceived self-efficacy to administer RAS and manage danger signs.
- Usage of 100 mg of RAS was high in both arms.

Limitations – Section 1

- The malaria vaccine trial operating in the very same facilities, village health posts and communities that were sampled by RASIEC raises concerns and possible bias.
- Ideally this would have been highlighted at district meetings during district selection.
- The HMIS data and how cases of severe malaria, danger signs and deaths related to severe malaria in children 5 years are captured and reported raises questions on how to interpret and use the HMIS data.

Results - Section 2

Section 2: HSA danger sign recognition, response & management

The data presented in this section explores the HSAs capacity to recognise and manage a child with danger signs – including assessment choices (weighing, testing etc.), drug administration (RAS and other) and whether or not HSA exposure to the RAS IEC intervention increased the likelihood of an HSA correctly identifying the danger signs in a child \leq 5-year-old and administering RAS in accordance with the WHO aligned national treatment guidelines.

HSA - Capacity to recognise and manage danger signs

Most of the data in this section of the results originates from actual case management of a child with danger signs reported in the household and phone tracking component of the study. Table 19 however, presents the results from the HSA interviews – reported capacity to recognise danger signs, respond and administer RAS. There is a marked amelioration among the exposed HSAs across the three measures.

Table 19: Capacity to recognise danger signs, respond & administer RAS (HSAs-reported)

Knowledge of severe malaria danger signs – HSAs	Exposed		Unexposed		Comment Improvement > among:
	#	%	#	%	
Knowledge (perceived) of severe malaria danger signs					
Remained incorrect	1	7.1	2	22.2	
Remained correct	4	28.6	2	22.2	
Improved	7	50.0	2	22.2	Exposed
Deteriorated	2	14.3	3	33.3	
Improvement 1: No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)					
Yes (Remained good/Improved)	11	78.6	4	44.4	
Improvement 2: No (Remained poor) vs Yes (Improved)					
Yes (Improved)	7	87.5	2	50.0	Exposed
Improvement 3: No (Remained poor/Deteriorated) vs Yes (Improved)					
Yes (Improved)	7	70.0	2	28.6	Exposed

HSA Correct actions for severe malaria danger signs	Exposed		Unexposed		Comment Improvement > among:
	#	%	#	%	
HSA Correct actions for severe malaria danger signs					
Remained incorrect	1	7.1	2	22.2	
Remained correct	8	57.1	4	44.4	
Improved	4	28.6	3	33.3	Exposed
Deteriorated	1	7.1	0	0.0	
Improvement 1: No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)					
Yes (Remained good/Improved)	11	78.6	4	44.4	
Improvement 2: No (Remained poor) vs Yes (Improved)					
Yes (Improved)	7	87.5	2	66.7	Exposed
Improvement 3: No (Remained poor/Deteriorated) vs Yes (Improved)					
Yes (Improved)	7	70.0	2	28.6	Exposed

Table 19: Continued

HSA Confidence (perceived self-efficacy) when administering RAS	Exposed		Unexposed		Comment Improvement > among:
	#	%	#	%	
HSA Confidence (perceived self-efficacy) when administering RAS					
Remained incorrect	1	7.1	2	22.2	
Remained correct	8	57.1	4	44.4	
Improved	4	28.6	3	33.3	No difference
Deteriorated	1	7.1	0	0.0	
Improvement 1: No (Remained poor/Deteriorated) vs Yes (Remained good/Improved)					
Yes (Remained good/Improved)	12	85.7	7	77.8	
Improvement 2: No (Remained poor) vs Yes (Improved)					
Yes (Improved)	4	80.0	3	60.0	Exposed
Improvement 3: No (Remained poor/Deteriorated) vs Yes (Improved)					
Yes (Improved)	4	66.7	3	60.0	Exposed

The results show that for the HSA comparisons, the improvement in the:

- HSAs knowledge of severe malaria danger signs;
- HSAs correct response to severe malaria danger signs and;
- HSAs confidence in administering RAS

was more among the HSAs in the exposed arm.

HSA - Danger sign recognition

The WHO – Global Malaria Programme provides the description below for danger signs for severe malaria.

For community health workers and in place with limited diagnostic capacity for severe malaria, the WHO algorithm for giving rectal artesunate for pre-referral treatment of severe febrile illness in children provides the following description of danger signs for severe malaria:

- Fever AND
 - Convulsions or Unusually sleepy or unconscious or
 - Not able to drink or feed anything or Vomits everything

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Table 20 reviews the tracking cases and the danger signs in order of magnitude reported in each study arm, and Table 21 compares the danger signs reported by the caregiver with those identified by the HSA during phone tracking.

With the exception of recognition of 'inability to drink/eat/swallow', looking at percentages, HSAs in the exposed arm were reporting all the key danger signs with fever more frequently than HSAs in the unexposed – consistent with the information on their job aids and as emphasized during their refresher training - *that danger signs were signs that presented in addition to fever.*

Table 20: Danger signs reported by HSA to study on the day of the case (Phone Track)

Danger signs reported	Exposed n=57 households		Unexposed n=31 households		Comparison	
	#	%	#	%	p-value	Comment
Very Hot-with temperature of 38.5 or history of high fever	53	91.4	22	68.8	0.006	Higher in exposed
AND						
Not able to drink/eat/suckle	24	41.4	18	56.3	0.176	Higher in unexposed
Vomiting everything-cannot keep down food or drink	22	37.9	10	31.3	0.526	Higher in exposed
Patient is confused or very sleepy cannot be woken	20	34.5	7	21.9	0.212	Higher in exposed
Coma/Loss of consciousness	13	22.4	4	12.5	0.399	Higher in exposed
Extreme weakness-unable to stand or sit without support	10	17.2	1	3.1	0.089	Higher in exposed
Severe Anaemia	7	12.1	2	6.3	0.482	Higher in exposed

Table 21 looks at danger sign recognition between study arms and shows that danger signs reported by the HSA during the phone track call are not always aligned with those reported by the mother. The signs of repeated vomiting, inability to eat or suckle and lethargy are reported less frequently by the HSA. Whereas reports of fever, an altered state of consciousness and convulsions were more frequently aligned with the caregiver's report of symptoms. This may suggest that a HSA may be quicker to note the extreme danger signs and may risk missing the more subtle ones – such as vomiting, lethargy and inability to suckle, that require more in-depth history taking.

Table 21: Danger sign recognition for the same case: HSA versus caregiver recall

Danger signs	Caregiver Recall		HSA Phone track Recall	
	#	%	#	%
Fever or recent history of fever	85	95.5	75	84.3
Unconsciousness/altered state of consciousness	14	15.7	16	18.0
Recent hx of convulsions/Convulsions observed	42	47.2	42	47.2
Repeated vomiting/vomiting everything	54	60.7	32	36.0
Unable to eat/suckle	60	67.4	41	46.1
Lethargy/weak/sleepy	73	82.0	11	12.4

This could in part explain why very few of the caregivers interviewed during the HHS at endline, who reported a recent event of severe febrile illness and presented at the VHC with their sick child, received RAS. HSAs tended to be less aware of the signs such as lethargy, inability to suckle or vomiting, than a caregiver, and therefore may be administering oral antimalarials in these cases or may be diagnosing uncomplicated malaria. No HSAs were measuring fever with a thermometer, however caregivers frequently recalled fever as one of the sign/symptoms afflicting their sick child, while HSAs did not.

HSA - Care administered at VHC

The WHO-recommended response to a child with danger signs at community level is to **examine/assess**, **determine RAS dose** (estimate by age or weight), **administer**, **refer** and **facilitate transport** without unnecessary delay. The importance of swift care and time management when managing a very sick child was emphasised in both the job aid and the refresher training. Across both study arms, two thirds of the patients were cared for by the HSA within less than half an hour from arrival at the VHC. However 30-40% waited for care for more than half an hour with a very sick child.



Two-thirds of the caregivers covered in Table 22 spent half an hour at the VHC, the rest spent more than half an hour at the VHC including waiting time, which at the VHC is typically minimal. The care provided during VHC visit is presented in the tables below, relaying both the perspective of the HSA and the caregiver.

Care provided at the VHC – defined as Correct

- Examine/assess
- Determine RAS dose (by age or weight if possible)
- Administer RAS pre-referral intervention
- Refer
- Follow-up – not assessed here

Table 22: Length of time at the VHC – caregiver recall (HH Tracking)

Length of time spent at the VHC (caregiver recall)	Tracking					Comparison	Comment
	Exposed n=56		Unexposed n=33				
	#	%	#	%			
Half an hour	39	72.2	20	60.6	0.076		
One hour	13	24.1	7	21.2			
Between 2 and 5 hours	2	3.7	6	18.2			
A long wait at the VHC - more than half an hour (Yes)	15	27.8	13	39.4	0.260	Slightly longer wait in the unexposed arm	

The series of Tables 23, 24 and 25 present the data around the care provided by the HSA – as reported by caregiver and HSA. Consistent with the findings in Table 23 the child was assessed/examined for danger signs more in the exposed arm (as reported by both HSA and caregiver) – however, reports of weighing were not aligned with those of the caregiver, and neither were reports of a finger/toe prick/mRDT. In the exposed arm, HSAs report performing an mRDT in nearly 30% of the tracked consultations prior to administration of RAS and referral - all the cases that were tested received RAS and were referred.

There are different opinions as to whether a CHW/HSA, in the interest of time, should conduct an mRDT when managing a young child with danger signs suggestive of severe malaria. The practice was not promoted in the IEC materials or during the training and instead the 'assess' - 'treat' - 'refer' was promoted. However, the mRDT features as an important part of severe febrile illness management in iCCM and the mRDT is often a routine practice for HSAs who suspect malaria and dissuading those HSAs who chose to do an mRDT from doing so may require careful thought.

Table 23: Care administered – HSA (Phone Tracking)

Care Administered (HSA recall)	Tracking					
	Exposed Salima n=56		Unexposed Ntchisi n=33		Comparison	
	#	%	#	%	Comparison p-value	Comment
Temperature taken (Yes)	2	3.5	1	3.1	1.000	
Child assessed/examined for danger signs (Yes)	57	98.3	18	56.3	<0.001	Higher in unexposed
Age determined (Yes)	57	98.3	30	93.8	0.287	
Weight determined (Yes)	0	0	3	9.4	0.042	Only in unexposed
Malaria test done at the visit (Yes)	17	29.3	1	3.1	0.003	Higher in exposed
Other medication given	5	8.6	0	0	0.156	All in exposed

Table 24: Care Received - caregiver (HH Tracking)

Care Received (caregiver recall)	Tracking					
	Exposed Salima n=56		Unexposed Ntchisi n=33		Comparison	
	#	%	#	%	Comparison p-value	Comment
Child weighed? (Yes)	5	8.9	1	3.0	0.406	Higher in exposed
Child examined? (held/inspected) (Yes)	46	82.1	16	48.5	0.001	Higher in exposed
mRDT (finger prick done?) (Yes)	12	21.4	10	30.3	0.349	Higher in unexposed
RAS given in bottom. (Yes)	56	100.0	33	100.0	1.000	
Other medication given? (Yes)	6	10.7	5	15.2	0.539	Higher in unexposed
Any information on malaria prevention? (Yes)	13	23.2	13	39.4	0.105	Higher in unexposed

Table 25: Care Received - caregiver (HH Tracking)

Care administered/Care received	HSA Phone track Recall		Caregiver Recall	
	#	%	#	%
Examined child	74	83.2	62	69.7
Approximate weight	2	2.3	6	6.7
Tested for malaria using RDT	17	19.3	23	25.8
Other meds given other than RAS—pills, syrup, ORS	5	5.8	12	13.5
HSA Administered RAS	88	98.9	89	100.0
Given referral slip	86	97.7	89	100.0

Overall, there was strong evidence that the odds of the correct HSA practices being carried out was higher in the exposed arm (Table 26).

Table 26: Outcome Indicators

Outcome Indicators	Study arm				p-value	Crude Adjusted			
	Exposed		Unexposed			Confidence Interval		p-value	Comments
	#	%	#	%		Lower	Upper		
HSA services - HSA perspective (Correct)	12	36.4	45	80.4	<0.001	5.07	79.03	<0.001	Strong evidence that the odds of the correct HSA practices are higher in the Exposed arm

Table 27: Correct HSA services relative to age of child

Age of sick child (in months)	Correct HSA services received (HSA perspective)				p-value	Odds Ratio	Confidence Interval		p-value
	No		Yes				Lower	Upper	
Mean (sd)	34.0	18.0	22.4	11.2	<0.001	0.95	0.92	0.98	0.001
Median (IQR)	36.0	19.5 - 49	21.0	15 - 27	0.003				

In Table 27 both the mean and median show that the likelihood of receiving correct HSA services is more among the younger sick children. In addition, there is evidence of the odds of correct HSA services being offered increases with a decrease of the age of the children (that is the younger sick child) - Odds ratio 0.95 (CI: 0.92 - 0.98).

HSA - Dosing in relation to RAS

WHO guidelines call for the following dosing for RAS:

A single dose of 10 mg/kg/body weight of artesunate should be given as a suppository rectally as soon as presumptive diagnosis of severe malaria has been made.

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Upon reviewing the phone track data where HSAs reported on the dose administered and the child's age, it emerged that 20 – 30% of the children received sub-optimal dosing of RAS, inconsistent with their age. A formula was set up to generate an indicator of the right dosage using the combination of the dosage and the child's age.

- 84 of the children were administered 100 mg
- 5 were administered 200 mg.

In the exposed arm, 84.5% of the cases were administered the correct dosage, while in the unexposed arm, 71.9% were given the correct dosage. The tendency was to under-dose. In general, the children were not weighed and therefore dosing was based on age. The exposed HSAs had access to a dosing table but in 16% of the cases the HSAs administered the incorrect dose based on the age of the child. We do not know if they adjusted the dose downward because they determined that the child's weight was lower or if this was a clinical error. Weighing scales are typically used or available.

- **Right dose:**
100 mg and age ≤ 36 months
OR
200 mg and age > 36 months
- **Low dose:**
100 mg and age > 36 months
- **High dose:**
200 mg and age ≤ 36 months

ZAKA	Kuchokera miyezi isanu ndi umodzi mpaka zaka zitatu	Kuchokera zaka zitatu mpaka zaka zisanu mchimodzi
KULEMERA	Kuchokera 5kg kufikira 14kg	Kuchokera pa 14kg mpaka 20 kg
MULINGO 10 mg/kg	Mbulu umodzi wa mankhwala oyika njila yopangila chimbudzi (1 x 100 mg) 	Mibulu iwiri ya mankhwala iyika njila yopangila chimbudzi (2 x 100 mg) 



Comparing dosage and child recovery, 46.5% of those that had the right dosage reported recovery; while 38.9% of those that got the wrong dosage recovered. There is also no evidence of an association between dosage and child recovery, as reported by caregivers at HH tracking follow-up.

HSA - Additional Medications Administration

Five (8.6%) of the cases in the exposed arm were administered additional medicines at the VHC other than RAS. All 5 received artemether-lumefantrine oral – a treatment dedicated for uncomplicated malaria and not to be administered with RAS. There were no cases in the unexposed arm of other medicines being administered alongside RAS.

Key Findings – Section 2

Knowledge of danger signs, correct actions/response, and management (RAS)

- HSAs in the intervention arm demonstrated more capacity to recognise danger signs, respond and administer RAS than those in the control arm.
- Overall, there was strong evidence that the odds of the child undergoing the correct HSA practices were higher in the exposed arm.

Care provided at the VHC

- Of the children presenting with danger signs to the VHC during the tracking phase, more were assessed/examined (as reported by HSAs and caregivers) in the intervention arm as compared to the control arm.
- 100% of the 84 tracked danger sign cases received RAS in the VHCs that were stocked with 100 mg RAS, there was no more likelihood of receiving RAS in intervention arm as compared to the control arm of the study.

Dosing, medication, child response

- Nearly 30% of the cases presenting with danger signs at the VHC underwent an mRDT. All the cases that were tested were also given RAS and referred.
- Children were more likely to receive the correct dose in the intervention VHCs, but the difference was not significant. In the intervention arm, 84.5% of the children administered RAS were given the correct dosage for their age/weight, while in the control arm, 71.9% were given the correct dosage.
- Those that were given the incorrect dosage were underdosed and given 100 mg instead of 200 mg.

Limitations – Section 2

- Details of the management of the child were collected through HSA recall and complemented by follow-up with the caregiver at household.
- In order to identify severe malaria cases, daily communication with the HSA by field workers inquiring about danger case details was necessary. This may have introduced some bias, however, both study arms received the same daily contact and the calls began before the intervention was initiated.

Results - Section 3

Section 3: HSA referral

This section addresses whether HSA exposure to the RASIEC intervention positively influenced the HSA referral practice.



The introduction of referral slips in both study arms significantly improved this part of the intervention evaluation. During the course of the RASIEC study, the referral slip emerged as a key tool for HSAs and use of the referral slips and anecdotal evidence gathered in conversation with the HSAs in the exposed arm during routine monitoring revealed that the referral slip was the most useful component of the toolkit. Even though the referral slip was not officially part of the toolkit, it was perceived as such. As shown in the unexposed arm, where all cases were referred, use of the referral slip did not need to be accompanied by the IEC toolkit to be of great use.



Patient Loads

The tables below provide the patient load and referral context – showing the HSAs patient load per day as reported by the HSA and their personal estimate of the regularity of referral. Mean number of patients seen by the HSA ranged between 12 and 21 per week during the most recent malaria season. HSAs confirmed that they routinely refer more than 10% of their patients and during the most recent malaria season - the majority estimated referring between 11 and 25%. Referral slips could play a very important role in facilitating this process.

Table 28: HSA VHC Patient Load (HSAS)

HSA VHC patient load	Baseline				Endline			
	Exposed Salima n=14 VHCs		Unexposed Ntchisi n=9 VHCs		Exposed Salima n=14 VHCs		Unexposed Ntchisi n=9 VHCs	
	#	%	#	%	#	%	#	%
Average number of patients a week								
mean (sd)	10.8	10	20.8	11.6	13	24.1	7	21.2
Median (IQR)	4	4 - 20	8	7 - 15	18	(5 - 28)	7	(6 - 10)

Table 29: HSA Referrals (HSAS)

Average referrals	Baseline				Endline			
	Exposed n=14 VHCs		Unexposed n=9 VHCs		Exposed n=14 VHCs		Unexposed n=9 VHCs	
	#	%	#	%	#	%	#	%
Referred more than 10% of the patients (Yes)	9	64.29	8	88.89	7	50	5	55.56
% of cases referred								
none		14.3		0.0		0.0		0.0
< 11%		35.7		11.1		50.0		44.4
11% - 25%		35.7		77.8		50.0		44.4
26% - 50%		14.3		11.1		0.0		11.1

The reported patient load in the exposed arm doubled at endline, while there was fairly no change in the patient load in the unexposed arm. However, there was a reduction of referral at endline relative to the baseline for both the exposed and unexposed arms. These were based on recall and not on clinic records.

Referral

During the refresher training to orient the HSAs to the toolkit – HSAs were advised that an appropriate referral **to improve the chances of a caregiver/parent adhering to referral after administered RAS** required giving a referral slip and facilitating the referral, either through planning support or otherwise.

Of the 89 danger cases tracked from June 2019 to February 2020, 100% received RAS and 100% received a referral slip, as reported by the tracked caregivers. All referrals were verified by reviewing the referral booklet during routine monitoring and tracking them to the health facility where they were retrieved.

Referral – defined as Correct

- Give referral slip
- Support referral (planning of travel/accompany/lend or arrange transport)

Table 30: Referral & reported child health – caregiver (HH Tracking)

Caregiver Report	Tracking			
	Exposed n=56		Unexposed n=33	
	#	%	#	%
RAS administered	56	100.0	33	100.0
Referral given (Yes)	56	100.0	33	100.0
Verbal only	0	0.0	0	0.0
Verbal with a slip	56	100.0	33	100.0

Referral post-RAS administration was completed for the 89 cases of reported danger signs. No difference was noted between exposed and unexposed arms with regards to HSA capacity to refer post-RAS since all cases were referred. Referral slips proved to be an intervention in their own right, well received by HSAs who reported that it formalized the referral process and caregivers reported that it played an important part in the response they received at the health facility. This is a key and unexpected finding of this study.

Key Findings – Section 3

The availability and utilization of the referral slips

- All VHCs were supplied with a triplicate carbon copy referral book
- All HSAs used the referral slip booklet for all tracked referrals.

Patient load and percentage of referral

- 100% of the 89 tracked danger sign cases who received RAS in the VHCs were given a referral slip.
- No difference was noted between intervention and control arms with regards to HSA capacity to refer post-RAS.

Impact of the utilization of the referral slips

- The referral slip emerged as a key tool for HSAs and use of the referral slips and anecdotal evidence gathered in conversation with the HSAs in both arms during routine monitoring and with the intervention arm during refresher training revealed that the referral slip was the most useful and valued component of the toolkit.
- As shown in the control arm, use of the referral slip did not need to be accompanied by the IEC toolkit to be of significant use. Referral slips proved to be an intervention in their own right and caregivers reported that they played an important part in the referral process.

Limitations – Section 3

- The study assessed the influence of the IEC materials and not the referral booklet.
- The referral slip availability in the unexposed VHCs was introduced to ensure fairness. Ideally the influence of the referral slips would have been measured within a separate arm of the study, since it may have behaved as a cue to action in its own right and caused significant bias in the comparison of referral practices in response to the job aids.

Section 4

Caregiver characteristics/resources, knowledge, attitude, response (treatment seeking) & poster observation

This section of the report discusses the impact of posters (with information on danger signs and response to danger signs for children 5 years and under) which are mounted in catchment areas, may have on the likelihood of a caregiver recognizing the danger signs and care seeking for danger signs/severe febrile illness from the nearest VHC. Data originates from the household survey (HHS) and from the tracking (HH Tracking) of cases presenting at the VHC with danger signs during the 9 months of tracking.

Demographics of the caregivers are presented first to set the scene, followed by reported exposure to the intervention posters as recounted by household respondents at endline and from tracked households after an episode of danger signs. Thereafter, data on changes in community malaria and RAS-related knowledge and treatment-seeking behaviour are presented using a few of the constructs from the Health Belief Model (Baker, 1974) included in the original list of indicators. Finally, comparisons between the caregivers and treatment-seeking choices for danger signs are presented.

Caregiver Characteristics - Demographics

Every attempt was made to interview all the baseline households at endline. However, in 8 cases this was not possible in the exposed arm due to households relocating to different villages. No migrations or relocations were noted in the unexposed arm. At the household, it was not always possible to speak to the same caregiver interviewed at baseline. Upon review of respondent gender out of a total of 220 households at endline, 13.6% showed a change in the gender of the primary caregiver being interviewed, giving some indication of the percentage of different respondents. The potential for this to influence the pre- and post-intervention comparisons is raised as a limitation.

The majority of the primary caregivers at baseline and endline were female, with approximately 10% male. With a median age of 29 years and 27 years in the exposed and unexposed arms respectively, the majority had some primary education, 20% had no education in the exposed arm, and slightly less had no form of education in the unexposed arm (9-13%). The ability to read was more apparent among respondents in the unexposed arm, although the large majority of respondents across both arms were either unable to read or read with difficulty: reinforcing the need for IEC materials with images that do not require reading ability (Table 31) and raising questions whether posters with written words are the best way to reach communities of this nature – noting that preferred medium of communication is radio (see Table 43).

Table 31: Demographics of caregivers: gender - age – education (HHS)

Origins & Residency	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison p-value	Exposed n=165		Unexposed n=55		Comparison p-value
	#	%	#	%		#	%	#	%	
Caregiver gender										
Male	13	7.5	7	12.7	0.234	15	9.1	6	10.9	0.691
Female	160	92.5	48	87.3		150	90.9	49	89.1	
Caregiver age										
Median (IQR)	29	(25 - 33)	27	(23 - 32)	0.092	29	(25 - 35)	27	(23 - 34)	0.119
Highest level of Education										
Never	34	19.8	5	9.1	0.012	35	21.2	7	12.7	0.001
Primary	123	71.5	38	69.1		120	72.7	35	63.6	
Secondary and higher	15	8.7	12	21.8		10	6.1	13	23.6	
Ability to read										
Unable	78	45.1	18	32.7	0.270	83	50.3	15	27.3	0.001
With difficulty	23	13.3	9	16.4		23	13.9	5	9.1	
Easily	72	41.6	28	50.9		59	35.8	35	63.6	

The source of income upon which the household relied varied slightly from baseline to endline – with those relying on seasonal agriculture or fishing varying the most, with more households in the unexposed arm depending on agriculture. Significantly more households in the exposed arm were without income. The households were very poor with an average range of money available for food each month across the two arms of \$10 to \$13.

Significantly more households in the unexposed arm had access to power at endline (solar or other), the majority of households 'owned' their house. Access to media (radio or tv) ranged between 27% and 43%, phone access between 42% and 61% and access to own transportation between 36% and 69% (See Tables 32-34).



Table 32: Source of income (HHS)

Source of income	Baseline					Comparison p-value	Endline				Comparison p-value
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55				
	#	%	#	%			#	%			
No income	61	35.3	11	20.0	39	23.6	3	5.5	<0.001		
Agriculture/Fishing	49	28.3	34	61.8	62	37.6	42	76.4			
Small Business Shop/ Service/Vendor/ Laborer	63	36.4	10	18.2	64	38.8	10	18.2			

Table 33: Amount of money available each month to buy food (HHS)

Amount of money available for food each month	Baseline		Endline	
	Exposed n=173	Unexposed n=55	Exposed n=165	Unexposed n=55
Median (IQR)	5,000 MWK (4,000 -10,000)	6,000 MWK (5,000- 20,000)	7,000 MWK (3,500 - 13,000)	5,000 MWK (2,000 - 10,000)
Median \$ Range	\$5.40 - \$17.65	\$6.70 - \$27	\$4.75- \$17.65	\$2.70 - \$13.50
Mean	9,087 MWK	10,209 MWK	10,052 MWK	8,000 MWK
Mean \$	\$12.35	\$13.80	\$13.66	\$10.80

Table 34: Home resources (HHS)

Home resources	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Power source	42	24.3	22	40.0	40	24.2	28	50.9
Radio or TV access	47	27.2	24	43.6	49	29.7	19	34.6
Phone access	77	44.5	34	61.8	70	42.4	34	61.8
Own transportation	83	48.0	20	36.4	114	69.1	25	45.5
House ownership	117	67.6	48	87.3	151	91.5	50	90.9

On average, a caregiver in the exposed arm cared for 4 children of which 2 were aged less than 5 years, while those in the unexposed arm had fewer children, caring for 2 children of which 1 was aged less than 5 years. Approximately 50% care for 1-3 children.

Table 35: Children cared for by the caregiver (HHS)

Children cared for by caregiver	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Total Number of children								
mean (sd)	3.6	2.0	2.9	2.0	3.8	1.8	3.1	2.0
Median (IQR)	3	(2-5)	2	(1-4)	4	(3-5)	2	(1-5)
Children 5 years and under cared for by caregiver								
mean (sd)	1.4	0.7	1.2	0.4	2	0.7	1	0.5
Median (IQR)	1	(1 - 2)	1	(1 - 1)	1	(1 - 2)	1	(1 - 1)

The tracked caregivers of the children who presented at the VHC with danger signs were comparable: primarily female (89 – 97%), with more male caregivers in the exposed arm. The majority of the caregivers were under 30 years of age and cared for an average of 3 children in the control arm and 4 in the exposed arm (Table 36). It was determined that the caregivers who were tracked were representative of the overall population.

Table 36: Demographics of caregivers who visited the VHC with danger signs (HH Tracking)

Demographics of caregivers	Tracking			
	Exposed n=56		Unexposed n=33	
	#	%	#	%
Caregiver age				
30 years or less	35	62.5	22	66.7
> 30 years	21	37.5	11	33.3
Caregiver sex				
Male	6	10.7	1	3.0
Female	50	89.3	32	97.0
# of children cared for by caregiver				
Mean (sd)	4	1.9	3	1.7
Median (IQR)	3	(1-5)	3	(1-4)

Caregiver - Perceived Knowledge

Basic malaria knowledge and prevention knowledge (Table 37) was high at baseline in both arms and did not change at endline. Basic malaria knowledge – overview, cause and prevention were not addressed in the IEC materials distributed during the study and remained stable from baseline to endline.



Overview of malaria – defined as Correct

- Malaria is an illness that comes from mosquitoes
- Malaria is a dangerous illness (convulsions, vomiting, weakness)
- Malaria is a fever illness (febrile illness)

Causes of malaria – defined as Correct

- Mosquitos – small parasites – stagnant water

Prevention of malaria – defined as correct

- Prevent by sleeping under a mosquito net
- Preventing stagnant water
- Keeping grass cut/homestead clear of grass

Table 37: Basic malaria knowledge (HHS)

Knowledge of malaria - caregiver	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Correct knowledge of Malaria (yes)								
Overview	137	79.2	46	83.6	138	83.6	47	85.5
Causes	107	61.9	44	80.0	113	68.5	43	78.2
Prevention	138	79.8	51	92.7	134	81.2	51	92.7

At baseline, knowledge of malaria signs and symptoms and recognition of danger signs was highest in the exposed arm and improved in both arms, however the improvement was very significant in the unexposed arm. Future analysis could consider whether this is attributable to the ongoing Malaria Vaccine Trial. There was weak evidence of an increase in the knowledge of severe malaria on the exposed arms, as shown by the Odds Ratio (OR) and adjusted ORs in the overall comparison for the 'Overview knowledge of malaria'.

Table 38: Caregiver – knowledge of severe malaria signs and symptoms (HHS)

Knowledge of severe malaria - caregiver	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison	Exposed n=165		Unexposed n=55		Comparison
	#	%	#	%	p-value	#	%	#	%	p-value
Symptoms of severe malaria	88	50.9	6	10.9	<0.001	131	79.4	54	98.2	0.001
Recognition of danger signs	88	50.9	5	9.1	<0.001	127	77.0	54	98.2	<0.001 unexposed

Knowledge of the symptoms of malaria and recognition of danger signs among caregivers increased in both arms during the study. However, the increase was significantly larger in the unexposed arm. No confounders could be identified, and this unprecedented change may be attributed to the trial but would need to be determined.

Caregiver - Health Seeking Behaviour and related perceptions

Whether or not a caregiver adopted a behaviour (in this case seeking care promptly) depends whether value was assigned to the result, in this case, to the child recovering or improving. The expectation is that a seeking care from the VHC, if one has confirmation that there is lifesaving medicine available there, will prevent severe sickness and even death. Respondents were asked questions and asked whether they strongly agreed, agreed, disagreed or strongly disagreed.

The constructs in Table 39 can sometimes shed light on engagement in a behaviour – in this case health seeking in response to dangers signs and were used when formulating the indicators and analyzing the results.

Table 39: Caregiver – knowledge of severe malaria signs and symptoms (HHS)

Perceived susceptibility: a subjective assessment of risk of a health problem or consequence. If an individual perceives that s/he is susceptible, s/he may engage in a behaviour to reduce that risk. In the case of a child with severe malaria, does a mother perceive that her child is at risk of severe malaria, when the child has fever and a danger sign. A caregiver who perceives this as a high risk is more likely to engage in behaviours to decrease the risk.

Perceived severity: the subjective assessment of the severity of a health problem and its potential consequences. Individuals who perceive the problem (in this case danger signs) as serious are more likely to engage in behaviours to prevent or reduce its severity.

Perceived threat: combination of perceived severity and perceived susceptibility depending on extent of knowledge about the condition. A higher perceived threat leads to a higher likelihood of engagement in risk reducing behaviour.

Perceived benefits: an individual's assessment of the value or efficacy of engaging in a behaviour to decrease risk or severity of disease – in this case, will going to the VHC have a benefit for a child with danger signs?

Perceived barriers: refer to an individual's assessment of the obstacles to behaviour change. Even if an individual perceives a health condition as threatening and believes that a particular action will effectively reduce the threat, barriers may prevent engagement in the health-promoting behaviour.

Self-efficacy: individual's perception of his or her competence to successfully perform a behaviour - confidence in one's ability to effect change in outcomes (i.e., self-efficacy).

Cues to action: that a cue, or trigger, is necessary for prompting engagement in health-promoting behaviour.

- **Internal:** pain/symptoms/emotions
- **External:** events/media/posters/HSA advice/illness of a friend

The intensity of cues needed to prompt action varies between individuals by perceived susceptibility, seriousness, benefits, and barriers.

Modifying variables

Individual characteristics including demographic, psychosocial, and structural variables, can affect perceptions (i.e., perceived seriousness, susceptibility, benefits, and barriers) of health-related behaviours.

Demographic variables include age, sex, race, ethnicity, and education etc.

Psychosocial variables include personality, social class, peer & reference group pressure, etc.

Structural variables include knowledge about a given disease and prior contact with the disease, among other factors.

HBM suggests that modifying variables affect health-related behaviours indirectly by affecting perceived seriousness, susceptibility, benefits, and barriers.

Source: https://en.wikipedia.org/wiki/Health_belief_model#:~:text=Cues%20to%20action,of%20internal%20cues%20to%20action.

The table below presents data with regards to perceived severity and perceived barriers to care.

Table 40: Perceived severity & perceived barriers (HHS)

Perceived severity & perceived barriers	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison	Exposed n=165		Unexposed n=55		Comparison
	#	%	#	%	p-value	#	%	#	%	p-value
Perceived severity <i>Malaria not serious and does not need treatment</i>	25	14.5	3	5.5	0.098	21	12.7	2	3.6	0.073
Perceived severity <i>Home treatment just as effective</i>	45	26.0	9	16.4	0.143	35	21.2	6	10.9	0.089
Perceived severity of Danger Signs (High)	106	61.3	15	27.3	<0.001	135	81.8	55	100.0	0.001
Perceived Barriers										
Health facility too far/ no travel money	152	87.9	48	87.3	0.908	144	87.3	51	92.7	0.334
Health services (Clinics, VHC) not effective	145	84.3	51	92.7	0.174	147	89.1	51	92.7	0.605
HSA not regularly available	15	8.7	2	3.6	0.375	71	43.0	44	80.0	<0.001
Long waits at the health centre	23	13.3	3	5.5	0.145	29	17.6	8	14.6	0.603

Of interest to the study was whether there was an improvement in the knowledge of the severity of danger signs. Both the caregivers in the unexposed and exposed arms showed an improvement but the increased perception of malaria severity in the unexposed arm at endline was more significant.

Caregiver - Attitude to RAS & Awareness of Availability

Rectal artesunate was considered an acceptable intervention in both study arms (Table 41). In fact, acceptability at baseline RAS was high and remained so throughout the course of the study. However, a more significant change was in relation to 'knowledge/awareness of availability of the drug.' At baseline only 7% of the respondents in both arms knew that RAS was/might be available at the village health clinic – which in many cases it was not. Over the course of the study this increased by 47% in the exposed arm and by 27% in the unexposed arm in response to the drug being in stock/available at the VHC. This could be a powerful cue to action – with the change evident in both arms but more significant in the exposed arm.

In terms of response to danger signs in a small child, at baseline caregivers were well aware of the importance of seeking care for danger signs and the majority knew that the outcome of not treating malaria was death, convulsions, unconsciousness or a 'dangerous situation' – this awareness remained the same at endline. Caregivers recognise severe illness and the importance of seeking care – possible exposure to the IEC materials did not change this indicator. This suggests that caregivers do respond to danger signs and recognise the danger of these symptoms and any delay in accessing care would be when the symptoms are milder – such as in the earlier stages of malaria.

Table 41: Caregiver – RAS acceptability & availability (HHS)

RAS Acceptability & Availability	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison	Exposed n=165		Unexposed n=55		Comparison
	#	%	#	%	p-value	#	%	#	%	p-value
Considers RAS acceptable	167	96.5	54	98.2	1.000	163	98.8	54	98.2	1.000
Knows about RAS availability at the VHC	13	7.5	4	7.3	1.000	89	53.9	19	34.6	0.013

Table 42: Caregiver - Knowledge of response to danger signs & knowledge of outcomes of non-treatment (HHS)

Knowledge of response to danger signs & knowledge of outcomes of non-treatment	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison	Exposed n=165		Unexposed n=55		Comparison
	#	%	#	%	p-value	#	%	#	%	p-value
Knows appropriate response time after danger signs - within 24 hours	171	98.8	55	100.0	1.000	165	100.0	54	98.2	0.250
Knows the outcome of non-treatment	172	99.4	55	100.0	1.000	165	100.0	55	100.0	-

Knowledge of the symptoms of malaria and recognition of danger signs among caregivers increased in both arms during the study. However, the increase was significantly larger in the control arm. No confounders could be identified, and this unprecedented change may in part be attributed to the malaria vaccine trial.

Caregiver - Cue to Action

A key research question was whether exposure to the information on the poster in the exposed arm influenced danger sign identification and health seeking behaviour. Exposure to the poster could include direct exposure to the intervention (seeing & understanding the poster) or indirect exposure - hearing anyone talk about the poster or the information on the poster. The poster would represent a 'cue to action' or trigger, or the stimulus needed to trigger a decision-making process – in this case to seek care for danger signs. An external cue includes things like media and advice as opposed to internal cues, which may include symptoms or witnessing symptoms in the case of the caregiver.

Table 43 below looks at this and shows that among respondents across each study arm the most preferred IEC channel for receiving information about severe malaria was radio broadcast or via advice from friends. Advice from the knowledgeable neighbours was not a favoured IEC channel. Advice from the HSA regarding severe malaria was not favored as a cue to action at baseline but was more valued at endline.

Table 43: Household reported cue to action in response to severe malaria

Household reported cue/prompt to act in response to severe malaria - household response	Baseline					Endline				
	Exposed Salima n=173		Unexposed Ntchisi n=55		Comparison p-value	Exposed Salima n=165		Unexposed Ntchisi n=55		Comparison p-value
	#	%	#	%		#	%	#	%	
Media related cue/prompt										
Messages broadcasted on the radio	161	93.1	51	92.7	1.000	160	97.0	47	85.5	0.004
Posters and pictures mounted in the village/my community	97	56.1	50	90.9	<0.001	158	95.8	18	32.7	<0.001
Belief and listening to HSA advice	60	35.5	1	1.9	<0.001	105	63.6	48	87.3	0.001
Advice from knowledgeable neighbours e.g. health volunteer	54	31.4	0	0.0	<0.001	81	49.1	31	56.4	0.350
Advice from my friends	168	97.1	52	94.6	0.404	157	95.2	49	89.1	0.111
Other cue to action										
The death of a child from malaria/danger signs in the village	86	50.0	8	14.6	<0.001	109	66.1	51	92.7	<0.001
Knowledge of availability of medicine for danger signs at the village health clinic	51	30.0	9	16.4	0.054	96	58.2	53	96.4	<0.001

Of interest is that posters mounted in the community became a more valued cue to action in the exposed arm over the course of the intervention period. The other two external cues to action that were not IEC related: namely the death of a child in the village from malaria/danger signs and knowledge that medicines are available in the village clinic were the most significant external cues to action for the unexposed site where posters were not mounted but drugs were available. The knowledge that drugs are available and in stock may account for much of the change in the unexposed arm.

Caregiver - Malaria prevention efforts

The study did not explore malaria prevention efforts beyond the use of malaria nets. The majority of respondents at baseline and endline had at least one mosquito net and used it, with the minority either having a net and not using it or not having one at all – the latter increasing slightly over the 12 months of the study.

Table 44: Malaria Prevention – reported mosquito net use among caregivers (HHS)

Reported Mosquito net use	Baseline				Endline			
	Exposed Salima n=173		Unexposed Ntchisi n=55		Exposed Salima n=165		Unexposed Ntchisi n=55	
	#	%	#	%	#	%	#	%
Have a mosquito net and uses it	165	96.5	54	100.0	157	95.2	52	94.6
Have a mosquito net but does not use it	2	1.2	0	0.0	1	0.6	0	0.0
Have no mosquito net	4	2.3	0	0.0	7	4.2	3	5.5

Caregiver - Poster Visualization

Since posters and pictures mounted in the community were considered a significant cue to action in the exposed arm over the course of the study, Table 45 and Table 46 outline levels of exposure and readiness or likelihood to look at posters. Table 45 shows that 80% of the respondents in the endline in the exposure arm reported seeing the poster – indicating quite significant coverage across the catchment area. Figure 15 illustrates where the posters were mounted.



Figure 15: Where the posters were mounted.

Table 45: Posters related to danger signs – exposure (HHS)

Posters/messages of danger signs	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison	Exposed n=165		Unexposed n=55		Comparison
	#	%	#	%	p-value	#	%	#	%	p-value
Saw a poster relating to danger signs (Yes)	14	8.1	1	1.8	0.126	132	80.0	6	10.9	<0.001
Understood the poster* (Yes)	10	71.4	1	100.0	1.000	122	92.4	5	83.3	0.398

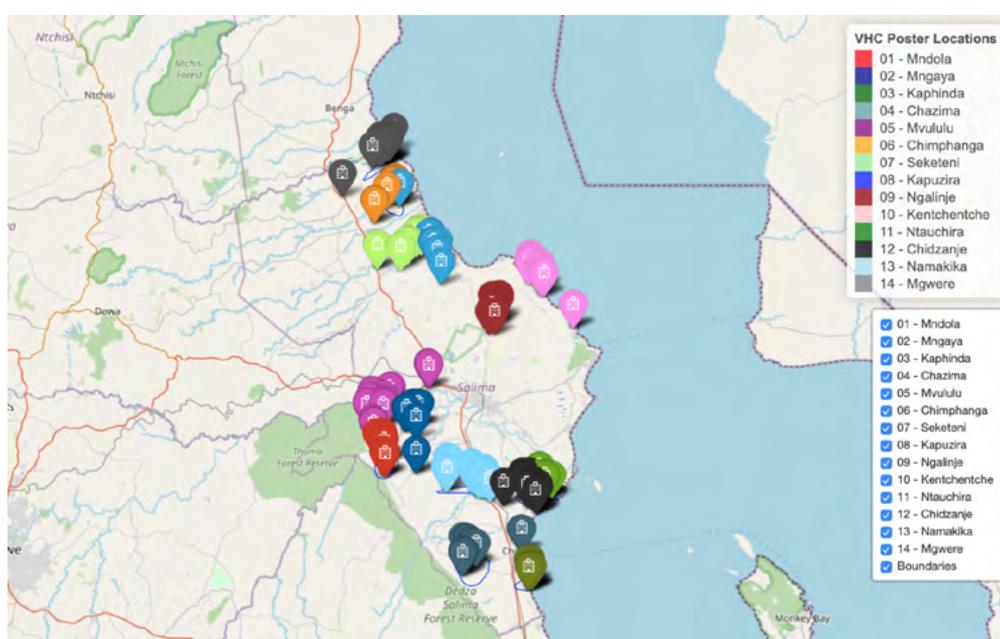
* Understood the poster: Stated that the poster was related to danger signs of malaria and to seek care when the child is sick with danger signs.

Table 46: Posters related to danger signs – exposure (HH Tracking)

Posters/messages of danger signs	Tracking				
	Exposed n=56		Unexposed n=33		Comparison
	#	%	#	%	p-value
Saw a poster relating to danger signs (Yes)	29	51.8	3	9.1	<0.001
Did the information you learned on the poster influence your recent response to danger signs (Yes)	27	93.1	3	100	0.639

Table 47: Where did you see the poster on danger signs and malaria (HH Tracking)

Locations where posters were seen most recently	Exposed n=29		Unexposed n=1	
	#	%	#	%
At the HSA home	15	51.7	1.0	100
At shop/trading centre/tearoom/business	2	6.9	0.0	0
At or near a school	1	3.5	0.0	0
At Head-man's house or central house	1	3.5	0.0	0
At community meeting place (church/central place/meeting tree)	5	17.2	0.0	0
At VHC/TBA/Under 5 clinics	5	17.2	0.0	0

**Figure 16:** Intervention posters in intervention arm: Location based on GPS coordinates

Of the cohort of caregivers who were tracked following an episode of severe malaria, 51.8% had seen a poster or been exposed in some way to the intervention. This is 30% fewer than saw the poster in the representative sample accessed during the household survey. The place where the tracked household caregiver had seen the poster most recently was the HSA's home (51.7%) , followed by in the community or at the VHC (17% each) as compared to those in the HHS who had primarily seen the poster in locations within the community.

Further exploration of the tracking data was to determine whether those tracked households that had seen the posters demonstrated a prompter response to the danger signs: comparing the caregiver seeing the poster with caregiver response and child health outcome as reported by the caregiver at time of follow-up, showed no evidence of association. Looking at percentages for seeing poster versus child outcome at follow-up: for those that saw a poster in the exposed arm, 86.2% had a child outcome of child good health.

Those who had seen the poster in the exposed arm said it had influenced their health seeking choices, only one caregiver in the unexposed arm had seen a poster and this too had influenced health seeking choices, a poster most likely associated with the malaria vaccine trial.

As part of routine monitoring the study documented any malaria-related posters across the catchment areas. The most common posters that were detected throughout the study are included below. In general, posters related to health-related issues and they were primarily visible at health facilities or health posts.



Figure 17: Ongoing campaigns in the study catchment areas

Table 48 shows that most household survey respondents in the community at large who had seen the poster had seen it recently – even as recently as the day of the interview. In the case of the exposed arm, this served as a confirmation that posters were still being seen at the end of the study despite the challenges with removal and damage reducing the number available to be seen.

Table 48: Response to a poster

Posters/messages of danger signs	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
When was the poster most recently seen?								
Recently saw poster – no specific day recalled	3	21.4	0	0.0	65	49.2	2	33.3
Today	0	0.0	0	0.0	47	36.4	1	16.7
Yesterday	3	21.4	0	0.0	18	14.0	1	16.7
A few days back	0	0.0	0	0.0	14	10.9	0	0.0
Last week	4	28.6	0	0.0	10	7.8	1	16.7
A few weeks back	7	50.0	1	100.0	40	31.0	3	50.0

The majority of respondents were unable to read and responded positively to the posters despite lack of literacy. Over 80% of household survey respondents had seen the poster and 92.4% understood the poster - determined based on their capacity to recall the content of the poster.

Project posters were seen primarily in the community and the majority of respondents reported that they were keen to look at the posters when first mounted in order to learn something and because of curiosity. Those who were less likely or unlikely to look at a poster attributed this to their inability to read, however the majority of respondents who could not read confirmed that they would still be keen to look at a poster with images or request someone to read the poster to them. What was not captured in the survey is how often a community member will look at the same poster. In other words, how soon the novelty of the poster wears off.

Posters/messages of danger signs	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Likelihood of looking at poster?								
Highly likely	146	85.9	49	89.1	119	87.5	53	96.4
Reason for Likelihood								
Seeking understanding: <i>'I want to learn something'</i>	85	56.3	30	60.0	81	62.3	29	53.7
Curiosity <i>'What is going on here'</i>	42	27.8	17	34.0	36	27.7	17	31.5
Importance of information <i>'This must be important'</i>	24	15.9	3	6.0	13	10.0	8	14.8

Posters/messages of danger signs	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Reason for Unlikelihood								
Cannot read	18	94.7	4	80.0	5	100.0	1	

Maintaining Posters

Maintaining posters in good condition as part of community IEC raises anticipated and unanticipated logistical challenges. The unanticipated challenges included systematic removal of posters by youth as a rebellious act. This was addressed with headmen and the challenge was overcome. On other occasions posters were removed and then later retrieved inside homes, where they had been used as decoration and wallpaper. Time and funds permitting it would have been of interest to do some ethnographic research to better understand this phenomenon. Other posters were damaged by UV exposure sun and rain and wear and tear. The biggest challenge was removal of the posters, perceived as colourful by residents, to use as wall decorations/wallpaper in households. Poster design, production and mounting would need to be adapted – however the posters that were placed in locations with custodians such as tea rooms and shops remained in good condition. Over half the 200 posters were damaged or absent by the end of the study. Maintaining constant visualization of posters and ensuring that posters are replaced when removed or damaged by weather needs to be factored into long term sustainability of this kind of intervention.



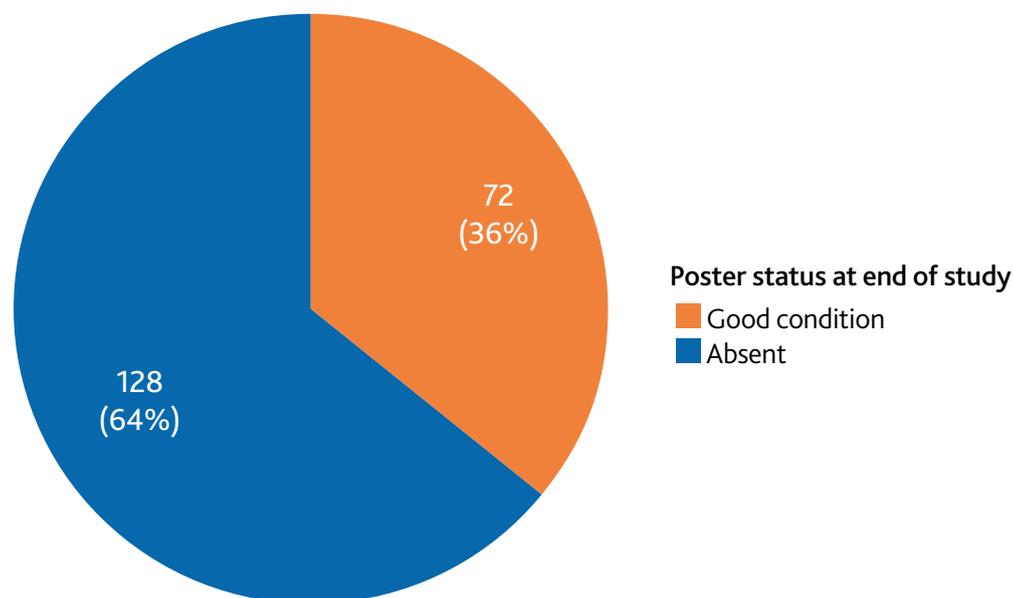


Figure 18: Status of posters at endline

Posters were mounted in various locations after baseline, using the detailed suggestions of the household survey respondents. The table below lists the preferred locations as communicated by respondents during baseline – posters were mounted on specific trees, in marketplaces and at junctions.

Table 49: Suggestions at baseline of best locations for poster mounting (HHS)

Poster Mounting Locations	Exposed	Unexposed
Community Tree/Baobab	46.7%	44%
Market place/Trading centre/Grocery/Shop/Restaurant/Tearoom	13.5%	33.3%
Road/Road junction	10.6%	10.7%
Other suggestions: Borehole, Community leader residence, church/mosque, bike depot, HSA, school, village centre		

Caregiver - Treatment seeking

As the study had the intention of improving the continuum of care in relation to community case management of severe malaria by enhancing health seeking for danger signs, it was necessary to establish how regularly residents of the catchment area chose to access care. The table below shows that 100% of HHS respondents in the unexposed arm and 96-97% of respondents in the exposed arm knew about the nearest VHC, with over 85% in both arms having visited a VHC in the past year, primarily for childhood illness – i.e. those conditions that fall within iCCM. There was however a slight reduction in high (>2 times) VHC visiting from baseline to endline. We would have expected at least the same response and not a reduction.

Table 50: Treatment seeking from the VHC (HHS)

VHC visiting	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison p-value	Exposed n=165		Unexposed n=55		Comparison p-value
	#	%	#	%		#	%	#	%	
VHC visiting										
Know nearest VHC (Yes)	168	97.1	55	100.0	0.340	158	95.8	55	100.0	0.197
Ever visited in past year (Yes)	167	96.5	53	96.4	1.000	144	87.3	49	89.1	0.722
'I frequently visit the VHC' (Yes)	85	49.1	16	29.1	0.009	49	29.7	7	12.7	0.012
Frequency of visiting the VHC in last season										
Low (<= 2 times)	57	33.0	34	61.8	<0.001	70	42.4	38	69.1	0.001
High (>2 times)	116	67.1	21	38.2		95	57.6	17	30.9	
Reason for visit										
Illness of a child	154	90.6	53	98.2	0.430	133	80.6	51	92.7	0.036
Antenatal care	3	1.8	0	0.0		2	1.2	0	0.0	1.000
Mother child clinic	10	5.9	1	1.9		13	7.9	0	0.0	0.042
Other	3	1.8	0	0.0		0	0.0	0	0.0	-

One of the treatment-seeking indicators measured the first point of care for severe malaria/severe febrile illness/danger signs. For the majority of HHS respondents, the Village Health Clinic was the first point of care for severe childhood illness (Table 51). The top 3 reasons given were: because of proximity, because the services are deemed adequate/fast and because the VHC is the known and the required first stop. Narrative responses revealed some experiences of bypassing the VHC and going directly to the health centre, only to be sent back by health workers at the health facility, instructed to access care at the VHC. Alternative sources of care, including traditional healers or drug shops did not feature as a popular first access service. Through the results it is apparent that the community understands the functionality of the VHC: a first point of care of childhood illness, consistent with purpose of the VHC.

Caregivers accessed through HH tracking were also asked to describe their reasons for choosing the VHC as the first port of call for their recently sick child with danger signs. Their primary reasons were - *they were certain that they would get assistance there and that the VHC is the recognised first place to take a sick child*. Reconfirming the community's understanding and acceptance of the VHC and its role in their health seeking trajectory.

Table 51: Reasons for choosing VHC as source of care for child with danger signs (HH Tracking)

Reasons for choosing VHC as source of care for child with danger signs	Tracking			
	Exposed n=56		Unexposed n=33	
	#	%	#	%
I know I will get assistance there	26	46.4	6	18.8
I know this is the first place to go when my child is sick	6	10.7	14	43.8
I know I cannot help the child alone	11	19.6	1	3.1
I know I will get fast urgent care there	7	12.5	7	21.9
I know I will get assistance and be referred	3	5.4	0	0.0
I know it is nearby	2	3.6	4	12.5
It is my last resort/I am turned away elsewhere	1	1.8	0	0.0

In trying to determine if communities were simply frequenting the VHC out of necessity instead of preference, the study asked caregivers to distinguish between first accessed service and preferred service. The VHC was the preferred point of care for the majority of caregivers. Overall, there was an increased preference for the VHC over the health centre/hospital from baseline to endline, with a marked increase in preference in the exposed arm. Raising the question whether the training, support and communication with the HSAs as part of the study, had changed the prevailing attitudes toward the care available at the VHC.

Table 52: Most preferred place to access health care in the event of febrile illness (HHS)

Preferred Health Service	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Most Preferred Health Service								
VHC/HSA	99	58.2	36	65.5	113	68.9	40	72.7
Health centre/hospital	71	41.8	19	34.6	51	31.1	15	27.3
Traditional/Alternative/ Drug Store	1	0.6	0	0.0	1	0.6	0	0.0

Table 53: Health Service accessed first in the event of febrile illness (HHS)

Health Service Accessed first	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Service Accessed First								
HSA/VHC or volunteer	111	64.2	48	87.3	135	81.8	53	96.4
Health centre or hospital	56	32.4	6	10.9	27	16.4	1	1.8
Alternative - Traditional Healer/ Drug Store	6	3.5	1	1.8	3	1.8	1	1.8
Reason why these services accessed first								
Proximity	67	38.7	16	29.1	69	41.8	28	50.9
Adequate services/Fast care	66	38.2	13	23.6	54	32.7	15	27.3
Known first stop for health services	40	23.1	26	47.3	42	25.5	12	21.8

The majority of respondents (HHS) who recently frequented the VHC, accessed it on foot, with a majority reaching the VHC within 1 hour or less. Travel times to access the VHC did change from baseline to endline but may have been influenced by a change in the responding caregiver (see limitations) or on the weather and related access issues at the time of the interview, with more reporting accessing care faster at endline.

Table 54: Mode of transport to access care at VHC (HHS)

Mode of transport to access care & travel time	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Mode of transport to accessed health service								
On foot	131	75.7	51	92.7	133	80.6	51	92.7
On bike/motorbike	42	24.3	4	7.3	32	19.4	4	7.3
Travel time to accessed health service								
Less than 30 minutes	57	33.0	21	38.2	74	44.9	26	47.3
30 minutes — 1 hour	48	27.8	16	29.1	43	26.1	13	23.6
1-2 hours	27	15.6	7	12.7	39	23.6	9	16.4
2 or more hours	38	22.0	11	20.0	7	4.2	7	12.7
Do not know	3	1.7	0	0.0	2	1.2	0	0.0

Having established that the VHC is the preferred first point of care, the study explored health seeking behaviour during the most recent episode of severe febrile illness in the preceding season.

The respondents at baseline and endline were asked to reflect on a most recent situation when their child (5 years and under) fell sick with a severe febrile illness. Unlike during the tracking household interviews, the features (signs and urgency) of the most recent episode of severe febrile illness referred to during the household survey could not be cross checked with a clinic response and therefore condition of the child could not be verified, nor could the date of the recalled event. Table 55 shows the 'most recent' danger signs reported by the caregiver. Fever combined with refusal to eat and lethargy/low energy were the most reported sign.

The majority of respondents reported visiting the VHC – with slightly more doing so in the exposed arm. Among the household survey respondents those who experienced at least one danger sign, more than 90% (in both arms at baseline and endline) reported seeking care within 24 hours of the onset of danger signs. There was no significant change in response time over the course of the study. Upon accessing care, the majority were given oral medication with 7 cases reporting that they received RAS - all of these who received RAS were resident in the exposed arm catchment areas.

These results suggest that caregivers during the household survey were recalling a most recent episode of malaria of which the severity could not be verified. Upon arrival at the village clinic the majority were administered oral medication, except for 7 cases in the exposed site.

Table 55: Child with febrile illness - experience in the most recent malaria season (HHS)

Child with malaria & action taken	Baseline				Endline			
	Exposed n=173		Unexposed n=55		Exposed n=165		Unexposed n=55	
	#	%	#	%	#	%	#	%
Had a child with danger signs - YES								
High fever - hot body only	114	65.9	23	41.8	121	73.3	34	61.8
Refusal to eat	71	41	18	32.7	62	37.6	28	50.9
Lethargy & weakness	70	40.5	18	32.7	52	31.5	29	52.7
Vomiting everything	66	38.2	14	25.5	49	29.7	16	29.1
Convulsions	17	9.8	12	21.8	17	10.3	7	12.7
LOC	5	2.9	4	7.3	8	4.9	3	5.5

Prompt treatment seeking for serious illness was already high - there was no significant change over the course of the study period. It seems that caregivers are very likely to seek out a health care provider when faced with danger signs - which the caregiver perceives as a serious illness. The type of symptoms experienced, and the perceived severity of the symptoms impact on the likelihood of a caregiver promptly seeking care. This raises the question whether a poster illustrating the signs of advanced illness will influence caregiver health seeking and whether the emphasis should be on taking action before danger signs appear.

Table 56: Child with febrile illness - experience in the most recent malaria season (HHS)

Child with malaria & action taken	Baseline				Endline			
	Exposed n=116		Unexposed n=24		Exposed n=120		Unexposed n=34	
	#	%	#	%	#	%	#	%
Among those that experienced at-least one of the danger signs:								
At-least one danger sign	116	67.1	24	100	120	98.4	34	100
Timely response time to seeking health care (within 24 hours) - Yes	105	90.5	24	100.0	120	98.4	34	100
Visited the VHC	76	65.5	21	87.5	90	73.8	30	88.2
Given RAS	3	4.6	2	13.3	7	9.1	0.0	0.0
Given oral malaria meds	60	90.9	13	88.7	72	93.5	18	100

Caregiver - Perceived barriers to seeking care for a child with danger signs

Barriers to seeking care can influence health seeking choices as noted in the Health Belief Model (HBM) (Becker, 1974) (Champion & Skinner, 2008). When given the opportunity to list the challenges and or barriers there were 3 common responses across baseline and endline presented below.

Table 57: Barriers mentioned at Baseline/Endline (HHS)

Challenges faced by caregiver with a child with danger signs

(top 3 consistent across baseline/endline and between study arms):

#1: Transport Limitation – long distances

#2: No reported problems/nothing that was not insurmountable

For example: "it is just how it is", "We managed"

#3: Lack of drugs at the facilities – VHC or Health Centre

Other barriers listed:

- Slow care due to long queues
- Lack of finances
- Unavailability of the HSA
- Having a sick child

Looking at differences in the VHC access barriers between the exposed and unexposed arms among household survey respondents, for the exposed arm the major barrier was transportation to the VHC, while for the unexposed was the unavailability of the HSA at the VHC.



Caregivers were also asked to reflect on the challenges they faced most recently when caring for a child with severe malaria. The challenges were more frequently reported in the exposed arm, where distances and logistical challenges with terrain were visibly more evident. However, the greatest challenge among the tracked caregivers in the exposed arm was the: 'The intensity of the child's illness/the stress of caring for a sick child.'

Table 58: Length of time at the VHC – caregiver recall (HH Tracking)

Challenges to getting to the VHC	Tracking				Comment	
	Exposed n=56		Unexposed n=33		Comparison	
	#	%	#	%	p-value	
The intensity of the child's illness/stress of a sick child	32	57.1	3	9.1	<0.001	Stress/intensity of the child's illness more pressing challenge in the exposed arm
Long distances to travel	25	44.6	0	0.0	<0.001	Long distance travel more pressing challenge in the exposed arm
Funding & funding transport to the hospital	19	33.9	2	6.1	0.004	Financial constraints more pressing in the exposed arm
Nighttime travel	9	16.1	2	6.1	0.201	
A sick parent and a sick child	4	7.1	1	3.0	0.647	
No childcare for other children	2	6.1	2	6.1	0.625	
The HSA not being available/absent	2	3.6	7	21.2	0.012	Unavailability of HSA a greater challenge in the unexposed arm
Being turned away at HF with a sick child/ told to go to VHC	1	1.8	2	6.1	0.552	
Disturbing the HSA at night	1	1.8	0	0.0	1.000	
HSA being too slow giving care	0	0.0	2	6.1	0.135	
No challenges experienced	5	8.9	19	57.6	<0.001	More reports of no challenges in the unexposed arm

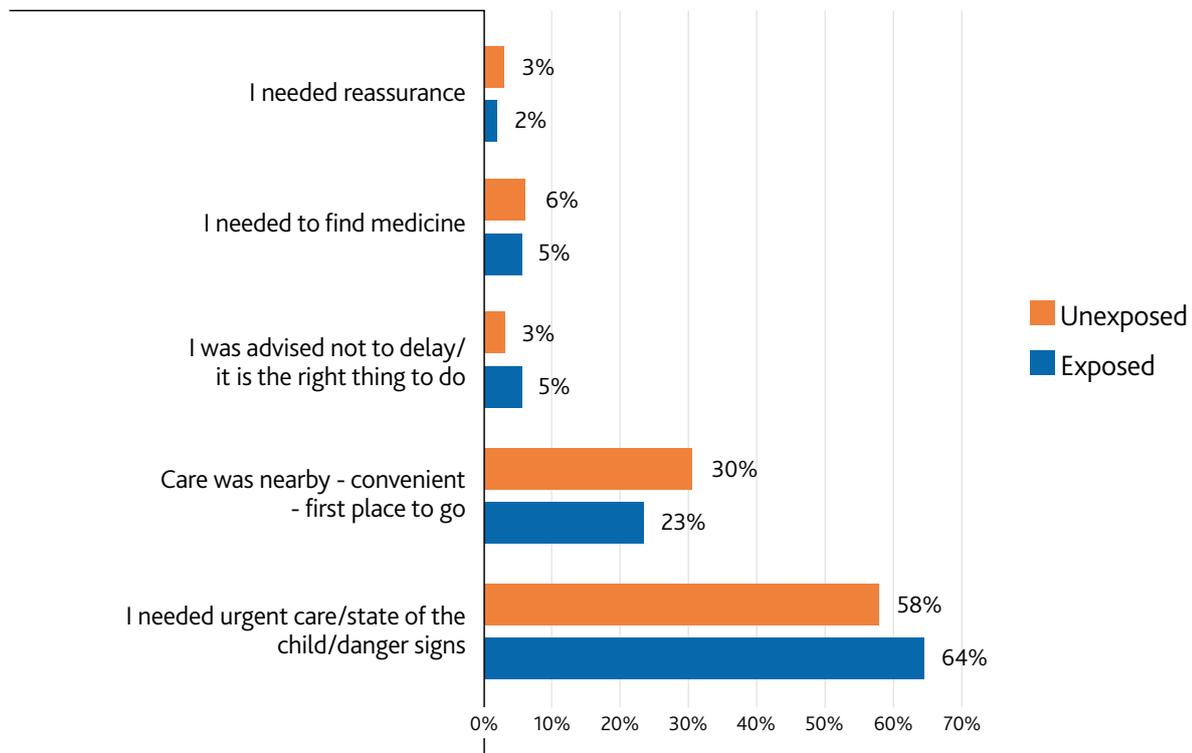


Figure 19: Reasons for not delaying treatment seeking (HH tracking)

Key Findings – Section 4

Caregiver and household characteristics and resources/wealth

- The majority of responding caregivers were unable to read and reported responding positively to the pictorial posters despite their lack of literacy.

Caregiver knowledge of malaria and danger signs, malaria prevention

- Knowledge of the symptoms of malaria and recognition of danger signs among caregivers increased in both arms during the study. The increase from baseline to endline was significantly larger in the control arm. No confounders could be identified, and this unprecedented change may be partially attributable to the trial that was conducting IEC in 56% of RASIEC's control arm.

Caregiver response to danger signs, attitude to RAS

- All caregivers recognised severe illness and the importance of seeking care – possible exposure to the IEC (posters) during the course of the study did not influence this outcome. This is suggestive that caregivers naturally respond promptly to the dangerous nature of danger signs.

Caregiver treatment seeking, and barriers to seeking care

- Among those caregivers who experienced witnessing at least one danger sign in their child, more than 90% (in both arms at baseline and endline) sought treatment within 24 hours of the onset of the danger sign(s). Treatment seeking for an emergency was already high - there was no significant change during the study period.
- There were few reports of delay in accessing care following onset of danger signs. Any delay in accessing care was attributed to challenges of transport or finance.
- The VHC was the preferred point of care for the majority of caregivers.
- Overall, there was an increased preference for the VHC over the health centre/hospital from baseline to endline, with a marked increase in preference in the exposed arm.

Poster observation and maintenance in the community

- Posters mounted in the community were perceived as a more valued cue to action in the intervention arm than in the control arm, over the course of the intervention period.
- In the intervention arm, over 80% of household survey respondents had seen the poster at endline and 92.4% of these understood the poster i.e. were able to recall the content of the poster. Important finding - this confirmed the importance of pre-testing content.

Limitations – Section 4

- Change in primary caregiver being interviewed at endline due to original caregiver not being present - raises potential for this to influence the pre- and post-intervention comparisons in relation to knowledge and practices.
- The presence of a community IEC component to the Malaria Vaccine Trial may have influenced community awareness of malaria and its dangers.
- Posters were removed frequently and were not the preferred IEC route.

Section 5

Caregiver referral compliance & care received at the referral health facility

This section of the report focuses on the continuum of care from VHC to the referral health centre. Referral experience was captured by HHS and household tracking questionnaires alongside traced and retrieved referral slips.

Caregiver Compliance

Compliance is described as - the extent to which the patient's behaviour matches the prescriber's recommendations. The health worker decides on the suitable action and the caregiver is expected to comply unquestionably: in this case, with referral for post-RAS intervention treatment.

During the household tracking interviews, caregivers reported on their compliance with referral post-RAS administration. The reported compliance with referral post-RAS was over 96% for both arms – with no significant difference noted between the study arms. The majority reported that they reached the referral health facility within 2 to 5 hours of visiting the VHC – complying within the 24-hour instruction. All 7 who exceeded the 24 hours were from the exposed arm of the study.

Table 59: Referral compliance and referral experience - caregiver (HH Tracking)

Referral Compliance & Experience	Tracking				
	Exposed n=56		Unexposed n=33		Comparison
	#	%	#	%	p-value
Caregiver adhered to referral (Yes)	54	96.4	32	97.0	1.000
Referral slip had a positive impact on the response at the health facility (Yes)	51	94.4	27	84.4	0.120
Time between VHC visit and health facility visit					
Half an hour	10	18.5	6	18.8	0.201
One hour	10	18.5	6	18.8	
Between 2 and 5 hours	20	37.0	14	43.8	
Between 6 and 12 hours	6	11.1	5	15.6	
Between 13 and 18 hours	1	1.9	0	0.0	
Between 19 and 24 hours	0	0.0	1	3.1	
More than 24 hours	7	13.0	0	0.0	
Timely adherence to referral - within 24 hours (Yes)	47	87.0	32	100.0	<0.001

All caregivers were issued a referral slip. The referral slips were considered especially useful in facilitating referral: 84.4% in the unexposed arm and 94.4% in the exposed arm stated that the referral slip had a 'positive' impact on the response they received at the referral health facility. The study field team were able to retrieve 62% of the referral slips from the health facility, 1% were retrieved from the household. Of the 26% that were not retrieved at the referral centre, health facility staff claimed that slips had been discarded due to staff turnover and new staff who had yet to be informed on how to file the referral slips in the study folder. These referrals were verified against the copies at the VHC and the carbon copies retrieved for confirmation of referral.

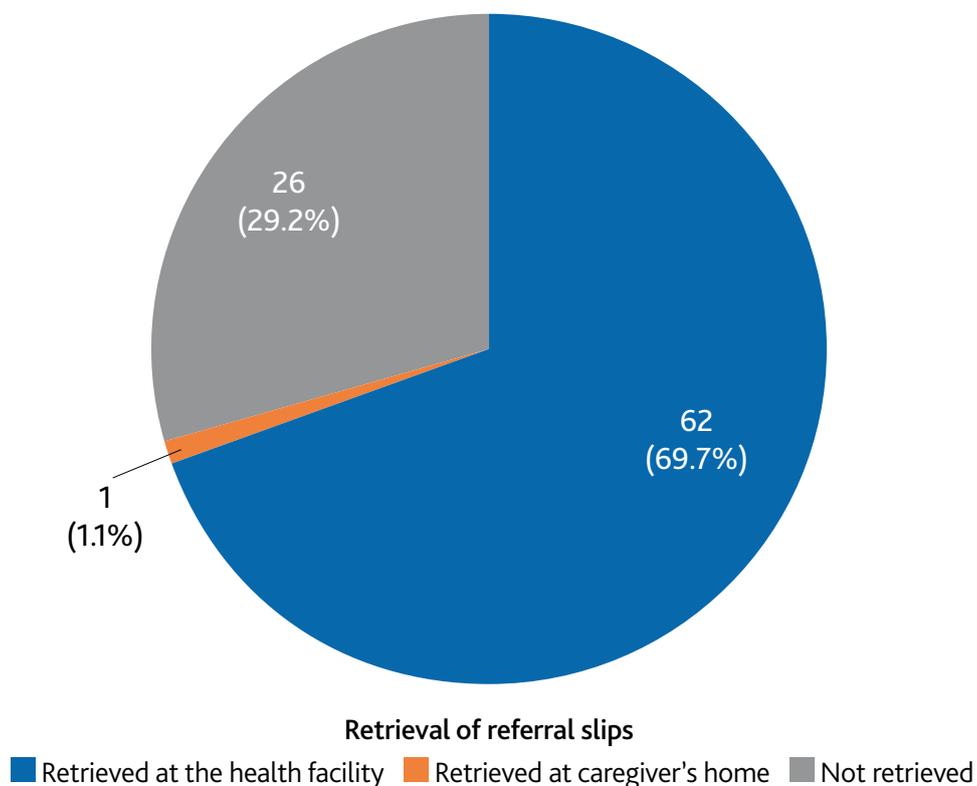


Figure 20: Referral slips retrieval

Compliance with referral was extremely high and essentially equal in both arms. HSA exposure to the IEC job aid did not make a significant difference to compliance levels. The role of the referral slip in the referral process was not independently evaluated in this study – but both caregivers and HSAs in both study arms reported that they considered the referral slip a most valuable intervention.

Cost of Referral

The caregivers in the unexposed arm reported significantly higher costs of the travel to the referral facility (mean: \$3 for those in the exposed arm versus \$9 for those in the unexposed arm), although this did not affect compliance, since 100% of the tracked cases complied with the referral within 24 hours regardless of the cost. Further exploration could determine whether this difference in cost was due to the choice of mode of transport (walking/push bike versus motorbike) and whether this choice influenced the timeliness and whether the education and wealth index affected this choice.

Table 60: Cost of travel to the facility for referral – caregiver (HH Tracking)

Cost of travel to the health facility – tracking cases	Tracking		
	Exposed Salima n=56	Unexposed Ntchisi n=33	Comment
Mean (sd)	2,374 MWK \$3	6,806 MWK \$9	Higher in the unexposed arms
Median (IQR)	1,000 - 3,200	2,000 - 6,000	

Non-compliance

There were 5 cases who did not comply with referral to the health centre and accessed alternative options post-referral. Some went home, others went to a traditional birth attendant (TBA) or another VHC, private care facility or drug shop. Their trajectories are described below. All the case studies from the tracking phase of the study are also available for future analysis around health seeking choices and overcoming barriers to care.

Table 61: Case trajectory for non-complying caregivers (HH tracking)

Care trajectory post VHC for non-complying caregivers	Arm	Status of the child at follow-up
1) Having waited an hour for the HSA, after RAS and ACT (LA) were given, mother went home and did not comply with referral.	Unexposed	Child is in good condition at study follow-up
2) After the VHC visit and receiving RAS, caregiver went to the traditional birth attendant (TBA) for follow-up treatment but then eventually went to the health facility for post-referral care.	Exposed	Child is in good condition at study follow-up
3) After receiving RAS, did not comply with referral and went to visit a village health clinic in neighbouring catchment area and was given LA.	Exposed	Child is in poor condition at study follow-up
4) After receiving RAS at the VHC, caregiver went home due to long distance and cost, but after 24 hours caregiver finally decided to seek care further care privately.	Exposed	Child is in poor condition at study follow-up
5) After receiving RAS at the VHC, caregiver went home, bought Panadol at shop and gave Panadol repeatedly.	Exposed	Child is in poor condition at study follow-up

Note: definition of 'good condition': combined score of mothers' perception of child's wellness on the day of interview and observation by field worker: child is active, playful, engaging and appears well.

Barriers to complying with referral

The barriers to complying with referral did not differ from previous barriers presented in relation to health seeking in general, in this case transport barriers dominated followed by care-related barriers – long waits, no medications on arrival and disinterested health workers.

Table 62: Barriers to complying with referral (HHS)

Barriers to seeking care – compliance with referral	Baseline					Endline				
	Exposed n=173		Unexposed n=55		Comparison p-value	Exposed n=165		Unexposed n=55		Comparison p-value
	#	%	#	%		#	%	#	%	
Transport barriers – primarily due to lack of money	99	57.2	34	61.8	0.547	99	60.0	41	74.6	0.052
Care-related barriers - (long waiting, no meds, disinterested health workers)	18	10.4	13	23.6	0.013	22	13.3	12	21.8	0.132
No barriers	58	33.4	10	18.2	0.030	44	26.7	5	9.1	0.007

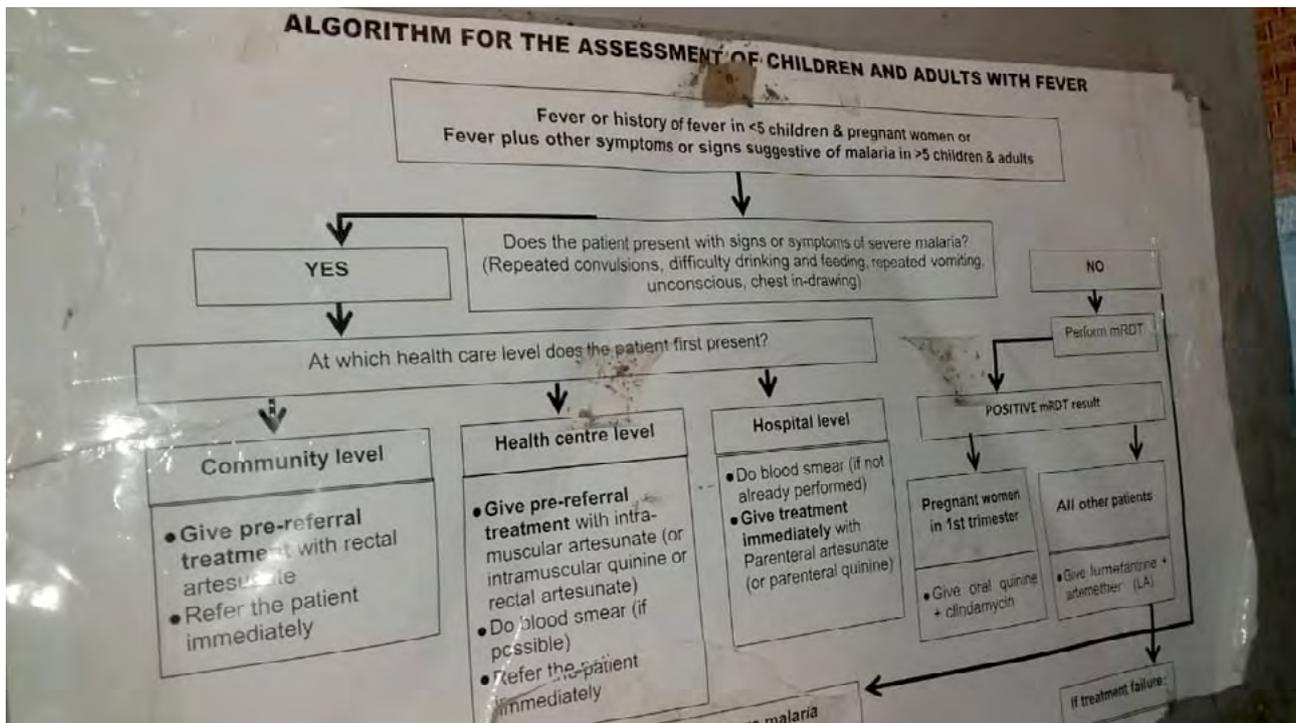
Referral Centre Care

Immediate referral
to a facility where
comprehensive treatment
can be provided

Children and adults

- Step 1. Injectable artesunate (for at least 24 h)
- Step 2. ACT (full 3-day course once patient tolerates oral treatment)

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The table below presents the caregiver recall of the care received at the referral centre.

Table 63: Care received at referral centre - caregiver (HH Tracking)

Care received at the Referral Facility (tracking)	TRACKING by STUDY ARM				Comment	Grouped	
	Exposed n=56		Unexposed n=33			Both arms combined n=89	
	#	%	#	%		#	%/sd/IQR
Child weighed (Yes)	18	33.3	6	18.8	Higher in exposed	24	27.0
Examination—held/inspected (Yes)	40	74.1	18	56.3	Higher in exposed	58	65.2
Malaria test done (Yes)	36	66.7	19	59.4	Higher in exposed	55	61.8
Medication given (Yes)	42	77.8	28	87.5	No difference	70	78.7
Suppository administered/given again (Yes)	8	14.8	3	9.4	Higher in exposed	11	12.4
Caregiver receives information on malaria prevention (Yes)	18	33.3	10	31.3	No difference	28	31.5
Length of health facility visit (in hours)							
Mean (sd)	15.7 hours		32.2 hours		Admission more likely in the unexposed arm & for longer	21.9 hours	33.7 hours
Median (IQR)	2.5 1–7 hours		5.0 2–72 hours			3 hours	(1–24) hours
Caregiver satisfied with the care received at the health facility (Yes)	41	75.9	27	84.4		68	76.4

Different aspects of the health service were recalled by the caregivers – ranging from weighing, examination, finger prick, additional suppositories (these suppositories may have been artesunate rectal capsules or another suppository witnessed by the caregiver) and counselling. Of most interest in relation to WHO guidelines for post-RAS management of severe malaria, was whether the child was admitted or treated as an outpatient. Admission for a minimum of 24 hours is usually expected after RAS administration for severe malaria to allow for observation during administration of parenteral injectable artesunate or quinine. Of the tracked cases, 30% reported receiving parenteral treatment (referred to as 'drip' or 'injection') at the referral facility and of those 30%, 65% were admitted. Admission was more likely in the unexposed arm and admission also lasted longer - average of 32 hours in the control arm versus 15.7 hours in the intervention arm. Satisfaction with care was also higher among the caregivers managed in a referral centre in the unexposed arm. The majority of children who were cared for post-RAS on an outpatient basis were dispensed pills of some kind and sent home. The study cannot confirm whether the pills dispensed were ACT or antipyretics, such as paracetamol.

Table 64: Care received at referral facility by arm - caregiver (HH Tracking)

Study arm	IV/DRIP or INJECTION	Admitted, Observed, Outpatient			Total
		Admitted	Observed	Outpatient Only	
ALL	Yes	17	3	6	26
	No	4	8	48	60
	Total	21	11	54	86
Unexposed	Yes	13	3	1	17
	No	1	3	11	15
	Total	14	6	12	32
Exposed	Yes	4	0	5	9
	No	3	5	37	45
	Total	7	5	42	54

Based on the information gathered from caregiver recall, with particular focus on admission and initial parenteral treatment, there was strong evidence that the odds of 'correct' health facility services are higher in the unexposed arm.

Table 65: Odds of receiving correct services post-RAS at the health facility

Outcome indicators	Study arm				p-value	Crude Adjusted			Comments
	Exposed n=56		Unexposed n=33			Confidence Interval		p-value	
	#	%	#	%		Lower	Upper		
Health facility services (Correct)	19	57.6	15	26.8	0.004	0.08	0.57	0.002	Strong evidence that the odds of 'correct' health facility services are higher in the unexposed arm

Child Health Outcome

The study's primary focus was on the continuum of care from household to referral centre, focused primarily on health seeking and compliance with referral. Child outcome for the purposes of this study were based on caregiver report at the homestead, no less than 7 days post-RAS, on how the child responded to the RAS and on how well the child was on the day of the interview.

After the first phase of severe malaria management, i.e. RAS, over 90% of caregivers from both study arms reported an improvement in the condition of their child soon after leaving the VHC having received RAS: *the child either regained consciousness, began to eat/drink/feed, became less sleepy, more playful or the fever went away.*

Table 66: RAS administration & response to RAS (Tracking)

RAS administration & response to RAS (caregiver report)	Tracking				
	Exposed n=56		Unexposed n=33		Comparison
	#	%	#	%	p-value
Child showed improvement soon after VHC visit (Yes)	52	92.9	31	93.9	1.000

At the second phase, caregivers at follow-up were asked about the child's health status and speed of recovery, after leaving the health facility, either after admission or outpatient care. Those children observed to have poor health status by the field workers (all medically qualified) at the time of follow-up interview, were more likely to have experienced slow recovery post-health facility care, while those with good health had a higher percentage with fast recovery.

Table 67: Health status and speed of recovery post-health facility (HH tracking)

Child Health status (Interviewer perspective)	Speed of Recovery					
	Fast		Moderate		Slow/No recovery	
	Count	Percent	Count	Percent	Count	Percent
Poor	3	10.0	6	14.3	9	52.9
Good	27	90.0	36	85.7	8	47.1

Meanwhile, those with poor health at the time of the HH tracking follow-up, a slightly higher percentage had received incorrect services at the health facility: i.e. no admission and no parenteral treatment.

Table 68: Health status and correct health facility services (HH tracking)

Child Health status (Interviewer perspective)	Correct Health facility services offered (Caregiver perspective)			
	No		Yes	
	Count	Percent	Count	Percent
Poor	13	23.6	5	14.7
Good	42	76.4	29	85.3

For those 6 cases that showed no improvement after the VHC, case study reviews would be helpful – however on review none of these cases were underdosed for their age.

Key Findings – Section 5

Caregiver compliance & barriers to compliance

- Compliance with referral was extremely high and essentially equal in both study arms.
- Whether or not the HSA making the referral had been exposed to the IEC job aid did not make any significant difference to the caregiver's compliance with referral post-RAS.
- Transport barriers primarily due to lack of finance were the most significant barrier to complying with a referral. The cost of travel to the referral centre was significantly different between the two study arms and further analysis would be needed to understand this difference.

Health facility care/services

- 30% of all tracked cases who had been administered RAS and complied with referral received parenteral care at the referral facility and even less (24%) were admitted.

Referral slip

- Caregivers in both study arms perceived the referral slip as having a significant influence on the response received at the health facility.

Child outcome analysis

- Child response to RAS was positive except for 6 cases, none of whom were underdosed.
- Correct caregiver outcomes were higher among the caregivers originating from the control arm. There was strong evidence that the odds of the HSA giving the correct care in relation to RAS and danger signs was higher in the intervention arm. However, there was weak evidence that the odds of a positive child outcome were higher among households with caregivers reporting a correct response to danger signs. All tracked households accessed care and were referred, there were two deaths recorded, one in each arm.

Limitations – Section 5

- The referral slip availability at the unexposed VHC may have caused some bias for the comparison of referral compliance. The referral slip behaved as an intervention in its own right but was not evaluated as such.
- The study's primary focus was on the continuum of care from household to referral centre, focused primarily on health seeking and compliance with referral. The study was not designed to capture the details of the care received at the referral centre despite the caregiver reports highlighting concerns about the follow-up care received post-RAS.

Limitations

A number of limitations/difficulties were listed in the protocol. The table below presents the limitation and the proposed mitigation approach outlined before the study was initiated. A review/update is provided retrospectively reviewing the progress of the study. A number of limitations that were not anticipated, that have been previously raised in the Results Sections are added to this comprehensive list.

Table 69: Limitations cited in protocol & post-study review

Limitations/Difficulties	Mitigation Strategies Review post-study
Access to homestead and VHCs during rainy season	<p>Mitigation: Travel times and necessary delays will be factored into plans.</p> <p>Review: Access to homesteads was a significant challenge that was overcome.</p>
Farming season - many rural households are on their farmsteads during the rainy season – finding caregivers at home during the baseline and endline may be a challenge.	<p>Mitigation: Travel times and necessary delays will be factored into plans.</p> <p>Review: 8 households at endline had relocated temporarily due to farming. Change in primary caregiver being interviewed at endline due to original caregiver not being present - presented potential for this to influence the pre- and post-intervention comparisons in relation to knowledge and practices.</p>
Phone reception and reaching HSAs at an agreed time each day will depend on network.	<p>Mitigation: The IMCI team communicates with HSAs using mobile network, if network issues arise, the research team will adjust timing and repeat.</p> <p>Review: Certain HSAs located in areas without reliable network were reached via WhatsApp messaging, others called the fieldworkers daily when they were in an area with network.</p>
Accessing homesteads when a child has been ill, and the caregiver chose not to pursue referral or was not referred by the HSA can raise challenges.	<p>Mitigation: For all tracking visits, the field workers will be in regular communication with the village health volunteer who is the HSA's extension worker at the village level. Field workers are qualified nurses and will work with the health volunteer to ensure that children requiring follow-up care are escorted to the VHC for follow-up - subsequent care/follow-up/referral of the child. The choice of the HSA assistants or health volunteers to be used in the exercise was selected based on their knowledge of the community and the service they already provide in the community.</p> <p>Review: The majority of caregivers complied with referral. All household visits were done with a health volunteer who assessed the child and in cases where the child had not recovered fully, accompanied the caregiver to the HSA for additional care.</p>
Visiting homestead in rural Malawi, other needs made be visible and requests for assistance made to research team.	<p>Mitigation: Field workers will be trained to divert all social or health welfare questions to the structures that are in place through the VHC and a health volunteer. The study has the support of the DHMT and they are receptive on regular communication throughout the study period.</p> <p>Review: Household respondents were reimbursed for their time and no other requests were received from community respondents. HSAs were also reimbursed for their time and airtime. Requests for assistance were received from HSAs asking for funds to repair village health clinics, these were redirected to DHMT.</p>

Limitations/Difficulties	Mitigation Strategies Review post-study
<p>There is a risk of bias that becomes apparent at the 7-day mark after a visit to the VHC – this visit may affect treatment seeking behaviour after the 7-day mark.</p>	<p>Mitigation: No post-VHC visit will be made to the household until 6-7 days after the caregiver has attended the VHC. This will limit our influence on the caregiver's response. The study recognizes this potential influence, and the sample selection of the households that participate in the tracking phase is accordingly based on the prevalence of severe malaria cases as reported by the health care providers and adjusted for health seeking behaviour. The study could identify no other way to determine the extent to which caregivers follow through with referral advice given by HSAs or to determine health seeking choices when an HSA has not referred a case of severe febrile illness. The study will not track cases where caregivers who chose not to seek care at the VHC.</p> <p>Review: All follow-ups were made 7 days or more after the VHC visit. The majority complied with referral to the health centre within 24 hours of the visit to the VHC.</p>
<p>The two arms are adjacent, and a spillover effect could hypothetically occur.</p>	<p>Mitigation: The exposed and unexposed groups are far apart enough that the intervention information should not spill-over to the unexposed group. This can be confirmed by the maps of the study areas. The endline questionnaire will however identify the caregivers and/or HSA source of information relative to their response and any adjustments for this bias will be made in the analysis.</p> <p>Review: The study became aware of two occasions residents of the intervention arm sought care from health facilities and VHCs across the border in the control arm.</p>
<p>Hawthorne effect <i>The inclination of people who are the subjects of a study to change or improve the behaviour being evaluated only because it is being studied and not because of the intervention.</i></p>	<p>Mitigation: There is potential of a Hawthorne effect in relation to the tracking phase of this study during phone contact which could be interpreted as intensive HSA supervision. This, however, can be minimized by introducing tracking during baseline and the study will be contacting the HSAs in both the exposed and unexposed groups.</p> <p>Review: Tracking calls began during the baseline, most of the communication with the HSA happened via messaging and was brief and focused, due to network challenges, there were no opportunities for additional supervision related conversation.</p>
<p>Additional Limitations (not predicted during planning)</p>	
<p>Referral slips</p>	<p>The referral slip availability at the unexposed VHC may have caused some bias for the comparison of referral compliance. The referral slip behaved as an intervention in its own right but was not evaluated as such.</p> <p>The study's primary focus was on the continuum of care from household to referral centre, focused primarily on health seeking and compliance with referral. The study was not designed to capture the details of the care received at the referral centre despite the caregiver reports highlighting concerns about the follow-up care received post-RAS.</p>
<p>Malaria Vaccine Trial</p>	<p>The malaria vaccine trial operating in the very same facilities, village health posts and communities that were sampled by RASIEC raises concerns and possible bias and confounding factors. Ideally this would have been highlighted during arm meetings during arm selection.</p>

Conclusion

The study intended to inform future programming in relation to Information – Education – Communication (IEC) delivery targeting severe malaria community case management.

The study set out to determine if a simple IEC package targeting community members and first-line health workers in local language, in hard-to-reach communities, affected knowledge, attitude and practice and in turn enhanced the continuum of care from the homestead to the referral health centre.

Despite, over 80% coverage and associated poster visualization and information recall, the posters did not significantly influence knowledge and VHC health seeking practice among the communities in the intervention arm. It emerged that in general caregivers in both study arms do not delay care when their child has severe danger signs. Any delay that occurred, occurred prior to the presentation of danger signs, highlighting the need for IEC materials to alert caregivers to the more subtle signs and symptoms of malaria when it is not yet a life-threatening emergency and where testing and treatment are the priority: encouraging health seeking before the case is an emergency. Posters proved to not be the most useful mode of message delivery, with a large number of the posters removed within the 9-month intervention period. At the outset, the study team recognised that posters represented a single communication element and that ultimately a more comprehensive BCC campaign would be required to impact behaviour further - once the information was circulating in the community. Alternative message delivery channels such as radio that can reinforce the message regularly were preferred by the community respondents and avoid the loss of interest that may result once a poster has been seen repeatedly.

Nevertheless, the finding that those residents who had been exposed to the posters understood the content was encouraging. This was an important finding given that this was the first time the poster had been used in real-life setting.

The study had hypothesized that the presence of an IEC toolkit among HSAs operating in a setting with minimal on the job supervision or continuing education would enhance knowledge and practice among HSAs, as it relates to the management of

malaria danger signs. The HSAs who were exposed to the IEC toolkit did show higher levels of knowledge and their practice was positively influenced, and overall they offered a higher quality of care as compared to the HSAs in the control arm.

Do messages about danger sign recognition and response distributed throughout the catchment area enhance health seeking and compliance with RAS referral advice?

- Messages were seen frequently and recently.
- Messages were understood & recalled.
- Messages did not influence response to danger signs, as this response to the emergency was already in place.

If HSAs are supported with simple job aids and information booklets on RAS accompanied by a brief refresher training, does it improve assessment and administration of pre-referral RAS and onward referral by the community health worker?

- Exposed HSAs had more knowledge and awareness of severe malaria management.
- HSAs who were exposed to the intervention offered higher quality assessment and care.
- Referral practice was influenced by the presence of the referral booklet which was a very effective tool and enhanced referral greatly.

What are the key issues interfering with comprehensive care for the child with severe malaria?

- Comprehensiveness of the care received at the referral health centre post-RAS highlighted the need to provide IEC across the different points of care in the continuum to ensure the benefits of one intervention are not lost.

The introduction of regular supplies of RAS to all the VHCs in the study area resulted in consistent availability of a commodity in sites where it had previously not been regularly at hand. This in itself had a significant influence on health seeking due to the resulting word of mouth news observed in both the study arms, making community members aware of a service that was deemed available and effective, indirectly influencing awareness, knowledge and even practice in both study arms. In addition, the influence the referral booklet would have on the study outcomes was underestimated in the study design, and as a result the role of the referral booklet was not evaluated. The introduction of a triplicate referral slip booklet alongside the RAS commodity proved to be a very useful tool for both the caregiver and the HSAs: influencing the care, compliance and reception at the referral health centre. The availability of the two components - commodity and referral slips - combined to play an important role in enhancing the continuum of care and closing the gap from VHC to referral facility.

The care received at the health facility following RAS referral did not fall within this small IEC study's objectives. The incorrect assumption was made that once the referral was made and the caregiver complied, the child would be received at the referral facility, admitted and administered the correct care as per WHO guidelines. However, the findings based solely on caregiver recall at follow-up revealed that the majority of the cases post-RAS were not admitted and did not receive parenteral care, despite receiving a referral note indicating that the child had been administered RAS. The quality of the treatment received at the referral facility highlighted more information and education needs along the continuum of care, that extend beyond caregiver compliance and arrival at the next point of care.



What follows are some recommendations for future RAS interventions for consideration:

Future IEC development and work with frontline village health clinics should also be accompanied by an updated intervention targeting the next level of care. In addition, any IEC intervention would need to be coupled with ongoing clinical support supervision guidance and patient care standards at both the village clinic and at the health facility reinforcing good clinical practice and implementation of national guidelines.

Introducing referral slips to enhance the continuum of care should be considered alongside consistent supplies of RAS. This is a cost-effective tool that can be easily produced and implemented. HSA refresher trainings, more frequent supervision, improvement of the VHC infrastructure and HSA remuneration to encourage them to remain living in the hard-to-reach communities should be considered seriously. There is definite concern that now that study is complete and study field teams are not ensuring regular stocks of RAS on site and referral centres are not processing referral slips, there is a concern that the quality of care will suffer and that the momentum from the study. In addition, MMV and its team is willing to collaborate with Malawi MoH to ensure that aspects of the intervention that proved to be of most use (the IEC toolkit for the VHC) be supplied to the HSAs in the control district and ongoing support to those in the intervention site.

The dataset for this study is extensive and this report presents only a portion of the study results and interpretation is in line with the budget allocated to the study. However, the database housed on the MMV server and the detailed case studies provide many opportunities for more in-depth analysis and exploration, and should be considered an ideal opportunity for a series of publications on key aspects of the continuum of care as it relates to severe malaria community case management and the insights gathered during this intervention study in Malawi highlighting operational solutions for iCCM and ways to enhance the continuum of care.

Appendix A

Indicator List

Key Indicators

Note: RM = routine monitoring; HSAS = HSA Survey; HSA@VHC track = tracking of HSAs; HHS = household survey; HH-VHC Track = Tracking cases from VHC to HH.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 1A What is the reality on the ground of community case management of severe febrile illness in a country promoting RAS pre-referral (capacity, commodities, stock-ins-stock-outs, supervision, caregiver knowledge of malaria; caregiver response to danger signs, HSA knowledge and response to danger signs)?	#1-1 RAS usage	RM	Number of doses of 100 mg and 50 mg RAS used monthly by VHCs throughout the study period. Difference in the number of doses of 100 mg and 50 mg RAS used by VHCs in the exposed group relative to the unexposed group.
	#1-2 Frequency of Supervision & Training	RM	Proportion of HSAs receiving one MOH initiated supervisory visit per month throughout the study period and any differences in proportion in the exposed group relative to the unexposed group. Proportion of HSAs who report having received on-site malaria supervision in the month preceding the study and two months preceding the study.
	#1-3 Functional referral facilities	RM	Proportion of referral health facilities (those linked to the VHCs) with IV artesunate or quinine still in stock, at the end of every month throughout the study.
	#1-4 Functional VHC - conducive to RAS	RM	Proportion of VHCs with access to clean water, access to lighting at night & access to dry storage for drugs, as determined at the end of each month throughout the study.
	#1-5 Capacity at referral facilities	RM	Proportion of the referral health facilities linked with the enrolled VHCs with staff trained to manage severe malaria in children/administer treatment post-RAS as determined at the end of each month throughout the study.
	#1-6 Attitudes towards Supervision	HSAS	Proportion of HSAs with positive attitudes towards malaria supervision.
	#1-7 Attitudes towards RAS among HSAs	HSAS	Attitudes towards RAS among HSAs in enrolled VHCs at endline relative to baseline.
	#1-8 Malaria & Severe Malaria general knowledge among HSAs	HSAS	Differences in the proportion of HSAs with high, medium and low levels of malaria general & specific knowledge – among HSAs in enrolled VHCs in the exposed versus unexposed and at baseline versus endline.
	#1-9 RAS Guideline knowledge among HSAs	HSAS	Differences in the proportion of HSAs with high, medium and low levels of knowledge about RAS - in the exposed versus unexposed groups and at baseline versus endline.
	#1-10 Demographics of practicing HSAs	HSAS	Description of enrolled HSAs - age, gender, education, primary source of income & HSA level.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 1A Continued	#I-11 Level of English comprehension	HSAS	Proportion of enrolled HSAs with capacity to read and understand English.
	#I-12 Origins of HSAs	HSAS	Proportion of HSAs who were born and live in the catchment area.
	#I-13 Level of experience as HSA	HSAS	Proportion of enrolled HSAs with high – medium – low levels of experience as an HSA.
	#I-14 Perceived severity of danger signs - HSA	HSAS	Proportion of enrolled HSAs with high – medium – low levels of perceived severity of danger signs in children.
	#I-15 Cue to Action	HSAS	Proportion of enrolled HSAs with high – medium – low levels of Cue to Action in response to a child with danger signs.
	#I-15 HSA self-efficacy	HSAS	Proportion of enrolled HSAs with high – medium – low levels of self-efficacy in how to respond to a child with danger signs.
PART 1B <i>Exploratory/ Contextual</i>	#VI-1 Basic Infrastructure	RM	Number of VHCs with the basic infrastructure required for RAS in place.
	#VI-2a Cases of danger signs/SFI	RM	Number of SFI/danger sign cases reported during the tracking period in the enrolled VHC registers.
	#VI-2b Malaria prevalence	RM	Number of SFI/danger sign cases reported during the tracking period in referral health facility registers.
	#VI-3 Severe malaria interventions in each arm	RM	List of any events underway in the arms during the study period related to RAS or severe malaria.
	#VI-4 IEC channels	HHS	List of preferred health IEC channels from caregiver perspective. List of recommended locations for mounting IEC poster for best exposure – from caregiver perspective. List of recommended locations for mounting IEC poster for best exposure – from HSA perspective & likely exposure interval (time interval between when a poster goes up in a said location and how soon the respondent is likely to see it/look at it).
	#VI-5 Malaria prevention actions	HHS - observation	Proportion of number of households visited during tracking with an observed mosquito net available for the sick child.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 2 Does caregiver exposure to the RASIEC intervention increase the likelihood of a caregiver identifying danger signs and seeking treatment for danger signs/severe febrile illness from the nearest VHC?	#II-1a Severe malaria, treatment options & RAS knowledge – community	HHS	Difference in the proportion of caregivers with high, medium, low knowledge about severe malaria/danger signs & RAS purpose/availability at endline relative to baseline. Differences in levels (high-medium-low) of knowledge among caregivers who have an episode of severe malaria/dangers signs during the study – in the exposed group relative to the unexposed.
	#II-1b Severe malaria - perceived severity	HHS	Difference in the proportion of caregivers with high, medium, low levels of perceived severity of severe malaria at endline relative to baseline & during tracking.
	#II-1c Severe malaria - perceived susceptibility	HHS	Difference in the proportion of caregivers with high, medium, low levels of perceived susceptibility to severe malaria at endline relative to baseline & during tracking.
	#II-1d Severe malaria - perceived susceptibility	HHS	Difference in the proportion of caregivers with high, medium, low levels of perceived susceptibility to severe malaria at endline relative to baseline & during tracking.
	#II-2a RAS acceptability among caregivers	HHS	Difference in the proportion of caregivers with high – medium – low levels of perceived acceptability of pre-referral RAS at endline relative to baseline & during tracking.
	#II-2b Perceived RAS benefits among caregivers	HHS	Difference in the proportion of caregivers with high – medium – low levels of perceived benefits of using RAS - at endline relative to baseline & during tracking.
	#II-4 (TBC) Treatment seeking	HHS	Difference in the proportion of caregivers of children <5 years old who report that the VHC is their preferred point to access MCH/ANC or other childcare (other than severe febrile illness) at endline relative to baseline.
	#II-4a Treatment seeking – first point of care for severe malaria/ severe febrile illness/ danger signs from a VHC.	HHS	Difference in the proportion of caregivers of children <5 years old who report that the enrolled VHC is their preferred point to access care for severe febrile illness/ danger signs at endline relative to baseline.
	#II-4b Factors that encourage treatment seeking for severe malaria from VHC.	HHS HV-SFI HH-VHC	Most common reasons for preference to access care for severe febrile illness/danger signs at closest VHC at baseline and endline and tracking.
	#II-4c Perceived barriers to seeking care for severe malaria in a child	HHS HV-SFI HH-VHC	Difference in the proportion of caregivers with high – medium – low levels of perceived barriers to seeking care for a child with danger signs - at endline relative to baseline & during tracking.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 2 Continued	#II-4d Cue to Action	HHS HV-SFI HH-VHC	Difference in the proportion of caregivers with high – medium – low levels of perceived barriers to seeking care for a child with danger signs - at endline relative to baseline & during tracking.
	#II-5a Treatment seeking - first point of care for severe malaria/ severe febrile illness/ danger signs – from other than VHC or referral facility.	HHS HH-VHC HV-SFI	Difference in the proportion of caregivers of children <5 years old who during a recent episode of severe febrile illness/danger signs chose to access care at any western medicine location other than VHC or referral centre at endline relative to baseline.
	#II-5b Factors that encourage treatment seeking for severe malaria from VHC.		
	#II-6a Treatment seeking - first point of care for severe malaria/ severe febrile illness/ danger signs from an alternative/non-western source of care.	HHS HV-SFI HH-VHC	Difference in the proportion of caregivers of children <5 years old who during a recent episode of severe febrile illness/danger signs report choosing to access care from an alternative care source (non-western – non-VHC) at endline relative to baseline. Most common reasons for preference to access care for severe febrile illness/danger signs at an alternative care source reported.
	#II-6b Factors that encourage treatment seeking for severe malaria from VHC.		
	#II-7a Treatment seeking - first point of care for severe malaria/ severe febrile illness/ danger signs from referral centre.	HHS HV-SFI HH-VHC	Difference in the proportion of caregivers of children <5 years old who during a recent episode of severe febrile illness/danger signs report choosing to access care directly from a referral health centre and to bypass the VHC/HSA at endline relative to baseline.
	#II-7b Factors that encourage first point of care treatment seeking for severe malaria from referral centre.		Most common reasons for preference to access care for severe febrile illness/danger signs at referral health centre (by-passing VHC).
	#II-8a Time interval between recognizing signs and attending VHC.	HHS HH-VHC	The mean duration between recognising signs and attending the VHC.
	#II-8b Time interval between VHC visit and attending Referral centre.	HHS HH-VHC	The mean duration between attending the VHC and reaching the health facility for continued treatment.
#II-9 Self-Efficacy.	HHS HV-SFI HH-VHC	Difference in the proportion of caregivers with high – medium – low levels of self-efficacy to handle severe malaria – from community to VHC/or local care options at endline relative to baseline & during tracking.	

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 3 Does HSA exposure to the RASIEC intervention increase the likelihood of an HSA correctly identifying the danger signs in a child <5 years, minimizing missed opportunities of administering RAS in accordance with the WHO aligned national treatment guidelines?	#III-1 RAS acceptability among HSAs.	VHC-Track RM	Difference in the proportion of cases of children <5 years who present at the VHC with severe febrile illness/danger signs who are managed by HSAs according to WHO aligned National RAS guidelines and those who are not, in the exposed group relative to the unexposed group.
	#III-3 HSA practices in relation to managing danger signs.	VHC-Track HSAS	List of actions (in line with the RAS guidelines) taken by HSAs in response to a <5-year-old case of severe febrile illness & danger signs in the exposed group compared to the unexposed group. List of actions (not in-line with the RAS guidelines), taken by HSAs in response to a <5-year-old case of severe febrile illness & danger signs in the exposed group compared to the unexposed group.
	#III-4 Severe malaria knowledge & RAS knowledge	VHC-Track HSAS	Difference in the proportion of HSAs with high, medium and low-level knowledge about severe malaria & RAS at baseline relative to endline.
	#III-5 HSA practices in relation to malaria.	VHC-Track HSAS	List of any additional malaria prevention actions taken by HSAs (reported by HSA and as reported by caregiver) when seeing a child with danger signs – in the exposed HSA group as compared to the unexposed HSA group.
	#III-6 Willingness to use RAS among HSAs.	HSAS	Difference in the proportion of HSAs that report willingness to use RAS at endline relative to those at baseline.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 4 Does HSA exposure to the RASIEC intervention increase the likelihood of an HSA formally referring a caregiver post-RAS administration in accordance with the WHO aligned national treatment guidelines?	#IV-1 RAS & Referral.	VHC-Track RM HSAS	Difference in the proportion of HSAs receiving a <5-year-old child SFI case who report administering pre-referral RAS and formally referring with a referral slip - in the exposed group relative to the unexposed group. Difference in the proportion of tracked caregivers who report that their <5-year-old child was given RAS and referred - in the exposed group relative to the unexposed group. Difference in the proportion of HSAs receiving a <5-year-old child SFI case who report administering pre-referral RAS but not formally referring with a referral slip - in the exposed group relative to the unexposed group.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 4 Continued	#IV-2 RAS without Referral.		Difference in the proportion of the tracked caregivers who report receiving RAS but not being formally referred - in the exposed group relative to the unexposed group. Difference in the proportion of HSAs receiving a <5-year-old child SFI case who report not administering RAS but formally referring with a referral slip - in the exposed group relative to the unexposed group.
	#IV-3 Referral without RAS.		Difference in the proportion of the tracked caregivers who report being referred but not receiving RAS - in the exposed group relative to the unexposed group.

RESEARCH QUESTION	INDICATOR	SOURCE	INDICATOR DESCRIPTION
PART 5 Does caregiver exposure to the RASIEC intervention increase the likelihood of a caregiver complying with a referral made by an HSA?	#V-1 Referral – primary caregiver	HH-VHC-Track	Proportion of the caregivers that receive RAS and are formally referred who report complying with the referral during the tracking period in the exposed group relative to the unexposed group. Proportion of the caregivers that don't receive RAS and are formally referred who report complying with the referral during the tracking period in the exposed group relative to the unexposed group. Number of study referral slips collected from the referral health facility weekly originating from the exposed group of VHCs and the unexposed group VHCs.
	#V-2 Referral compliance constraints & enablers (V-6)	HH-VHC-Track HHS HV-SFI	A list (sorted by majority) of constraints to complying with a referral – referenced referred caregivers that didn't comply. Difference in the proportion of caregivers with high, medium and low-level of perceived barriers to comply with referral post RAS at baseline relative to endline & tracking.
	#V-2b Perceived barriers	HH-VHC-Track HHS HV-SFI	
	#V-2c Perceived benefits		Difference in the proportion of caregivers with high, medium and low-level of perceived benefits of complying with referral post RAS at baseline relative to endline and tracking.
	#V-3a Caregiver compliance - reported	HH-VHC-Track	Number of caregivers who visit a public health centre after being referred by the HSA.
	#V-3b Caregiver compliance - confirmed	RM	Number of referral notes retrieved at the referral health facility.
	#II-4a Cue to Action	HHS HV-SFI	Difference in the proportion of caregivers with high – medium – low levels of Cue to Action - to seek care for a child with danger signs - at endline relative to baseline & during tracking.
	#V-5 Self-Efficacy	HHS HH-VHC	Difference in the proportion of caregivers with high – medium – low levels of self-efficacy to handle severe malaria – from VHC to Referral Health Centre at endline relative to baseline & during tracking.

Appendix B

Data Quality and Completeness Report

Overview

This report describes the data collection, data checking and data cleaning approaches that were undertaken to ensure the data was of good quality and complete.

Field workers collected Baseline, Daily Evaluation and Endline/Evaluation data on paper questionnaires. Information recorded as narratives in Chichewa was translated to English by the field research team on the day of collection and transmitted daily to team lead for post-coding. After the coding was completed, the data was entered into a secure electronic study database stored on a MMV server <https://rasiec.mmv.org>

List of data collection tools

Questionnaire name	Description
1. Household survey	Data collection at both Baseline and Endline
2. Health Surveillance Assistant Survey	Data collection at both Baseline and Endline
3. Routine Monitoring Tools 1, 2 and 3	
4. Tracking VHC to Household Tracking	Data collection at Endline/Evaluation
5. VHC HSA Tracking	Data collection at Endline/Evaluation

Data Checking

There are inconsistent findings within literature pertaining to “acceptable” error rates. Houston et al. (2018) posit that a 5% error rate within electronic databases should be used as the “gold standard” for determining the data quality.

In this study, paper-based data collection followed by single data entry was used. A sample comprising 10% of the household baseline data was double entered to check the overall quality of the data. An error rate of 5% or less would be deemed as an acceptable error. In the next section, we will describe the findings of the data checks.

The data accuracy is measured by the number of errors between the two datasets.

Statistic	Value
Number of variables	231
Number of observations in Live database (baseline)	228
Number of observations in Quality check database	25
Number of observations in common	25

The open-ended text responses as such as the narratives in Chichewa were excluded from the double data entry comparison.

- Total Number of data points: $25 * 231 = 5,775$
- Number of errors (data fields): 97
- Data Entry Accuracy Rate: $5678/5775 * 100 = \mathbf{98.32\%}$
- Error rate = $97/5775 * 100 = \mathbf{0.0168\%}$

Results

The error rate of the 10% records was 0.0168%. This value is less than the 5%, so it is an acceptable error rate.

Appendix C

The Toolkit

If your child has fever plus other danger signs

Fever of 37.5°C or more

1st step

REFUSAL TO FEED

REPEATED VOMITING

LETHARGY / UNCONSCIOUSNESS

CONVULSIONS

See your community health worker for administration of rectal artesunate.

Quickly go to the nearest health facility or hospital to get full treatment for your sick child.

2nd step

DO NOT DELAY.
Your child's life is at risk.

MINISTRY OF HEALTH OF MALAWI

NMCP

Public Poster

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Photo Gallery



Plotting out catchment areas with HSAs from Ntchisi District during study orientation.



Clifford Dedza (IMCI) conducting HSA training.



Austin Nkhoma, Monique Oliff and Defence Mkandawire.



John Sande (NMCP) leading an orientation meeting.



Mzungu Precious (Salima District) DHMT - co-leading refresher training of HSAs.



Lead field workers & Clifford Dedza (IMCI).



Dr John Phuka, Malawi PI, College of Medicine, during HSA refresher.



The field team: Austin Nkhoma, Felistas Somanje, Defence Mkandawire (Team Leader) and Jessie Hau.



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