# Appendices

С	ont	ent	S		
A	ppe	endic	ces		1
1		Mul	eba a	nd Misungwi RCT objectives	3
2		Clus	ter d	elineation and restricted randomization	3
	2.1	1	Cen	sus and mapping	3
	2.2	2	Rest	ricted randomization	4
3		Data	a colle	ection, consent forms and training manuals	5
	3.1	1	Hou	sehold malaria prevalence cross-sectional survey questionnaire	6
	3.2	2	Hou	sehold KAP survey questionnaire	11
	3.3	3	FGD	note taker form	12
	3.4	1	IDI S	Summary Form	13
	3.5	5	Colla	apsible net frame	13
	3.6	5	Data	a management and quality assurance	14
		3.6.2	1	Unique identification numbers: resident and net	14
		3.6.2	2	Merging and creating datasets	16
	3.7	7	Data	a quality assurance	17
		3.7.2	1	Household component	17
		3.7.2	2	Parasitological component	19
	3.8	3	Con	sent form	19
		3.8.2	1	Census/mapping consent form-English version	19
		3.8.2	2	Hamlet leader consent form	21
		3.8.3	3	Household and prevalence survey Consent forms: (English & Swahili versions)	23
		3.8.4	4	Children cohort follow up consent forms: (English versions)	31
		3.8.5	5	Children cohort follow up consent forms- (Swahili version)	35
		3.8.6	6	Net Study informed consent agreement	39
	3.9	Ð	Mar	nuals and training materials	44
		3.9.2	1	Standard Operating Procedure: HP IPAQ 114 Classic Handheld	44
		3.9.2	2	Standard Operating Procedure: TECNO DroiPad 7D Tablet	55
4		Add	itiona	al files for Chapter 4	66
	4.1 Sp	1 rayir	Surv ng (IR	vivorship and attrition of cohort nets by age and arms with and without Indoor Residual (S) (data from longitudinal survey)	67
	4.2 ne	2 t pro	Prop oduct	portion of net still present in the house and in serviceable condition (=functional survival) b and time point and median survival in years	эу 68
	4.3	3	Сох	regression analysis presenting unadjusted and adjusted Hazard ratio	68
	4.4	1	Mea	an (geometric) number of holes by zone (location) and by size	69

	4.5	Median survival of the nets by study arms	70
	4.6	Kaplan-meier survival estimates	70
5 in	Add cidence	itional files for Chapter 5: The effect of Dual-AI LLINs durability on malaria prevalence and	71
	5.1	Characteristics of the study nets distributed as part of the project in January 2019	71
	5.2	Study nets in good, damaged and too-torn condition (data from cross-sectional and cohort nets 72	)
	5.3 and ag	Multiple comparisons of the mean surface area of the holes in the study nets between nets type	es 73
	5.4	Mean holes per study net per survey by zones (data from cross-sectional survey)	74
	5.5	Mean height of the study net at t0, t30 and t36	75
	5.6	Source of nets in the study area	76
	5.7 childre	Association between sleeping under of different net physical condition and malaria prevalence n aged 6 months to 14 years in cross-sectional surveys	in 77
	5.8 childre	Association between net physical condition and malaria prevalence (in children cohort survey) n aged 6 months to 10 years at the end of follow-up period	in 78
	5.9	Time people get inside the house and close the main doors	79
	5.10	Interaction between net physical condition and net type	79
6	Add	itional files for Chapter 6: Community benefits of Dual-A.I LLINs over 3 years of use	81
	6.1	Malaria prevalence in non-net users and users (of study nets and other nets)	81
	6.2 study a	Distribution of clusters in each community usage category (≤ 40% and > 40%) per time point per arm	r 82
	6.3 chlorfe	Comparisons of malaria infection between users of pyrethroid-only LLIN and non-users in mapyr arm by survey timepoint	83
7 LL	Add .INs	itional files for Chapter 7: Acceptability of and preferences for dual-A.I LLINs compared to standa	ard 84
	7.1 LLIN us	Distribution of villages where focus groups and in-depth interviews were conducted: by levels o sage, and malaria prevalence per study arm	f 84
	7.2	Additional pictures from Eliud lukole's 6.14 km walk	85
	7.3 of LLIN	General perceptions, barriers and drivers to using LLINs, alternative uses, and perceived life spa s (qualitative study in Misungwi)	an 88
8 in	Mor Tanzar	nitoring of Fabric Integrity and Attrition Rate of Dual-Active Ingredient Long-Lating Insecticidal Ne nia: A Prospective Cohort Study Nested in a Cluster Randomized Controlled Trial	ets 93
9	Ento	mological Misungwi RCT results	94
1(	D C	issemination	95

#### 1 Muleba and Misungwi RCT objectives

Muleb	a RCT	Misungwi RCT				
Main ob	jective:	Main objective				
•	To determine the relative effectiveness of four vector control interventions for reducing malaria transmission and controlling vector populations in an area where An gambiae s.s is pyrethroid and carbamate resistant: 1/ a standard long lasting insecticidal net (LLIN), 2/ a LLIN which incorporates a PBO synergist, 3/ a long lasting indoor residual spray (IRS) formulation used in conjunction with standard pyrethroid LLIN or 4/ the long lasting indoor residual spray (IRS) formulation used in conjunction with the LLIN which incorporates a PBO synergist.	<ul> <li>To assess the efficacy of different types of bi-treated long lasting insecticidal nets for control of malaria in an area of Western Tanzania where the main malaria vectors are resistant to pyrethroid insecticide.</li> <li>Specific Objectives</li> <li>Primary specific objective</li> <li>The primary objective is to evaluate the efficacy of three bi-treated LN as compared to standard LN across the lifespan of the LNs (3 years) on malaria infection prevalence in children from 6 months to 14 years.</li> </ul>				
Specific	Objectives	• To assess the efficacy of each of the 3 hi-treated IN as				
1. 2. 3. 4.	To determine whether malaria transmitted by pyrethroid resistant mosquitoes can be controlled using the latest innovative preventive tools: a) Long lasting insecticidal nets that incorporate the synergist a PBO (Olyset Plus), b) Long lasting formulation of the OP insecticide pirimiphos-methyl (Actellic CS) for indoor residual spraying, c) Combination of both products. To demonstrate by means of a community randomised trial in NW Tanzania the protective efficacy of each of these interventions on the following outcomes: a) The reduction in malaria prevalence, b) Entomological inoculation rate EIR [a measure of transmission], c) The reduction in prevalence of anaemia, d) The force of infection (serological conversion rate), e) Selection of insecticide resistance genes. To define a strategy for using and establish in what situations it is possible to deploy just one of the interventions, both interventions, and when to switch from one type of intervention to another. To determine the cost-effectiveness of the interventions alone	<ul> <li>To assess the efficacy of each of the s bi-dreated LN as compared to standard LN         <ol> <li>over 24 months (as recommended by the WHO Vector Control Advisory Group) on malaria case incidence in children from 6 months to 10 years.</li> <li>over 3 years post intervention on prevalence of moderate and severe anaemia in children under 5 years old</li> <li>over 2 years post intervention on the entomological inoculation rate (EIR) as proxy for malaria transmission</li> </ol> </li> <li>To assess 1/net usage 2/ net survivorship, 3/ fabric integrity and 4/ insecticidal activity of LN in each arm through longitudinal LN follow up, insecticide content chemical analysis and bioassay test using standard susceptible and resistant strains.</li> <li>Safety: To assess if bi-treated LN have a safety profile similar to conventional LNs in the population of the trial study area Tertiary specific objectives</li> </ul>				
5. 6.	To demonstrate whether combination interventions can serve as a model insecticide resistance management strategy to delay the future selection of resistance. To provide international malaria control agencies with evidence to enable them to revise or redefine their malaria control	<ul> <li>To assess the incremental cost per percentage point reduction in malaria prevalence (as measured in the surveys for the primary endpoint), per malaria case averted (based on differences in incidence rates), and per disability-adjusted life- year (DALY) averted of each of the trial arms relative to one another and current practice.</li> </ul>				

#### 2 Cluster delineation and restricted randomization

#### 2.1 Census and mapping

The household census took place between 11th May and 7th July 2018. A total of 42,314 households (with 251,155 dwellers) were geo-located, 123,069 (49%) of the population are children under 15 years old. This survey covered 17/27 wards and 72/114 villages of the entire district. A total of 86 clusters were formed with core and buffer zones using a fried egg design before the baseline prevalence cross-sectional survey. A 600-meter buffer was created between two adjacent cores. Nets were distributed both in the core and buffer area but data collection is conducted only in the core zone. The core zone comprises 37,280 (88%) of all mapped households. The core zone retained

an average of 421 houses (Min 155 – Max 628) households with at least 1 child under 15 years for sampling. After a baseline survey, two clusters 22 and 47 were excluded from the study, because they had low participation from the community as they are more urban



Illustration clusters distribution in the study area. Core areas of the clusters are identified with plain color, lined shapes are buffer zones (Created by Charles Thick stun, 2018)

#### 2.2 Restricted randomization

After clusters were delineated, a baseline entomological and malaria prevalence survey was conducted. The main objective of the baseline surveys was to inform the randomization process. Restricted randomization was used to allocate the 84 clusters into four study arms. This method limited the imbalance of selected variables between study arms. There were six variables to balance, namely malaria infection prevalence, population density, LLIN usage, Social-economic status (SES), and predicted suitability for *An. gambiae*, suitability for *Anopheles funestus*. The maximum difference allowed between the arms was determined by studying the data distributions and considering their impact on the study findings (Table 10).

	Pf infection	Malaria infection				Suitability for An.	Suitability for An.
	prevalence (%)	prevalence (%)	ITN use (%)	Poor (%)	Population	funestus	gambiae
Intervention arm							
1	40.2	41.1	62.3	38.3	57,632	0.371	0.372
2	41.1	42.4	59.9	30.8	60,115	0.354	0.239
3	44.6	45.5	61.4	34.6	61,184	0.368	0.367
4	44.0	44.7	62.8	31.7	57,568	0.471	0.309
Study area mean	42.5	43.4	61.6	33.9	59,125	0.391	0.322
Minimum in any study arm	40.2	41.1	59.9	30.8	57,568	0.354	0.239
Maximum in any study arm	44.6	45.5	62.8	38.3	61,184	0.471	0.372
Maximum difference between the	study arms						
Absolute difference	4.4	4.4	3.0	7.6	3,616	0.117	0.133
Relative difference	10.3	10.1	4.8	22.4	6.1	30.0	41.4

A balance between the study arms in the final allocation (by Phillipa West, 2018)

# 3 Data collection, consent forms, and training manuals

# 3.1 Household malaria prevalence cross-sectional survey questionnaire

MiF0011							
Malaria Prevention Trial: Misungwi (MRC/WT/DFID) 🙈							
Household questionnaire Surv	Household questionnaire Survey (English) v2.0 27/06/2018						
		-					
Date (dd/mm/yy)	//						
Interviewer Initials							
Identification							
Hamlet Code							
Ward name							
Village Name							
Hamlet Name							
Cluster Number							
Household number/Unique address							
READ AND CO	MPLETE THE CONSENT						
Interview Information							
Question description	Options	Answer					
	Consent given	1					
	Ineligible (no children under 15)	2					
	Return later	3					
Consent result	Refused	4					
	Dwelling vacant for survey duration	5					
	Dwelling not found	6					
	Dwelling not visited	7					
Total number of visits	II						
Comments							
GO TO RESIDENT SECTION 1							

		Resi	dent li	st								
Resident No.	Usual residents and visitors	Relation to HH head	А	ae	s	ex	Pre	gnant		Res	idence	
	Please give me the <b>names</b> of the persons who usually live in your household and guests of the household who stayed here last night, starting with the interviewee. Record first name and an initial for family	What is the relationship of (NAME) to the head of the	How old is less than 0 in the Ye give numbe in ne	(NAME)?If 1 year write ars box and er of months at box.	ls (N ma ferr	AME) le or nale?	Is (I cu pre	NAME) rrently gnant?	Do (NA <u>usu</u> l <u>ive</u>	bes ME) <u>ally</u> here?	Did (N stay he <u>nig</u>	AME) re <u>last</u> <u>ht</u> ?
Q01	names Q02	Q03	Q	04	C	05	ov	<b>er 15</b>	Q	07	Q	)8
	01 = Interviewee		Only give Less tha	Months if n 1 yr old	м	F	Yes	No	Yes	No	Yes	No
01			Years	Months	1	2	1	0	1	0	1	0
02			Years	Months	1	2	1	0	1	0	1	0
03			Years	Months	1	2	1	0	1	0	1	0
04			Years	Months	1	2	1	0	1	0	1	0
05			Years	Months	1	2	1	0	1	0	1	0
06			Years	Months	1	2	1	0	1	0	1	0
07			Years	Months	1	2	1	0	1	0	1	0
08			Years	Months	1	2	1	0	1	0	1	0
09			Years	Months	1	2	1	0	1	0	1	0
10			Years	Months	1	2	1	0	1	0	1	0
11			Years	Months	1	2	1	0	1	0	1	0
12			Years	Months	1	2	1	0	1	0	1	0
13			Years	Months	1	2	1	0	1	0	1	0
14			Years	Months	1	2	1	0	1	0	1	0
15			Years	Months	1	2	1	0	1	0	1	0
* Codes for	Q3: Relationship to household head	98=don't k	now									
01=head		03=son/da	aughter		05=	paren	t			07:	other i	elative
02=wife/h	usband/partner	04=grando	child		06=	=brothe	er/siste	r		08:	=not rel	ated

Socio	Socio Economical Status								
No.	Question description	Options	Answer	lf	Goto				
	line the based of the bases about a second of	Yes	1						
9	Has the head of the household ever attended	No	0	0	11				
	school?	Don't Know	98	98	11				
		Primary	1						
10	What is the highest level of school the head	Secondary/technic	2						
10	of the household attended:	Higher	3						
		Don't Know	98						
		Yes	1						
	Has the head of the household WIFE ever	No	0	0	13				
11	attended school?	Not Applicable	2	2	13				
		Don't Know	98	98	13				
		Primary	1						
	What is the highest level of school the head	Secondary/technic	2						
12	of the household WIFE attended:	Higher							
		Don't Know							
<u> </u>	How many rooms are there in this								
13	household?	Number (Don't Know = 98)							
	>>Include all structures (huts etc)								
	How many sleeping places are there in this								
	household (beds. mattresses or mats)?								
14		Number							
	>>Ask for both inside the hut and outside								
		Grass/Papyrus/leaves	1						
	What is the main material of the roof?	Metal sheets	2		16				
15	(Observed)	Metal sheets & Grass/Papyrus/leaves	3		1				
		Other	4	4	15b				
15b	If Other type of roof specify	Free text							
		earth/sand	1	1					
		cement	2	2	17				
16	What is the main material of the floor?	Earth/sand & Cement		2					
		Other		4	16b				
16b	If Other type of floor specify	Ereo text	<del>_</del>		100				
100			1	1					
		Mid							
			2						
47			3	3	18				
17	what is the main material of the walls?	Brick and Mud	4	4	-				
			5	5					
		plastic sheeting	6	6					
			1	1	170				
1/b	IT Other type of wall specify	Free text							
		yes completely	1	1					
18	Are the walls plastered?	partially/damaged	2	2					
		no	0	0					
19	Are eaves open? (Is there is a gap between	Yes	1	1					
	the top of the wall and the roof?)	No	0	0					
		Intact	1	1					
20	Does the house have a ceiling?	Damage/Partial/traditional	2	2					
		No ceiling	0	0					
		Fishing/Farming/Selling cash crops	1	1					
	Where does the Households main income	Mining	2	2	22				
21		Buisness/Shop	3	3	~~				
		Medical/Teacher/Goverment	4	4					
		Other	5	5	21b				
21b	If Other kind of income specify	Free text							

		Check box			
		Electricity			
		Radio	 		
		mabila phone	 		
22	Does the household (any member) have any				
	of the following	Motorbike	<u> </u>		
		Car or truck	<u> </u>		
		Canoe or boat with motor			
		Sewing machine			
		Livestock		not checked	24
		Television			
		Canoe or Boat without motor			
			11		
	Number of animals the bousehold owns?	Poultry/birds			
		Costs and shaap			
23					
	if don't know write 9999	Pigs			
		Cows/Donkeys			
	Are the gest/sheep or cows staving inside	Yes	1		
23b	the house at night?	No	0		
		Don't Know	98		
	What is the main source of drinking water for				
24	members of your household? (Choose only				
	one)	Piped water			
		Piped into dwelling	1		
		Piped to yard/plot	2		
		Piped to neighbor	3		
		Public tap/standpipe	4		
		Dug well			
		Protected well	5		
		Unprotected well	6		
		Water From Spring	7		
		Rainwater	8		
		Surface Water (River/Dam/Lake/Pond/Strea	a		
		Other Specify	5		
25	what kind of tollet facility do members of				
	your nousenoid usually use?		1		
		Ventilated Inmproved Pit Latrine	2		
		Iraditional Pit Latrine	3		
		None/bush	4		
		Other, Specify			
26	What type of fuel does your household				
20	mainly use for cooking?	Firewood/straw	1		
		Charcoal	2		
		LPG/Natural gas	3		
		Biogas	4		
		Dung	5		
		Electricity	6		
		Paraffin	7		
		Other Specify			
<u> </u>	How many rooms in this household are used				
27	for sleeping?	Rooms number			
	Does the household own land used for	Yes	1		
28	farming?	No	0	No	30
20	If yes, indicate approximate size in acres	Acres			
23	>> if don't know write 98		II		

Vector measures part 1								
No.	Question description	Options	Answer	lf	Goto			
	Was the interior walls of your house sprayed	Yes	1					
30	in 2015 against mosquitoes spreading malaria disease?	No	0					
		Don't Know	98					
	Has the household ever used aerosol	Yes	1					
31	can/coil/repellent/ herbs or plants to protect themselves against mosquitoes?	No	0					
		Don't Know	98					
	How many mosquito nets does the household have? If don't know write 98	Number Nets		Net >0	33			
32				or DNK	44			

## GO TO NET SECTION IF Q32 NET >0

Vector measures part 2									
No.	Question description	Options	Answer	lf	Goto				
42	Summarize how many mosquito nets were used last night (based on the each net section)	Number nets used							
		Prevent malaria	1						
		Privacy	2						
		Warmth	3						
	What is the main reason the net was used?	Protection against mosquitoes	4						
13		Prevent Malaria & Protection against mosquitoes	5						
43		Protection against other insects	6						
		I was advised to use it by a CCA/Hamlet leader	7						
		Don't Know	98						
		Other, Specify	8						
43b	If Other reason for net used specify	Free text							
44	Comments								
	GO TO RESIDENT SECTION PART 2 (& SELECTION OF THE KID)								

# 3.2 Household KAP survey questionnaire



MALARIA PREVENTION TRIAL MULEBA KNOWLEDGE, ATTITUDES AND PRACTICES SURVEY KAP #2- APRIL 2015

Interview Information								
Date (dd/mm/yy)		Interviewer Initials						
Household Number (Address)		Hamlet Code						
Ward Name								
Village Name								
Hamlet Name								
Cluster								
Total No. Of Visits		Result*						
*Result Codes	1. Consent Given	2. Dwelling not found	3. Dwelling not visited					
4. Dwelling vacant for survey duration	5. Ineligible (no children under 15)	6. Refused	7. Return Later					
Comments								

Socio-Demographic Characteristics						
Question Categories						
Name of Head of Household						
Respondent Full Name						
Age	(Years)					
Sax	Male	1				
Sex	Female	2				

# 3.3 FGD note-taker form



BEHAVIORAL COMPONENT FOCUS GROUP DISCUSSIONS SUB PROTOCOL MALARIA PREVENTION TRIAL MULEBA

#### FGD NOTE-TAKER FORM

FGD Information			
Date (dd/mm/yy)		Note-Taker Initials	
FGD ID No.	1_1_1_1_1		
Audio File No.			
Cluster			
Comments			

Draw a seating diagram:

#### 3.4 IDI Summary Form



BEHAVIORAL COMPONENT IN-DEPTH INTERVIEWS SUB PROTOCOL MALARIA PREVENTION TRIAL MULEBA

Annex III INTERVIEW SUMMARY FORM

Interview Information			
Date (dd/mm/yy)	Interviewer Initials		
Participant ID No.	I_I_I_I_I		
Health Facility ID No. (If Applicable)	I_I_I_I_I		
Audio File No.			
Cluster			
Comments			

Themes to Cover		
Describe the atmosphere and context of the interview		
What were the main points made by the participant during the interview?		
What new information did you gain through this IDI, compared to previous IDIs?		

## 3.5 Collapsible net frame

The collapsible LLIN frame was used to mount the LLIN during hole assessment in the household. Field workers assembled it at each household and dismantled it before moving to the next selected household.





## **3.6** Data management and quality assurance

## 3.6.1 Unique identification numbers: resident and net

Individual ID numbers uniquely identified every person in the study. It is made up of three parts: hamlet code, household number, and resident number. Similarly, the net ID number was uniquely

identified by hamlet code, household number, and net number (Figure 1). The same individual could not be matched between surveys because the resident number for an individual could be different as it is determined by the order the residents are listed in the household questionnaire. Hamlet codes/numbers were unique and were assigned at the start of the project during household mapping activity. Household numbers, individual numbers, and net numbers were not unique because the household numbering was restarted for each cluster and the resident numbering and net numbering were restarted for each household.

At the time, ODK did not support the unique identification to be validated at the device level. To ensure that the questionnaire had unique identification numbers printed on the paper (called household list), field workers checked the completed questionnaires' unique ID numbers against the household list and marked with a pen if it was correct and rectified it otherwise before uploading the forms to the server. At the office, once STATA codes were run and the duplicates if the ID numbers appeared, the responsible field worker upon arrival at the office was immediately called to help rectify the error. This was done daily.

The household, resident, and net identification number was made up of:

- The household ID: Hamlet code/household number (HHno)
- The individual ID: Hamlet code/HHno/resident number (Resno)
- **Net ID:** Hamlet code/HHno/net number (Netno)
- Net user ID: Hamlet code/ HHno/Netno/Resno



Figure 1: Example of an individual/resident ID and net ID

#### 3.6.2 Merging and creating datasets

Four main datasets were created and used for the analyses in this thesis. The household dataset, the resident dataset, the net dataset, the LLIN durability dataset, and the selected children dataset. The household-level dataset contains one line for each selected household uniquely identified by its household ID. Net data, resident data, and selected children data were aggregated at the household level and merged with the household data (e.g. number of any LLINs or study LLINs per household number of residents per household, or number of nets used last night per household-).

A resident dataset was created with a line for each individual listed in the participating households. It included: individual-level data consisting (of demographics, details of the net they reported using, clinical results and the coupon data for children selected, and the status of the net [proportionate hole index (pHI)] for those sleeping under LLIN assessed for durability). Household-level data consisted of (household characteristics like structural material, and socio-economic status (SES); net data aggregated at the household level, and resident data aggregated at the household level). Finally, the cluster-level data consisted of community net coverage or usage, cluster SES, and cluster malaria prevalence.

Household-level data were joined to individual data including cluster-level data. Checks and corrections were made, where possible, to record where the households had missing residents and where residents were matched to the households that did not participate in the study. If the issues could not be rectified, the records were removed from the analysis [these were mainly done in Muleba]. In Misungwi, there were more restrictions in the questionnaire to avoid missing, inconsistent, and mismatching responses.

Once household data and individual data had been merged, a set of household-level variables was created such as household crowding (number of residents/number of sleeping rooms in the household), and number of residents per LLIN. These variables were added to the household dataset.

A net dataset was created with one line for each net and at least one line for each household. There was one line for each household so that ownership per household, and the proportion of household per cluster owning nets could be calculated. Cluster-level data and some household data including resident data aggregated at the household level, were merged into a net data set.

16

A table was created from the net dataset with one line for each individual using the net. This was so that it could merge into the personal dataset. The original net table lists the resident numbers of all individuals who slept under a net last night. The net table was reshaped to make one record for each sleeper under the net (Figure 2).



Figure 2: Illustration of datasets and the relationship between them during merging.

#### 3.7 Data quality assurance

This section demonstrates the steps taken to generate high-quality data and reduce possible sources of bias that have not already been explained in the results papers.

#### 3.7.1 Household component

#### 3.7.1.1 Design and pilot:

The household questionnaire was adopted from the Malaria indicator survey questionnaire and where necessary adjusted to fit the local situation or requirement of the study. The questionnaires, and consent forms were translated into Kiswahili (national language) and back-translated into English to ensure the correct translation. In Muleba the questionnaires (English version) were programmed using Pendragon Software and uploaded into the PDAs, the questions were asked in Haya or Swahili languages. In Misungwi the questionnaires (Swahili version) were programmed using Open Data Kit (ODK) and uploaded onto the Tablets/Smartphones, and the questions were asked in Swahili or Sukuma languages. The drop-down list in the Pendragon and ODK was used mostly to standardize answers. The household questionnaire was piloted several times to ensure the questions flow, jumps and skips were well aligned. The household survey (questionnaire, consent, GPS coordinates, and the whole process of introduction into the household) was then piloted for 2-3 days during the training week in the households surrounding the project office (not part of the study villages) and improvements were made based on the feedback.

#### 3.7.1.2 Training

Training included theory, discussion, and role-play, followed by field practice, which lasted for one week. The purpose of the project was introduced to the data collection teams, field workers, and clinicians. Field workers were taught the right way of asking questions, insisting that that could influence what answers they received. During training, field workers practiced the way they could approach the respondents, and were constantly assessed and given regular feedback. More than enough field workers were trained for each survey to enable the best to be selected and reserve to be kept whenever there was an emergency.

#### 3.7.1.3 Actual survey

On the first, second, and third days of each survey after the training week, all field worker teams worked in the same cluster and surveyed only half or less than half of the usual number of households per team. The following day, clinical teams too worked in that same cluster. This approach allowed a slower pace and enabled close supervision at the beginning of the surveys.

#### 3.7.1.4 Supervision

Each team had one team supervisor who was an experienced field worker. The team supervisor was mentored and coached by Prof Protopopoff and me. The tasks of the supervisor in the field were to check whether procedures were followed, questions were asked correctly, and answers were filled correctly. The supervisor was supposed to closely supervise the field worker for a minimum of two days and 5 questionnaires per week.

#### 3.7.1.5 Evening inconsistency, duplicates, and mismatch checks

In Muleba, every evening the supervisors collected the PDAs from the teams and handled them to the author of this thesis. Completed questionnaires were uploaded into the Microsoft Access database and then transferred into STATA Software Version 15. STATA codes were programmed to capture all inconsistencies, duplicates, and mismatches in the responses. Errors were corrected and the error form was filled appropriately. Supervisors and field workers were informed of the errors and where feasible, rectified them with the help of their notebooks. In Misungwi, this was done by the data manager.

#### 3.7.1.6 Morning briefings

Every morning feedback was given to the teams before going to the field to help them improve and avoid further errors.

18

## 3.7.1.7 Team reshuffles

Each week, individuals in the teams and team supervisors were changed around to ensure that the quality of the survey and the data collected was maximized. More experienced field workers were always teamed with less experienced ones and where possible each team had one female and one male field worker for security reasons [for those that worked in pairs].

## 3.7.2 Parasitological component

The clinical team contained highly experienced nurses and clinicians and was thoroughly trained in the process, procedures, and data reporting for each survey. More people were trained than required to provide replacement staff to cover for absence during the survey. The teams were supervised by a senior trial laboratory technician and epidemiologist. Forms were checked daily for missing data and feedback was given every morning.

## 3.8 Consent form

## 3.8.1 <u>Census/mapping consent form-English version</u>



# **INFORMATION AND CONSENT FORMS**

## ENUMERATION CONSENT AGREEMENT FOR HAMLET LEADER

## Introduction

Good morning. My name is \_\_\_\_\_\_. I work with PAMVERC Malaria Prevention Trial Misungwi. We work together with the Misungwi District Health office, the National Institute for Medical Research, the Kilimanjaro Christian Medical College, London School of Hygiene and Tropical Medicine. I am here to ask you some questions to get some information on your house.

## Purpose

The enumeration will provide a house and household register (each with an identification code) for selected villages within the Misungwi district.

## What will happen

If you agree to participate, we will carry out the following activities:

- 1. We will create a map of your village and hamlet boundaries using a satellite-tracking device to identify the location of your house within the village.
- 2. We will record the names of the head of household, the number of family members, and number of children from 6 months to 10 years and from 11 to 14 years.

**Risks:** We can see no risk in participating in the enumeration study.

**Benefits:** There will be a separate round of consent for the intervention study. The results of the study will help us learn how best malaria can be controlled.

**Confidentiality:** Your individual information will be kept private. The information gathered will be for use in the implementation and monitoring of the trial only and shall not be disclosed to any external or third party.

**Institutional Approval**: This study has been approved by the Ethics Committee of the London School of Hygiene and Tropical Medicine, Kilimanjaro Christian Medical College, and the Medical Research Coordination Committee at NIMR.

## Costs and compensation for participating in the study

You will not be asked to pay anything for you to participate in this study. The study will not reimburse you with any payment for taking part in the study.

If you have any questions or clarification pertaining to this project please feel free to ask the field workers and nurse or you may contact Study staff; Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390.



## FOMU YA MAKUBALIANO

## ENUMERATION CONSENT AGREEMENT FOR HAMLET LEADER

#### Muhutasari

Habari ya asubuhi. Jina langu ni \_\_\_\_\_\_. Ninafanya kazi PAMVERC katika mradi wa kuzuia malaria Missungwi. Tunafanya kazi kwa kushirikiana na ofisi ya Afya ya wilaya ya Missungwi, taasisi ya taifa ya utafiti wa magonjwa ya binadamu, chuo kikuu cha tiba cha Kikristo cha Kilimanjaro, na chuo cha London School of Hygiene and Tropical Medicine. Niko hapa kukuuliza maswali kupata baadhi ya taarifa za nyumba yako.

#### Dhumuni

Zoezi hili la uwekaji namba litasaidia kuandikishwa kwa nyumba na kaya (kila moja ikiwa na nambari maalumu ya utambulisho) kwa vijiji vitakavyochaguliwa katika wilaya ya Missungwi. Kitakachofanyika

Ukikubali kushiriki tutafanya mambo yafuatayo:

- Tutatengeneza ramani ya kijiji chako na mipaka ya kitongoji kwa kutumia kifaa maalumu cha ufuatiliaji satelaiti kupata maeneo yenye sifa za kijiografia, barabara, majengo ya umma na matumizi. Tutatumia kifaa hicho hicho kutambua eneo la nyumba yako katika kijiji.
- 2. Tutaorodhesha majina ya wenye nyumba idadi ya watu wanaokaa kwenye hiyo nyumba, na idadi ya watoto kuanzia umri wa miezi 6 mpaka miaka 10 na miaka 11 mpaka 14.

Madhara/athari: Hatuoni uwezekano wa kuwepo kwa madhara yeyote kwa kushiriki kwenye zoezi la uwekaji namba.

**Faida:** Kutakuwa na hatua ya pili ya kupata idhini ya utafiti. Matokeo ya utafiti huu yatatusaidia kujifunza namna nzuri zaidi ya kupunguza malaria.

**Usiri:** Taarifa yako itatunzwa kwa siri. Taarifa itakayokusanywa itakuwa kwa matumizi ya kuratibu na kufuatilia utafiti tu na hazitatolewa kwa mtu mwingine yeyote.

**Ruhusa ya taasisi:** Utafiti huu umeidhinishwa na kamati za maadili za chuo kikuu cha tiba cha Kikristo cha Kilimanjaro, na chuo cha London School of Hygiene and Tropical Medicine na kamati ya uratibu wa utafiti wa magonjwa ya binadamu.

## Gharama na fidia kwa kushiriki kwenye utafiti

Hutatakiwa kulipa chochote kwa wewe kushiriki kwenye utafiti huu. Mradi hautakulipa chochote kwa kushiriki kwako kwenye utafiti (NIMR).

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661.

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

## 3.8.3 Household and prevalence survey Consent forms: (English & Swahili versions)



## HOUSEHOLD AND MALARIA PREVALENCE SURVEY INFORMED CONSENT AGREEMENT

#### Introduction

Good morning. My name is \_\_\_\_\_\_\_. I work with PAMVERC Malaria Prevention Trial Misungwi. We work together with the Misungwi District Health office, the National Institute for Medical Research, the Kilimanjaro Christian Medical College, London School of Hygiene and Tropical Medicine. I am here to ask you some questions and do some simple tests to learn how well malaria prevention and treatment are working in Misungwi. To do this, we are gathering information by visiting a number of households in your community.

#### Purpose of the survey

To see if the malaria program works, we would like to ask you some general questions about your household, bed-net possession, and use. We want to see how common malaria is among people in your community by testing for parasites in their blood. Your responses to our questions and the results of our studies will help us learn how best to further improve malaria control in your community and the country.

#### <u>Procedures</u>

- If you agree to take part, we will ask you a number of questions about your family and household about bed nets used. Some people will be selected to be tested for malaria. I will ask all selected people to go to see a PAMVERC-employed nurse on the \_\_\_\_\_\_ (give the date of the consultation) in \_\_\_\_\_\_ (give the place). The nurse will take several small drops of blood from each selected person. The whole process should take about 30 minutes.
- The nurse will take a small amount of blood from the finger using a small needle. One drop of blood will be used to test for a rapid malaria diagnostic test and another drop to prepare the blood slide. This blood slide will be analysed in a laboratory in KCMC and may need to be kept for further analysis after the survey. A drop of blood will also be used to test for anaemia. The identity of the person will not be connected to these samples. We will also test whether the person currently has a fever.
- The results from the malaria rapid diagnostic test will be given the same day. If the person has malaria or fever, he will be provided with free drugs by the PAMVERC clinician. In case the person does not get better, you are requested to go to the nearest health facility immediately to receive alternative treatment according to the Ministry of Health policies. If we diagnose any person as having severe malaria or other diseases you will be immediately referred to nearby health facilities.
- Net inspection: If you agree to take part in this survey, we will ask you additional questions about the net you have (washing, type of sleeping bed, and repair) and would like also to see and inspect two nets in your house to assess the quality. This will help us determine for how long these nets can sustain different field conditions. Therefore, enables us to devise alternative measures for improving and strengthening nets to meet community needs. I will not damage the net, and after the interview, and will return it after the inspection.

#### Risks and Benefits

The tested person will feel pain for a few seconds when we take the blood from his/her finger. If the test shows that your child has malaria, or fever at the time of the survey, they will receive free treatment that the Ministry of Health recommends. These drugs are proven to be safe and effective, but any drug can cause side effects in a small number of patients. The nurse will discuss if treatment is needed.

## Voluntariness and confidentiality

It is entirely your choice to take part in or not take part in this survey as I have just described it. If you do agree to take part, your answers to all questions and the test results will be kept private and not revealed to anyone. If you agree to take part, you can also decide not to answer any of the questions that you do not want to, and you can refuse the blood tests.

## Costs and compensation for participating in the study

You will not be asked to pay anything for you to participate in this study. The study will not reimburse you with any payment for taking part in the study.

## Consent for long-term sample storage for future studies

We are also asking people who join this study if they will let the researchers use their blood samples for future studies. These future studies may help find new ways to prevent malaria or other diseases. If you agree, we will store your blood in the laboratory with a unique number and not with your name. Your sample will be stored for up to 25 years. We may share your test results with researchers at other organizations but we will not give them your name, address, or any information that could identify you. After the study has ended, we will remove any means to link the sample to you, and we will not be able to find your sample. If you do not wish to have your blood stored for future tests, you may still participate in our study.

Thank you very much for your time. Would you like to take part in this survey?

## HOUSEHOLD COPY – Household and child – Date: \_\_\_/\_\_\_/

## <u>Consent</u>

- The study has been explained to me, I have been given the opportunity to ask questions concerning this study. Any such questions have been answered to my satisfaction. I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits, if any.
- I agree for me and my child/children to take part.
- I also agree that the data generated from this study and the dried blood samples stored can be used in the future for other malaria-related research.

Name of participant	Signature/Thumb print
Relationship to the children	
Name of the witness	Signature
Name of	
interviewer	Signature

If you have any questions or clarification pertaining to this survey please feel free to ask the field workers and nurse or you may contact Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140; Dr Alphaxard Manjurano, 0756026661.

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390

## **PROJECT COPY – Household and child**



Date: \_\_/\_\_/\_\_\_ Cluster Number: \_\_\_\_ \_\_\_ Household Number:

## MALARIA PREVALENCE SURVEY INFORMED CONSENT AGREEMENT FOR THE **PARENT / GUARDIAN OF CHILDREN IN THE TRIAL**

#### Consent

- The study has been explained to me, I have been given the opportunity to ask questions • concerning this study. Any such questions have been answered to my satisfaction. I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits, if any.
- I agree for me and my child/children to take part.
- I also agree that the data generated from this study and the dried blood samples stored can be used in the future for other malaria-related research.

Name of participant	Signature/Thumb print
Relationship to the children	
Name of the witness	.Signature
Name of interviewer	Signature
If you have any questions or clarification p	pertaining to this survey please feel free to ask the field

workers and nurse or you may contact Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140 and Dr. Alphaxard Manjurano, 0756026661.

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390



# MKATABA WA RIDHAA KWENYE UTAFITI WA MAAMBUKIZI YA MALARIA: V1.0 19/01/2018

## Utangulizi

Habari ya leo. Jina langu ni

Ninafanya kazi na Mradi wa Kuzuia Malaria Missungwi PAMVERC. Tunafanya kazi pamoja na Ofisi ya afya ya wilaya, Taasisi ya Utafiti wa Magonjwa ya Binadamu (NIMR), Chuo Kikuu cha Kikristo cha Tiba Kilimanjaro (KCMC) na Chuo Kikuu cha Nchini Uingereza (London School of Hygiene and Tropical Medicine). Niko hapa kukuuliza maswali na kufanya vipimo kujifunza ni kwa kiasi gani tiba na kinga dhidi ya malaria vinafanikiwa hapa Missungwi. Katika kufanya hivyo, tunakusanya taarifa kwa kutembelea kaya katika kijiji chako.

## Dhumuni la utafiti

Kuona kama mradi wa malaria unafanikiwa, tutapenda kuuliza maswali juu ya kaya yako, umiliki wa vyandarua na matumizi yake, na kama nyumba yako ilipuliziwa dawa ya kupunguza malaria. Tunataka kuona malaria ni sugu kiasi gani kati ya watu kwenye jumuiya yako kwa kuwapima damu yao kama ina vimelea. Pia tutajaribu kutafuta vitu vinavyosababisha maambukizo ya ugonjwa wa malaria kwenye jamii yenu. Majibu yako kwa maswali yetu na matokeo ya utafiti huu vitatusaidia kujifunza namna bora ya kupunguza zaidi malaria kwenye jumuiya yako na nchi nzima kwa ujumla. **Utaratibu** 

- Kama utakubali kushiriki, tutakuuliza maswali kadhaa kuhusu familia na kaya yako, kuhusu vyandarua na matumizi yake. Baadhi ya watoto (wenye umri kati ya miezi sita na miaka 14) watachaguliwa na kupimwa malaria. Nitawaomba watoto wote watakaochaguliwa wakamwone mhudumu aliyeajiriwa na PAMVERC tarehe \_\_\_\_\_\_ mahali \_\_\_\_\_\_. Mhudumu wa afya atachukua matone madogo na machache ya damu kutoka kwenye kidole cha mtoto aliyechaguliwa. Zoezi la upimaji litachukua kiasi cha dakika 30.
- Mhudumu wa afya atachukua matone kidogo ya damu kutoka kwenye kidole cha mtoto kwa kutumia sindano ndogo. Tone moja la damu litatumika kupima malaria kwa upimaji wa malaria wa haraka yaani Rapid Malaria Diagnostic Test (mRDT), tone la pili litatumika kupima upungufu wa damu mwilini, na tone jingine litakaushwa kwenye kioo. Damu ya kwenye kioo hicho itachunguzwa kwenye maabara ya KCMC na kinaweza kuhifadhiwa kwa uchunguzi zaidi baada ya utafiti. Utambulisho wa muhusika hautaunganishwa na sampuli hizi za damu. Tutapima pia kama mtoto huyo ana homa kwa wakati huo.
- Matokeo ya upimaji wa malaria wa haraka yatatolewa siku hiyo. Kama huyo mtoto atakuwa na malaria au homa, atapewa vidonge na mtabibu wa PAMVERC bila kulipia. Kama muhusika hatapata nafuu, unaombwa kwenda kwenye kituo cha afya kilicho karibu mapema kupokea tiba mbadala kulingana na sera ya Wizara ya Afya. Kama mtoto yeyote atapimwa na kugundulika kuwa na malaria kali au ugonjwa mwingine atapata rufaa kwenye kituo cha afya cha karibu mapema iwezekanavyo. Pia takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokaushwa na kuhifadhiwa yanaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria tu hapo baadae.
- Uchunguzi wa Vyandarua : Kama utakubali kushiriki katika utafiti huu, tutakuuliza maswali ya nyongeza kuhusu chandarua ulichonacho (kufua, aina ya malazi, na kushona) na tungependa kuvikagua nyandarua viwili kutoka kwenye nyumba yako ili kutathimini ubora. Hii itatusaidia kufahamu ni kwa muda gani chandarua kinaweza kuhimili mazingira tofauti tufauti. Pia

itatusaidia kubuni njia nyingine madhubuti ya kuviboresha ili kukidhi mahataji ya jamii. Hivyo nitakuomba unioneshe vyandarua ulivyonavyo ili kuvifanyia uchunguzi. Sitakiharibu chandarua, bali ntakirudisha kikiwa salama.

## Athari na Faida

Mtu atakaye pimwa atapata maumivu kwa sekunde chache wakati wa kuchukua damu kutoka kwenye kidole chake. Kama kipimo kitaonyesha kwamba mtoto wako anayo malaria, au homa wakati wa zoezi hilo, atapata matibabu yanayoshauriwa na Wizara ya Afya bure. Vidonge hivi vimedhibitika kuwa ni salama na vyenye ufanisi, lakini dawa yeyote yaweza kusababisha madhara kwenye idadi ndogo ya wagonjwa. Mhudumu wa afya atajadiliana na wewe kama utahitaji dawa hiyo.

#### Uhiari na Usiri

Ni hiari yako kabisa kushiriki au kutoshiriki kwenye utafiti huu kama nilivyoelezea. Kama utakubali kushiriki, majibu ya maswali na matokeo ya vipimo yatatunzwa kwa usiri na bila kuoneshwa kwa yeyote. Kama ukikubali kushiriki, unaweza pia kuamua kutojibu maswali yeyote utakayotaka na unaweza kukataa vipimo vya damu.

**Gharama na fidia kwa kushiriki kwenye utafiti** Hutatakiwa kulipa chochote kwa wewe kushiriki kwenye utafiti huu. Mradi hautakulipa chochote kwa kushiriki kwako kwenye utafiti.

## Ridhaa ya uhifadhi wa sampuli kwa muda mrefu kwa ajili ya tafiti za baadaye

Tunawaomba pia watu watakaoshiriki kwenye utafiti huu endapo watawaruhusu watafiti kutumia sampuli zao za damu kwa ajili ya tafiti za hapo baadaye. Tafiti hizi za baadaye, zinaweza kusaidia kupata mbinu mpya za kuzuia malaria au magonjwa mengine. Endapo utaridhia, tutahifadhi damu yako kwenye maabara kwa kutumia utambulisho maalumu usiokuwa na jina lako. Sampuli yako itahifadhiwa hadi miaka 25. Tunaweza kuwapatia majibu ya vipimo vyako watafiti wa taasisi nyingine ila hatutawapatia majina yako, anwani au taarifa yoyote inayoweza kukutambulisha. Mara baada ya utafiti kwisha, tutaondoa njia zozote zile zinazoweza kuunganisha utambulisho wa sampuli na wewe, na hatutaweza kuipata sampuli yako. Endapo hutapenda sampuli yako ya damu ihifadhiwe kwa ajili ya vipimo vya hapo baadaye, bado unaweza kushiriki kwenye utafiti.

## Ahsante sana kwa muda wako. Je utapenda kushiriki katika utafiti huu?

NAKALA YA KAYA– Date: \_\_\_\_/\_\_\_/\_\_\_/

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu, nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu. Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Nakubali mimi na watoto wangu washiriki pia na vyandarua vyangu kukaguliwa.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Jina	Sahihi/Dole
Ghumba	
Uhusiano wako na watoto	

Jina			la
shahidi		Sahihi	
Jina	la	mtu	aliyewasilisha
fomu	Sal	nihi	•••••

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661.

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

#### NAKALA YA MRADI – Kaya na mtoto



Date: \_\_\_/\_\_\_/ Cluster Number: \_\_\_\_ Household Number: \_\_\_\_

#### FOMU YA MAKUBALIANO KATI YA MRADI WA KUZUIA MALARIA, MISSUNGWI- KAGERA NA WAZAZI/WALEZI WA WATOTO KWA MAJARIBIO

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu, nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu. Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Nakubali mimi na watoto wangu washiriki pia na vyandarua vyangu kukaguliwa.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Jina Ghumba			Sahihi/Dole
Uhusiano wako na v	watoto		
Jina			la
shahidi		Sanını	
Jina	la	mtu	aliyewasilisha
fomu	Sa	hihi	

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

#### 3.8.4 <u>Children cohort follow-up consent forms: (English versions)</u>

#### CHILDREN COHORT FOLLOW-UP CONSENT FORM

#### Introduction

Good morning. My name is \_\_\_\_\_\_\_. I work with PAMVERC Malaria Prevention Trial Missungwi. We work together with the Missungwi District Health office, the National Institute for Medical Research, the Kilimanjaro Christian Medical College, London School of Hygiene and Tropical Medicine. I am here to ask you some questions and do some simple tests to learn how well malaria prevention is working in Missungwi.

#### Purpose of the survey

To see if the mosquito net distributed works. We want to know to frequency of malaria infection among children in your community by testing for parasites in their blood. Your responses to our questions and the results of our studies will help us learn how best to further improve malaria control in your community and the country.

#### Procedures

If you agree to take part, we will ask one child from 6 months to 10 years will be selected at random from your household to attend every month the PAMVERC mobile clinic located in your hamlet or a nearby hamlet. We will ask you a number of questions about your child who has been selected including fever, sickness and treatment history, bed-net use, and any side effects from the use of bed net if any. We will take the temperature, if your child has signs and symptoms of malaria infection the nurse will take several small drops of blood from the selected child. The whole process should take about 30 minutes. The selected child will be followed for 1 year or until he/she reaches 10 years old.

The nurse will take a small amount of blood from the finger using a small needle. One drop of blood will be used to test for a rapid malaria diagnostic test. The identity of the person will not be connected to these samples.

The results from the malaria rapid diagnostic test will be given the same day. If the person has malaria or fever, he will be provided with free drugs by the PAMVERC clinician. In case the person does not get better, you are requested to go to the nearest health facility immediately to receive alternative treatment according to the Ministry of Health policies. If we diagnose any person as having severe malaria or other diseases you will be immediately referred to nearby health facilities.

#### **Risks and Benefits**

The tested person will feel pain for a few seconds when we take the blood from his/her finger. If the test shows that your child has malaria, or fever at the time of the survey, they will receive free treatment that the Ministry of Health recommends. These drugs are proven to be safe and effective, but any drug can cause side effects in a small number of patients. The nurse will discuss if treatment is needed.

#### Voluntariness and confidentiality

It is entirely your choice to take part in or not take part in this survey as I have just described it. If you do agree to take part, your answers to all questions and the test results will be kept private and

not revealed to anyone. If you agree to take part, you can also decide not to answer any of the questions that you do not want to, and you can refuse the blood tests.

## Costs and compensation for being in the study

You will not be asked to pay anything for you to participate in this study. You will receive reimbursement for your transport to come to the clinic or to deliver to the hospital. You also receive transport reimbursement to go back home. The total amount will be on average 2,000 Tsh for each visit.

## Consent for long-term sample storage for future studies

We are also asking people who join this study if they will let the researchers use their blood samples for future studies. These future studies may help find new ways to prevent malaria or other diseases. If you agree, we will store your blood in the laboratory with a unique number and not with your name. Your sample will be stored for up to 25 years. We may share your test results with researchers at other organizations but we will not give them your name, address, or any information that could identify you. After the study has ended, we will remove any means to link the sample to you, and we will not be able to find your sample. If you do not wish to have your blood stored for future tests, you may still participate in our study.

Thank you very much for your time. Would you like to take part in this survey?



HOUSEHOLD COPY – Household and child – Date: \_\_\_/\_\_\_/\_\_\_

# CONSENT

- The study has been explained to me, I have been given the opportunity to ask questions concerning this study. Any such questions have been answered to my satisfaction. I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits, if any.
- I agree for me and my child/children to take part.
- I also agree that the data generated from this study and the dried blood samples stored can be used in the future for other malaria-related research.

Name of guardian/parent	Signature/Thumb print
Name of the child selected	Relationship to the child
Name of the witness	Signature
Name of interviewer	Signature

If you have any questions or clarification pertaining to this survey please feel free to ask the field workers and nurse or you may contact Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140; Dr. Alphaxard Manjurano, 0756026661;

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390]

PROJECT COPY – Household and child			
	Date://	Cluster Number:	Household Number:
	_CHILDREN COHORT FOLLOW-UP CONSENT FORM		

#### CONSENT

- The study has been explained to me, I have been given the opportunity to ask questions concerning this study. Any such questions have been answered to my satisfaction. I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits, if any.
- I agree for me and my child/children to take part.
- I also agree that the data generated from this study and the dried blood samples stored can be used in the future for other malaria-related research.

Name of guardian/parent	Signature/Thumbprint
Name of the child selected Rela	ationship to the child
Name of the witness	Signature
Name of interviewer	Signature

If you have any questions or clarification pertaining to this survey please feel free to ask the field workers and nurse or you may contact Study staff; Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140; Dr. Alphaxard Manjurano, 0756026661;

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390]

#### 3.8.5 Children cohort follow-up consent forms- (Swahili version)

#### CHILDREN COHORT FOLLOW-UP CONSENT FORM

#### <u>Utangulizi</u>

Habari ya leo. Jina langu ni \_\_\_\_\_\_\_. Ninafanya kazi na Mradi wa Kuzuia Malaria Missungwi PAMVERC. Tunafanya kazi pamoja na Ofisi ya afya ya wilaya, Taasisi ya Utafiti wa Magonjwa ya Binadamu (NIMR), Chuo Kikuu cha Kikristo cha Tiba Kilimanjaro (KCMC) na Chuo Kikuu cha Nchini Uingereza (London School of Hygiene and Tropical Medicine). Niko hapa kukuuliza maswali na kufanya vipimo kujifunza ni kwa kiasi gani kinga dhidi ya malaria inafanikiwa hapa Missungwi.

#### Dhumuni la utafiti

Kuona kama chandarua zilizogawiwa zinafanya kazi vizuri. Tungependa kujua kiwango cha maambukizi ya malaria katika watoto kwenye jamii yenu kwa kuwapima vimelea katika damu yao. Majibu yako kwa maswali yetu na matokea ya tafiti hizi yatatusaidia kujifunza kuboresha njia za kuzuia malaria katika jamii yenu na nchi nzima kwa ujumla.

#### <u>Utaratibu</u>

Kama utakubali kushiriki, tutamchagua mtoto mmoja mwenye umri kati ya miezi 6 mpaka miaka 10 kutoka kwenye kaya yako atakaye hudhulia kila mwezi katika Kliniki ya PAMVERC iliyopo katika kitongoji chako au kitongoji jirani. Tutakuuliza maswali kadhaa kuhusu mtoto wako aliyechaguliwa pamoja na homa, ugonjwa na historia ya matibabu, matumizi ya chandarua, na madhara yoyote yatokanayo na matumizi ya chandarua. Tutapima pia joto, iwapo mtoto wako ana dalili za maambukizo ya malaria, muhudumu atachukua matone machache ya damu. Zoezi zima litachukua muda wa dakika 30. Mtoto aliyechaguliwa atafuatiliwa kwa muda wa miaka miwili au hadi atakapovuka miaka 10.

Muhudumu atachukua tone la damu kutoka kwenye kidole cha mtoto kwa kutumia sindano ndogo. Tone hilo la damu litatumika kupima malaria kwa kipimo cha haraka yaani MRDT. Utambulisho wa muhusika hautaungamanishwa na sampuli za damu.

Matokeo ya kipimo cha malaria yatatolewa siku hiyohiyo. Kama mtoto atakuwa na malaria au homa, atapatiwa matibabu bure na mtabibu wa PAMVERC. Iwapo mtoto atapata nafuu, utaombwa kwenda kwenye kituo cha afya kilicho karibu kupokea matibabu mbadala kulingana na sera ya Wizara ya Afya. Kama mtoto akikutwa na malaria kali au ugonjwa mwingine, atapewa rufaa mara moja kwenye kituo cha afya kilicho karibu.

#### Athari na Faida

Mtu atakaye pimwa atapata maumivu kwa sekunde chache wakati wa kuchukua damu kutoka kwenye kidole chake. Kama kipimo kitaonyesha kwamba mtoto wako anayo malaria, au homa wakati wa zoezi hilo, atapata matibabu yanayoshauriwa na Wizara ya Afya bure. Vidonge hivi vimedhibitika kuwa ni salama na vyenye ufanisi, lakini dawa yeyote yaweza kusababisha madhara kwenye idadi ndogo ya wagonjwa. Mhudumu wa afya atajadiliana na wewe kama utahitaji dawa hiyo.

#### Uhiari na Usiri

Ni hiari yako kabisa kushiriki au kutoshiriki kwenye utafiti huu kama nilivyoelezea. Kama utakubali kushiriki, majibu ya maswali na matokeo ya vipimo yatatunzwa kwa usiri na bila kuoneshwa kwa yeyote. Kama ukikubali kushiriki, unaweza pia kuamua kutojibu maswali yeyote utakayotaka na unaweza kukataa vipimo vya damu.

#### Gharama na fidia kwa kushiriki kwenye utafiti

Hautaombwa kulipia chochote ili kushiriki katika utafiti huu. Utarudishiwa nauli yako uliyotumia kufika Kliniki au hospitali. Utapokea pia nauli ya kukurudisha nyumbani. Kiasi cha Tsh 2,000/= kitatolewa kwa kila mahudhulio.

## Ridhaa ya uhifadhi wa sampuli kwa muda mrefu kwa ajili ya tafiti za baadaye

Tunawaomba pia watu watakaoshiriki kwenye utafiti huu endapo watawaruhusu watafiti kutumia sampuli zao za damu kwa ajili ya tafiti za hapo baadaye. Tafiti hizi za baadaye, zinaweza kusaidia kupata mbinu mpya za kuzuia malaria au magonjwa mengine. Endapo utaridhia, tutahifadhi damu yako kwenye maabara kwa kutumia utambulisho maalumu usiokuwa na jina lako. Sampuli yako itahifadhiwa hadi miaka 25. Tunaweza kuwapatia majibu ya vipimo vyako watafiti wa taasisi nyingine ila hatutawapatia majina yako, anwani au taarifa yoyote inayoweza kukutambulisha. Mara baada ya utafiti kwisha, tutaondoa njia zozote zile zinazoweza kuunganisha utambulisho wa sampuli na wewe, na hatutaweza kuipata sampuli yako. Endapo hutapenda sampuli yako ya damu ihifadhiwe kwa ajili ya vipimo vya hapo baadaye, bado unaweza kushiriki kwenye utafiti.

#### Ahsante sana kwa muda wako. Je utapenda kushiriki katika utafiti huu?

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu, nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu. Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Nakubali mimi na watoto wangu washiriki pia na vyandarua vyangu kukaguliwa.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Jina Ghumba			Sahihi/Dole
Jina la watoto aliye mtoto	echaguliwa	Uhusiano wako n	а
Jina shahidi		Sahihi	la
Jina fomu	la	mtu Sahihi	aliyewasilisha 

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC,
0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

PROJECT COPY – Household and child Date://		
Date:// Cluster Number: Household Number:		
_CHILDREN COHORT FOLLOW-UP CONSENT FORM		

#### <u>Dhumuni la utafiti</u>

Kuona kama chandarua zilizogawiwa zinafanya kazi vizuri. Tungependa kujua ni kiwango cha maambukizi ya malaria katika watoto kwenye jamii yenu kwa kuwapima vimelea katika damu yao. Majibu yako kwa maswali yetu na matokea ya tafiti hizi yatatusaidia kujifunza kuboresha njia za kuzuia malaria katika jamii yeu na nchi nzima kwa ujumla.

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu, nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu. Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Nakubali mimi na watoto wangu washiriki pia na vyandarua vyangu kukaguliwa.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Jina	ahihi/Dole Ghumba
Jina la watoto aliyechaguli	waUhusiano wako na watoto
Jina la shahidi	Sahihi
Jina la mtu aliyewasilisha f	omuSahihi

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

#### 3.8.6 <u>Net Study informed consent agreement</u>

# Net Study informed consent agreement

Introduction

Good morning. My name is \_\_\_\_\_\_. I work with PAMVERC Malaria Prevention Trial Muleba. We work together with the Muleba District Health office, the National Institute for Medical Research, the Kilimanjaro Christian Medical College, London School of Hygiene and Tropical Medicine.

#### The general purpose of the survey

We would like to include you in a study to find information on the quality and durability of the LLIN (net) you have been given earlier.

We would like to confirm how long the insecticide will last on the net. This is done by testing the nets in many households in several villages to find out how long they remain effective against malaria-transmitting mosquitoes. The strength of the netting material will be also looked at.

#### <u>Procedure</u>

If you are willing to participate in the study:

- we expect you to not give away or sell the study net;
- you are free to stop using the nets at any time but we would expect you to let investigators know the reasons why you stopped using them during the follow-up survey and to allow inspection of the nets;

Your household has been selected for repeated follow-up (every 6 months for 3 years). We could take your net away for analysis. These nets will be replaced at that time. I would therefore like to have your consent to be interviewed; this will last about 20-30 minutes. During the interview, I will ask you some questions about your household, the status of the nets given to you or your family members how you use your net, and side effects if any. I will ask you to show the net to me, so I can assess its quality by counting holes in the net. I will not damage the net, and after the interview, I will return it.

#### Adverse effects, risks, and participant protection

There is a remote possibility that you may get malaria even while using nets. This might be possible due to the biting of mosquitoes outdoors or early in the night while your family is not sleeping under the net. Thus, if you suffer from fever, you should immediately approach the health staff available in your nearby health center for treatment of possible malaria, as detailed below.

We are aware that pyrethroid insecticides are being used to treat the nets in the malaria control program. Permethrin, the insecticide used on the nets, has been tested before and has not been found to have any undue adverse effects in most people at the dose found on the nets. Transitory tingling or runny nose has been recorded when nets are used for the first time when taken from their package. There is no cause for alarm as these effects pass within a day or two

#### Voluntariness and confidentiality

It is entirely your choice to take part in or not take part in this survey as I have just described it. If you agree to take part, you can also decide not to answer any of the questions that you do not want to. If at any point in time during the study you take the decision not to participate any further, you are free to do so immediately and it will have no consequences, for example, your net will not be taken back from you. However, we will want to ask you questions to find out the reason why you decided to no longer use the net. We would also expect you to retain the net until our next visit so we can inspect its condition. Your individual information will be kept private.

# Costs and compensation for participating in the study

You will not be asked to pay anything for you to participate in this study. The study will not reimburse you with any payment for taking part in the study.

Thank you very much for your time. Would you like to take part in this survey?

# Consent section

- The study has been explained to me,
- I have been given the opportunity to ask questions concerning this study. Any such questions have been answered to my satisfaction.
- I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits,
- I also agree that the data generated from this study can be used in the future for other malaria-related research if any.

I agree to take part.

Name of guardian/parent	Signature/Thumbprint
Name of the witness	Signature
Name of interviewer	Signature

If you have any questions or clarification pertaining to this survey please feel free to ask the field workers or you may contact Study staff; Mr. Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwanza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390].

# **PROJECT COPY**



Cluster Number:	Household Number:	Date:	//

# Net Study Informed Consent agreement

# Purpose of the survey

You received a new LLIN and we would like to confirm how long the insecticide will last on the net. This is done by testing the nets in many households in several villages to find out how long they remain effective against malaria-transmitting mosquitoes. The strength of the netting material will be also looked at.

#### Consent section

- The study has been explained to me,
- I have been given the opportunity to ask questions concerning this study. Any such questions have been answered to my satisfaction.
- I understand participation is voluntary and I may revoke this consent at any time without penalty or loss of benefits,
- I also agree that the data generated from this study can be used in the future for other malaria-related research if any.

I agree to take part.

Name of guardian/parent	Signature/Thumb print
Name of the witness	Signature
Name of interviewer	Signature

If you have any questions or clarification pertaining to this survey please feel free to ask the field workers or you may contact Study staff; Mr. Eliud Lukole, PAMVERC, 0766240101; Dr. Jackline Mosha, NIMR Mwanza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

If you have any questions about your rights as a study patient, or if you think your child has been injured because of this study, please contact the Chairman of the National Health Research Ethics Committee (NatHREC) on 0222 121 400/390]

#### Mkataba wa Maridhiano katika utafiti wa Chandarua

#### <u>Utangulizi</u>

Habari za leo. Jina langu ni ...... Nafanya kazi na mradi wa PAMVERC wa kuzuia malaria hapa Muleba. Tunashirikiana na Chuo Kikuu cha Tiba cha Kilimanjaro, KCMC (Kilimanjaro Christian Medical College), Chuo kikuu nchini Uingereza, LSHTM (London School of Hygiene and Tropical Medicine) na Taasisi ya Taifa ya Utafiti wa Tiba, NIMR (National Institute of Medical Research).

#### <u>Dhumuni la utafiti huu</u>

Tungependa kukushirikisha katika utafiti huu katika kutafuta taarifa za ubora na uimara wa chandarua ulichopokea.

Tunataka kufahamu in kwa muda gani viuatilifu vilivyomo katika vyandarua vinadumu kwa muda gani. Hii inafanyika kwa kuvichunguza nyandarua katika nyumba nyingi katika vijiji kadhaa ili kutambua ni kwa muda gani vinakuwa mahili dhidi ya mbu waenezao ugonjwa wa malaria. Ubora wa nyuzi pia utachunguzwa.

#### <u>Utaratibu</u>

Kama uko tayari kushiriki katika utafiti huu:

- Hatutegemei ugawe au kuuza chandarua /vyandarua ulivyonavyo
- Uko huru kuacha kutumia chandarua wakati wowote lakini tunategemea utawaruhusu watafiti kujua sababu iliyokufanya uache kutumia vyandarua/chandarua katika kipindi cha ufuatiliaji pia utamruhusu kukagua chandarua/vyandarua.

Kaya yako imechaguliwa kufuatiliwa mara kwa mara. Tutakitoa nje chandarua chako kwa uchunguzi, na kukifunga kwenye vifaa vyetu na baadaye kukirudisha ndani. Naomba kibali ili nikuhoji, na mahojiano haya yatadumu kwa muda wa dakika 20-30. Katika mahojiano hayo, nitakuuliza maswali kuhusu kaya yako, hali ya chandarua ulichopewa na kwa jinsi gani unakitumia chandarua chako. Nitakuomba unioneshe vyandarua vyote ili kutathimini ubora wake. Sitakiharibu chandarua chako. Baada ya mahojiano nitakurudishia chandarua chako.

#### Madhara na ulinzi kwa mshiriki

Kuna uwezakano (japo mdogo) wa kupata malaria hata kama unatumia chandarua. Hii inawezekana kwa sababu ya kuumwa na mbu ukiwa nje ya nyumba au wakati wa jioni kabla ya kuingia ndani ya vyandarua vyenu. Hivyo, endapo utapata homa, kwa haraka nenda katika kituo cha afya kilichopo karibu ili upate ushauri wa kitaalamu.

Tunatambua kuwa dawa za Pyrethroid zimekuwa zikiwekwa katika chandarua katika programu ya kupambana na malaria. *Permethrin,* ambayo pia ni dawa inayotumika kwenye vyandarua, imeshafanyiwa majaribio na kugundulika kwamba haina madhara kwa waliowengi katika kipimo kilichopo kwenye chandarua. Muwasho wa ngozi au pua vimeonekana kutokea wakati chandarua kinapotumika kwa mara ya kwanza. Hakuna hatari yoyote kwani huu usumbufu huisha baada ya masaa au siku moja au mbili.

#### <u>Hiari na Usiri</u>

Ni hiari yako kukubali kushiriki au kutoshiriki kwenye utafiti huu kama nilivyokwisha elezea. Kama ukikubali kushiriki unaweza kuamua usijibu maswali yote utakayotaka. Pia, utafiti unavyoendelea kwa wakati wowote ukiamua kuchukua maamuzi ya kutoshiriki tena, uko huru kufanya hivyo mara moja na hakutakuwepo na madhara yoyote, kwa mfano hutanyang'anywa chandarua chako. Ila tutapenda kukuuliza sababu za kuacha kutumia chandarua na kujitoa katika utafiti huu. Tutapenda pia utunze chandarua chako mpaka tutakapo kutembelea tena hapo baadaye ili tukikaguae na kujua ubora wake. Taarifa zako zote zitatunzwa kwa siri.

# Gharama na fidia kwa kushiriki kwenye utafiti

Hutatakiwa kulipa chochote kwa wewe kushiriki kwenye utafiti huu. Mradi hautakulipa chochote kwa kushiriki kwako kwenye utafiti.

Ahsante sana kwa muda wako. Je, utapenda kushiriki katika utafiti huu?

NAKALA YA KAYA TAREHE : \_\_\_\_/\_\_\_/\_\_\_\_

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu
- nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu.
- Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Nakubali kushiriki.

Jina .....Sahihi/Dole Ghumba..... Jina la shahidi...... Jina la mtu aliyewasilisha

fomu.....Sahihi.....

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.



# Mkataba wa Maridhiano katika utafiti wa Chandarua

#### <u>Dhumuni la utafiti huu</u>

Ulipokea chandarua mpya hivyo tunataka kuthibitisha muda ambao dawa ya kuuwa mbu iliyomo kwenye chandarua itadumu. Zoezi hili linafanyika kwa kuvichunguza vyandarua majumbani katika vijiji mbalimbali ambayo itatupa muda ambao chandarua itakaa mahili dhidi ya mbu waenezao malaria. Nguvu na uhimara wa nyuzi za chandarua pia utachunguzwa.

#### MAKUBALIANO

- Nimepata maelekezo kuhusu utafiti huu
- nimepewa muda wa kuuliza maswali kuhusu huu utafiti. Maswali yote niliyokuwa nayo yamejibiwa kikamilifu.
- Naelewa kushiriki ni hiari na waweza kuvunja makubaliano haya saa yoyote bila adhabu au kupoteza haki yoyote.
- Pia nakubali takwimu zitakazopatikana kutoka kwenye utafiti huu na matone ya damu yaliyokauka na kuhifadhiwa inaweza kutumika kwa tafiti nyingine zinazohusiana na ugonjwa wa malaria hapo baadae.

Nakubali kushiriki.

Jina	Sahihi/Dole Ghumba
Jina la shahidi	Sahihi
Jina la mtu aliyewasilisha fomu	Sahihi

Kama utakuwa na wasi wasi au swali lolote kuhusu utafiti huu, tafadhali jisikie huru kuwauliza wanaofanya utafiti au Waganga au unaweza kupiga simu kupitia kwa Mr Eliud Lukole, PAMVERC, 0766240101; Dr Jackline Mosha, NIMR Mwnza, 0754404140; Dr Alphaxard Manjurano, 0756026661;

Endapo una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, au kama unadhani wewe au mwanao amepata madhara yoyote yaliyosababishwa na utafiti huu, tafadhali wasiliana na Mwenyekiti, Tume ya Taifa ya Maadili ya Utafiti wa Afya (NatHREC), kwa simu namba +255 222 121 400/390.

# 3.9 Manuals and training materials

# 3.9.1 <u>Standard Operating Procedure: HP IPAQ 114 Classic Handheld</u>

#### MALARIA PREVENTION TRIAL: MULEBA



Basic functions and buttons

There are a number of buttons on the front and sides of the PDA unit.

a) To turn the PDA on and off, press the power button (top right button).

b) The central button set located at the front of the PDA can be used to navigate and select options within menus.

c) To open the questionnaire program (Forms 5.1) use the bottom left button.

d) The stylus is located under a flap situated in the top right-hand corner of the unit.



# The stylus

The stylus is the main tool used for selecting options and navigating programs on the PDA. The stylus can be used to tap options on the screen and to drag scroll bars to navigate through lists.



Accessing the questionnaires

To open the questionnaires either:

Press the button situated on the bottom left-hand corner of the PDA (Call Open questionnaire)

or

Using the stylus select the start menu the select Forms 5.1 on the programs menu [Start – Forms 5.1]

Questionnaire main menu

To start a new questionnaire first open the questionnaire program (see 3). On the main menu screen displayed select the 'MULEBA FORMS' button using the stylus.



To open a new questionnaire select the 'Add a Household' button.

To view questionnaires that have already been completed using the stylus select the 'Review Households' button.



The household questionnaire

Once a new questionnaire has been started the user can answer questions in several ways:

Selection lists allow the user to choose options from a list using the stylus. The example below shows you how the different lists are presented.



Typed answers can be completed by using the stylus to select the answer space and then selecting the keyboard option at the bottom of the screen When the answer has been completed the keyboard can be removed by tapping this icon again.

Address	42789
Resident number	Select one 🕽
Resident name – give initials for sur name (press keyboard icon	first name and below to enter)
End Previous	Next 1
	7 8 9 0 - = 🕈
CAP a s d f o t	
Shift z x c v b	n m , . / ←
Cti áü ` \	↓ ↑ + →
	-

Yes or No answers can be selected using the stylus. The selected answer will be highlighted.

MRC-baseline-Main1.0			
Household possess	sions		_
Electricity?	Yes	No	
Radio?	Yes	No	
Mobile phone?	Yes	No	
Bicycle?	Yes	No	
Motorbike?	Yes	No	
Car/truck?	Yes	No	
Canoe/boat?	Yes	No	
End Previous Next			

Some questions are linked to a previous answer and will only appear if the answer has been selected. For instance 'Did you use the net last night' if the answer is NO the question 'Why was the net not used' will appear else it will stay hidden and you won't see it. This type of question is displayed in red.

When all the questions on a page have been completed the user can use the 'next' button to proceed to the next page.

Identification and Interview information section

These three pages in the PDA correspond to the first page of the questionnaire about household identification.

MRC-Post1-Main1.1	MRC-Post1-Main1.1	MRC-Post1-Main1.1	
POST 1 SURVEY	Household Address	Hamlet code -Unassigned-	
v5.0	Check Unique Address	Ward	
	+-1718191	Village	
Date - Set Date -	Del 4 5 6	Hamlet	
-Unassigned-	00 1 2 3	Cluster	
End (Previous) (Next)	End (Previous) (Next)	End (Previous) (Next)	

After the household number is entered you will have to press the "Check Unique Address" button. The address should be unique.

If the following message appears "You must enter unique values in the primary key fields" this means that an other house has been entered with the same number. You should first select the "ok" then look at the HH number you entered and correct it if you can.

If the household number you entered is the good one then press the "Check Unique Address" a second time and select the delete button. This will erase the record. Then select the review HH button find the record with the same number and change the number accordingly (if you can't find the good household number you will enter 999).

You will have to start again a new questionnaire for the house you are in.

Then you go to the Interview information page that asks the number of visits and the result.

MRC-baseline-Main1.0		
Inteview Information		
Total number of visits 1 2 3 4 5		
Result of visit (Lookup)		
Comments		
End (Previous) (Next)		

Result of visit question: As per the paper questionnaire you will have different possibility

When you select 'consent given' you will continue to fill out the questionnaire and press next to answer the following questions.

If you answer 'ineligible', 'refused', 'dwelling not found' or 'Dwelling vacant for survey duration', as with the paper questionnaire you will end the questionnaire. When you press the next button to finish the questionnaire the PDA will ask you to submit the record. If you are sure you want to save/submit the form select 'Yes'. The PDA will ask you a second time and you will tick the box. The questionnaire is then submitted.

MRC-baseline-Main1.0	MRC-baseline-Main1.0
Submit record?	Are you sure you want to submit the record?
(End) (Previous) (Next)	(End) (Previous) (Next)

When you arrive at a house closed you will select return later. A message will appear to ask you to end the questionnaire. When you go back to the houses for a second visit you will select the 'review household' button a list of all the houses that have been done with the result of the visit is displayed. You select the one you return to, then press next up to the interview information pages and change accordingly. For the number of visits you will select 2 if it is the second visit and change the result of the visit according to what you find, either there is still nobody and in this case, select 'Dwelling vacant for survey duration' or 'consent given' or...

A questionnaire should always be submitted before the end of the day otherwise it will stay in the PDA and won't be able to be downloaded to the computer.

# Adding residents

Each resident in a house can be added to the questionnaire. To access the residents' questions click the 'Muleba-residents' button when the Residents questions page is reached:

MRC-baseline-Main1.0		
Press button to go to residents section		
(MRC-baseline-Residents1.0)		
If residents section is complete, press next to go to questions about Socio- economic Status (SES)		
End (Previous) (Next)		

A screen appears then click the 'add' button to add a resident and follow the questionnaire until completed. If there are more residents in the household to include then click the 'add' button again. If all residents have been accounted for click the 'done' button. When returning to the Residents questions page click the 'next' button to proceed.



<u>Don't press the 'add' before being sure that you have an additional person living in the</u> <u>house.</u> If you already press 'add' and find out there is no additional resident select the 'end' button a message will appear to ask if you want to delete the record press 'yes'. The delete message will only appear if you don't enter the resident number. In case you already entered it end the record (it will remain) and you will notify the project manager when back.

The selection of the children is not done at this step which is different from the paper copy but will be asked at the end of the questionnaire.

Socio economical status

After the resident section, you will have to fill in the section on the socio-economical status. Answer the questions and press next to go to the next page.

MRC-baseline-Main1.0
Socio-economic Status
Has household head ever attended
Lookup)
What is the highest level of school attended by the household head? Lookup
(End)(Previous)(Next)

#### Bed Net campaign

Questions will be asked about the overall campaign evaluation

MRC-Post1-Main1.1 Overall net campaign evaluation
In the past six months, have you seen or heard any messages about malaria? 
End (Previous) (Next)

IRS and section others

After the bed net campaign, you will have to ask some questions on the side effects of Net and also on IRS and other preventive measures and treatments.

MRC-Post1-Main1.1 Indoor Residual Spraying Does the household have a sticker showing date of recent IRS application in 2015 (observe) 	MRC-Post1-Main1.1 n February 2015, has anyone sprayed the interior walls of your dwelling against mosquitoes? 	MRC-Post1-Main1.1 Other Has the household ever used aerosol can/coil/repellent/ herbs or plants to protect themselves against mosquitoes? 
End Previous (Next)	(End) (Previous) (Next)	End (Previous) (Next)

# Random selection of children

The selection of person (children) is done after the section "Other" and before the net section. To select the appropriate person you can view the resident list by selecting the 'Review eligible HH members' button and see the line number corresponding to the children.

MRC-Post1-Main1.1
Random Selection
Review eligible HH members
End (Previous) (Next)

Select the line corresponding to the children this will open the resident information. In the select one list choose select children.



Tick the box if the children have been selected. End the questionnaire

If there is another selected child repeat steps 2 and 3



#### **Bed Net sections**

This section has one question on the total number of net the household owns. If they own one net or more you will be directed to each net section.



Every net in a house can be added to the questionnaire. If you are team A, B, or C to access the standard bed net questions click the section button 'MRC-Post1-BedNet-each-net1.1". Team D should select the long bed net section "MRC-Post1-BedNet\_Long1.1".

MRC-Post1-Main1.1
Team A, B and C seletc the Bed Net Each net study button
(MRC-Post1-BedNet_each-net1.1)
Team D select the BedNet Long Study
(Mikt-Post1-BedNet_Jong1.1)
End (Previous) (Next)

Then as the resident section select the 'add' button to enter information for a new net



#### Comments page

On this page write any comments

MRC-baseline-Main1.0
Other comments
End (Previous) (Next)

Completing the questionnaire

When all household and resident questions are complete the questionnaire can be completed by following the onscreen instructions. When asked to "complete the form?" select the 'Yes' button. On the next page check the "Submit completed form?" box (see 6)

Further new household questionnaires can then be started and completed (See 4).

#### Errors, mistakes, and troubleshooting

An error message "You must enter unique values in the primary key fields" may appear if the user attempts to enter a record for a house or resident who has already been entered into the system. In this instance press ok and then by selecting previous check the address of the resident or the net identification number for mistakes.

Most errors and mistakes can be resolved by returning to the question with the incorrect answer and making a correction. Make sure that when you change some question answers you change also answers for related questions.

If a questionnaire cannot be corrected then the 'end' button can be selected. Then you can re-open by opening the review HH button.

Some questions have a limited set of possible answers. If an error message is shown please review the answer to the question to identify possible errors or typing mistakes.

The questions that are shown in the questionnaire depend on answers already given. For instance: only when the head of household goes to school the school level will be asked.

If an answer cannot be selected on the screen it is due to the question being unavailable based on previous answers. For instance if 'No bed net' is selected then 'Number of holes in a bed net' cannot be completed.

Dos and Don'ts

Do:

Always finish a questionnaire. Fill in as many answers as possible and complete questions for all residents. Complete and submit the questionnaire when this has to be done.

Work from the top of the page to the bottom. Start with the first question and work down the page.

Turn the unit off when not in use to conserve power.

Don't:

Click the 'end' button to resolve all problems.

Use any object, apart from the stylus, to tap the screen. Using alternate objects, e.g. pens, may damage the PDA.

Change settings on the PDA

# 3.9.2 <u>Standard Operating Procedure: TECNO DroiPad 7D Tablet</u>

# MALARIA PREVENTION TRIAL: MISUNGWI



Basic functions and buttons

# There are a number of buttons on the front and sides of the TABLET unit.



a) To turn the TABLET on and off, press the power button (second top right button).

b) The central icon set located at the front center bottom (Apps) of the TABLET can be used to navigate and select options within menus.

c) To open the questionnaire program (ODK Collect) tap Apps Icon then ODK Collect app.

Accessing the questionnaires

To open the questionnaires:

Tap the icon of the app situated on the bottom center of the TABLET.

Swipe left to see the ODK Icon and tap it to open the ODK collect app to open/run it.



Questionnaire main menu

To start a new questionnaire first tap the ODK collect icon.

On the ODK main menu, you will see several operations that the app performs.

On the main menu screen displayed select "FILL BLANK FORM" by tapping it. This will display a list of available forms/questionnaires.

To open a new questionnaire select by tapping on the questionnaire needed in our case it is the 'Census (Mapping) Form'.

To view questionnaires that have already been completed select by tapping on the 'EDIT SAVED FORMS' button.

To send questionnaires that have already been completed select by tapping on the 'SEND FINALIZED FORMS' button.

To view questionnaires that have already been sent select by tapping on the 'VIEW SENT FORMS' button.

To delete forms that are no longer of use questionnaires that have already been sent select by tapping on the 'DELETE SAVED FORMS' button.

<b>E</b>	1 16% 22:16
📑 Main Menu	
ODK Collect v1.5.0 Data collection made easier	
Fill Blank Form	
Edit Saved Form	
Send Finalized Form	
View Sent Form (2)	
Get Blank Form	
Delete Saved Form	

Census (Mapping) questionnaire.

Once a new questionnaire has been started the user can answer questions by typing answers or making choices and then swiping left to access the questions:

Typed answers can be completed by using the keyboard at the bottom of the screen When the answer has been completed swipe left for the next question.

Yes, No and I Don't Know answers can be selected by tapping on the right answer. The selected answer will be highlighted.

Some questions are linked to a previous answer and will only appear if the answer has been selected. For instance 'watoto wa miaka 0-5' if the answer is 'NDIO' the textbox to fill the number of children within that age range will appear otherwise it will take you to 'Watoto wa maiaka 6-10'.



When all the questions of a page have been completed the user swipes left to proceed to the next page.

Identification and Interview information section

These pages in the TABLET correspond to the first page of the questionnaire about household identification.

Record the GPS coordinates of the location you are as accurate as possible by at least 5m.

<b>—</b>			1 🗍 74%	22:20
Census(Mapping)	Form	l	34,	1
You should allow your of accuracy before rec GPS coordinates can only be	Tablet to rea ording the co collected when	ch at leas cordinate.	t 5m (~1	6ft)
St	tart GeoPoi	nt		
	0	$\triangleleft$		

Enter the initials of your name e.g. Eliud Lukole will be Eli

If the letters are filled correctly and have confirmed that it's your identification should select 'OK.please continue'.

If the following message appears 'NAMBA YA ANEYEHOJI sio sahihi' this means that the letters of identification that have been entered are not correct you should go back by swiping right to go and fill in the correct identification letters.

1 🗐 💭 🗊 🗍 8% 15:46	1 🖪 📾	1 🖪 🕮 👘 15:47
Census(Mapping) Form	Census(Mapping) Form	Census(Mapping) Form
1. Herufi za kwanza za majina ya mdodosaji:	Jina lako ni <mark>Eliud</mark>	NAMBA YA ANAYEHOJI Mgf sio sahihi
Eli	SK. Please continue.	
Eliminated Elite Eligible		
$Q^1 W^2 E^3 R^4 T^5 Y^6 U^7 I^8 O^9 P^0$		
ASDFGHJKL		
🛧 Z X C V B N M 🖾		
123 ,		

a. b. c.

#### HOUSEHOLD INFORMATION. (Utambuzi wa nyumba):

You will have to start by selecting a division from the list which will then take you to the list of the wards that are contained in that specific division.

From the list of wards, you will select a ward which will bring you to the list of villages contained in that specific ward selected.

Now select a village which after selection will also bring you to the list of hamlets of that specific village selected.

After all these selections you will be prompted to confirm if the hamlet you have selected is correct, if it's correct check/tick 'ok. Please continue by tapping it and swipe left to continue.

■ N 🖬 · · · · E 18% 16:11	🖪 N 🗃 🗌 18% 16:12	🖬 N 🗃 🗌 🗍 16:12	🖬 N 🗃 🕺 18% 16:12
Census(Mapping) Form	Census(Mapping) Form	Census(Mapping) Form	Census(Mapping) Form
<u>Utambuzi wa nyumba</u>	3.Kata	4.Kijiji	5.Kitongoji
2.Tarafa	NHUNDULU	Mwamagili	Mwamagili
	○ ISENGENGEJA	O Mwagiligili	O Kadoto
INONELWA	O MISASI	O Mwawile	O Ilula
O MBARIKA	OBUSONGO		O Mwandu
	O GULUMUNGU		🔿 Ilangafipa
O USAGARA	⊖ SHILALO		
	OBUHINGO		
	○ KASOLOLO		
	⊖ KIJIMA		

Otherwise, if it is wrong go back by swiping right and make the right choices of divisions, wards, and villages to get the correct hamlet.

Continue by filling in the household number which should be three digits. You will be asked to make sure that the household number is correct, if yes tap 'ok. Please continue and

continue to the next question. If wrong go back by swiping right and fill in the right household number.

Census(Mapping) Form		8% 16:12	Census(Mapping) Form	<u>∩</u> £ 18	% 16:13 
7.Namba ya nyumba Tarakimu 3			Namba ya nyumba ni		
123			123		
			Hakikisha ni sahihi kabla ya kendelea		
			CK. Please continue.		
	1				
	$\triangleleft$				

By tapping 'ok. Please continue' It will display a household ID which is a combination of clustereid and household no. You will be asked to make sure that the Household ID is correct before proceeding to the next question if yes continue.

		🗊 🗵 18	% 16:13
Census(Mapping) Form		94	1
Household ID ni			
001123			
Hakikisha ni sahihi kabla ya kendele	a		
🗹 OK. Please continue.			
	$\bigtriangledown$		

Additional Information: Household Personnel information.

To be provided by the person interviewed. He/she has to say what is the relationship status and you will choose among the listed relations. Then type the name of the head of the household.

Census(Mapping) Form	1 26°	k 17:29	Census(Mapping) Form		1 26 1	% 17:29
<u>Taarifa</u>			9.Jina la mkuu wa kaya			
8.Nani aliyetoa taarifa			L			
🔿 Mwenye kaya/Mwanafamilia						
Jirani						
O Mwenyekiti/CCA						
				$\triangleleft$		

Enter the total number of people in that particular household if known.

Otherwise, fill in 999 and confirm the number of people in that particular household is unknown by tapping ok to continue.

Confirm if that's the total number of people in that household and proceed.

Census(Mapping) Form	<ul> <li>☐ 26% 17:30</li> <li>☐ 1</li> </ul>	Census(Mapping) Form	☐ 25% 17:34	Census(Mapping) Form	<ul> <li>■ 25% 17:34</li> <li>■ ■ ■</li> </ul>
10.Idadi ya watu katika kaya (999 l	kama hajui)	10.ldadi ya watu katika kaya (999 999	kama hajui)	Je, imeshindikana kujua watu wat Veneshindikana kujua watu wat Veneshindikana kujua watu watu watu watu watu watu watu wa	naoishi katika kaya hii?
Census(Mapping) Form	25% 17:34	Census(Mapping) Form		17:34	$\bigtriangledown$
10.ldadi ya watu katika kaya (999 k 23	kama hajui)	Je, watu wanaoishi katika kaya	nii ni 23 ?		
			4		

Filling a total number of children in the particular Household.

Filling number of children in a household is grouped according to different age ranges

Each group age- range will have three options,

Ndiyo – This will allow you to fill the number of children in that particular age group range if chosen

Hapana- this will be chosen if there are several children in that particular age group range.

Sijui- This will be chosen if the number of children in that particular age group range is unknown.

		1 1 749	6 05:40
Census(Mapping) Form		<u>я</u>	i.
Watoto wanaoishi kwenye	kaya		
11. Watoto wa miaka 0-5			
O Ndiyo			
$\bigcirc$ Hapana			
⊖ Sijui			
	1		
	$\checkmark$		

Upon completion of filling in the total number of children in that particular household the form will calculate and if the total number of children is greater than total the number of people of people in that particular household then you will be required back to question ten and fill every information given to you careful and correctly otherwise you will not be able to continue till the information given and recorded is correct and precise.



If the information after the calculation does not require you to go back to the question. One has to make sure that the information given is correct by reading it.

THANK THE PERSON FOR PARTICIPATING AND GIVING YOU HIGHER TIME TO COMPLETE THE QUESTIONNAIRE.



Dos and Don'ts

Do:

Always finish a questionnaire. Fill in as many answers as possible and complete questions for all residents. Complete and submit the questionnaire when this has to be done.

Work from the top of the page to the bottom. Start with the first question and work through to the last page.

Turn the unit off when not in use to conserve power.

Don't:

Click the 'end' button to resolve all problems.

Use any object to tap the screen. Using alternate objects, e.g. pens, may damage the TABLET.

Change settings on the TABLET

# 4 Additional files for Chapter 4

#### 4.1 Survivorship and attrition of cohort nets by age and arms with and without Indoor Residual Spraying (IRS) (data from longitudinal survey)

With/without IRS	Study arms	with IRS, (Number	of nets=381)	Study arms w	ithout IRS, (Numb	er of nets=376)	p-value comparison between	
Net age	12 months	24 months	36 months	12 months	24 months	36 months	and 36 months respectively	
Nets labelled in visited households	N=315	N=304	N=345	N=340	N=317	N=273		
Attrition rate-category1: % (95% CI)	4.8 (2.7-8.3)	37.8 (25.4-52.1)	61.2 (60.5-61.8)	2.4 (3.0-15.3)	28.7 (13.9-50.0)	57.1 (33.4-78.0)	p=0.094, p=0.016, and p=0.313	
Attrition rate-category2: % (95% CI)	7.3 (6.3-8.5)	11.5 (8.5-15.5)	14.8 (9.6-22.0)	5.6 (4.9-6.3)	12.9 (4.0-34.4)	11.7 (8.5-15.9)	p=0.371, p=0.589, and p=0.268	
Attrition rate-category3: % (95% CI)	0.3 (0.0-4.3)	1.0 (0.4-2.2)	0 (0-0)	0.3 (0.0-3.9)	0.6 (0.6-0.7)	0 (0-0)	p=0.957, p=0.620, and p=N/A	
Missing nets*	66	77	36	36	59	103		

Attrition rate-category1: for nets that have been destroyed or disposed of due to wear and tear (poor condition) in surveyed households; Attrition ratecategory2: for nets not available for sleeping under for reasons other than poor fabric integrity (given away, stolen, sold or used in another location, withdrawn by PAMVERC staff) in surveyed households; Attrition rate-category3: for nets used for other purposes in surveyed households; \* Missing nets from households that were not interviewed due to either (dwelling vacant, a dwelling not found, and refused) and were not included in the denominator when calculating survivorship and attrition

# 4.2 The proportion of net still present in the house and in serviceable condition (=functional survival) by net product and time point and median survival in years

Not product	Perc	Median survival in years		
Net product	12 months	24 months 36 months		(95% CI)
Standard LLIN (Olyset net)	88.0 (85.4-90.1), N=329	42.4 (35.9-49.3), N=308	17.9 (14.7-21.5), N=309	1.85 (1.67-2.06), N=348
PBO LLIN (Olyset plus)	86.7 (65.2-95.8), N=326	37.2 (18.5-60.7), N=313	15.4 (4.8-39.7), N=309	1.63 (1.38-1.87), N=368

p-Value for the comparison between 2 nets functionally surviving, p=0.7971, p=0.5371, and p=0.6929 at 12, 24 and 36 months, respectively

#### 4.3 Cox regression analysis presenting unadjusted and adjusted Hazard ratio

Net product	Total net	Number of events = net	Unadjusted Hazard ratio	*Adjusted Hazard ratio
		lost	(95% CI), p-value	(95% CI), p-value
Standard LLIN (Olyset net)	348	276 (79.3%)	1.0	1.0
PBO LLIN (Olyset plus)	368	301 (81.8%)	1.13 (0.86-1.48), p=0.39	1.14 (0.96-1.35), p=0.15

\*Adjusted for IRS (with or without IRS)

	Longitudinal survey					Cross-sectional survey												
	12 m	onths	24 m	onths	36 m	onths	4 mc	onths	9 ma	onths	16 m	onths	21 m	onths	28 m	onths	33 m	onths
	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset	Olyset
LLIN type	net	Plus	net	Plus	net	Plus	net	Plus	net	Plus	net	Plus	net	Plus	net	Plus	net	Plus
	(N=270)	(N=256	(N=159)	(N=165)	(N=75)	(N=86)	(N=113)	(N=65)	(N=95)	(N=83)	(N=126)	(N=106)	(N=105)	(N=107)	(N=139)	(N=88)	(N=72)	(N=57)
Geometric mean nu	mber of h	oles by zo	one															
Zone1: Upper	3.1	2.5	7.3	5.9	7.3	9.2	2.4	2.0	2.6	2.2	3.7	2.9	3.2	3.2	4.5	3.3	5.5	3.5
Zone2: Mid-upper	3.7	3.1	7.9	7.4	7.4	9.8	2.6	1.9	2.6	2.7	5.7	3.2	5.1	2.8	4.5	2.8	7.0	4.7
Zone3: Mid-lower	5.3	5.0	7.5	6.5	8.6	7.0	4.3	2.8	4.8	3.5	6.2	4.2	6.5	3.8	5.3	3.7	7.0	7.6
Zone4: Bottom zone	6.0	6.3	6.8	7.4	5.7	7.9	4.0	3.3	5.7	4.8	4.9	4.5	7.1	6.3	4.4	5.9	8.4	6.3
Roof	2.8	2.2	5.1	5.7	7.7	4.2	1.7	1.0	1.8	2.5	2.7	2.4	2.6	3.2	3.0	3.1	5.1	3.5
Geometric mean nu	mber of h	oles by si	ze															
Size1:(0.5-2 cm)	10.4	8.6	17.9	16.3	16.5	22.9	5.1	3.7	5.2	5.0	8.4	6.9	10.9	8.3	8.4	8.0	14.1	10.9
Size2: (2–10 cm)	3.2	2.8	4.7	4.9	6.0	6.1	2.3	1.7	3.1	2.7	4.5	3.0	4.1	3.2	3.2	3.6	6.2	4.9
Size3: (10-25 cm)	1.8	1.9	2.5	2.9	2.6	3.2	1.8	1.6	2.3	2.3	2.2	1.6	2.4	1.5	1.6	2.1	3.1	2.3
Size4 (> 25 cm)	1.2	1.7	1.9	2.7	2.4	2.6	1.5	1.1	1.7	1.7	1.5	2.2	1.8	1.4	2.0	1.9	2.7	1.9

# 4.4 Mean (geometric) number of holes by zone (location) and by size

NB: Standard LLIN (Olyset Net), PBO LLIN (Olyset Plus)

4.5	Median	survival	of the	nets	by study	' arms
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Net product	Median survival in years (95% Cl), N	p-values for Log-rank test for equality of survivor functions								
Comparison between net arms regardless of IRS status										
Standard LLIN arms (Olyset net)	1.85 (1.67-2.06), N=348	p=0.1487								
PBO LLIN arms (Olyset plus)	1.63 (1.38-1.87), N=368	p 0.2.07								
Comparison between IRS arms regardless o	of net type									
Non-IRS arms	1.89 (1.83-1.99), N=356	n=0.0103								
IRS arms	1.62 (1.38-1.83), N=360	p=0.0103								
Comparison between the four arms										
Standard LLIN (Olyset net) without IRS	1.89 (1.67-2.05), N=179									
Standard LLIN (Olyset net) with IRS	1.83 (1.40-2.08), N=169	p=0.0036								
PBO LLIN (Olyset plus) without IRS	1.97 (1.65-2.07), N=177	p 0.0000								
PBO LLIN (Olyset plus) with IRS	1.40 (1.21-1.63), N=191									

4.6 Kaplan-Meier survival estimates



# 5 Additional files for Chapter 5: The effect of Dual-AI LLINs durability on malaria prevalence and incidence

		Physical properties									
LLIN brand	netting fabric)	Fibre	Denier	Bursting strength	Dimensional stability*	Netting mesh size	Net dimensions				
Interceptor®	Alpha-cypermethrin 200 mg	Polyester	100	≥405 kPa	≤5%	24 holes/cm <sup>2</sup>					
Interceptor <sup>®</sup> G2	Alpha-cypermethrin 100 mg + Chlorfenapyr 200 mg	Polyester	100	≥405 kPa	≤5%	24 holes/cm <sup>2</sup>	Length: 180				
Royal guard®	Alpha-cypermethrin 220 mg + Pyriproxyfen 220 mg	Polyethylene	120	≥400 kPa	≤5%	20 holes/cm <sup>2</sup>	Width:160cm Height: 180cm				
Olyset <sup>®</sup> Plus	Permethrin 800 mg + PBO 400 mg	Polyethylene	150	≥250 kPa	≤5%	6 holes/cm²					
*Dimensional stability	of netting to washing (shrinkage/	expansion in botl	h directior	ns)							

#### 5.1 Characteristics of the study nets distributed as part of the project in January 2019



5.2 Study nets in good, damaged, and too-torn condition (data from cross-sectional and cohort nets)
Hole surface area (survey: net		Std.	Bonferroni	
type)	Mean	Err.	Groups*	95% CI
12months: Pyrethroid (PY)-LLIN	340	111.72	А	221.82-458.61
12months: Chlorfenapyr-PY LLIN	355	102.14	А	237.02-473.22
12months: Pyriproxyfen-PY LLIN	527	121.49	AB	300.27-752.85
24months: Pyrethroid (PY)-LLIN	755	108	ABC	578.19-932.05
12months: PBO-PY LLIN	990	120.99	BCD	742.84-1238.14
24 months: Chlorfenapyr-PY LLIN	994	111.53	BCD	784.35-1203.8
30 months: Pyrethroid (PY)-LLIN	1039	126.59	BCD	818.87-1259.36
24months: Pyriproxyfen-PY LLIN	1114	113.12	CD	872.47-1355.44
36months: Pyrethroid (PY)-LLIN	1242	104.46	CD	918.67-1564.86
36months: Pyriproxyfen-PY LLIN	1301	133.37	CDE	1004.88-1597.98
30 months: Chlorfenapyr-PY LLIN	1358	133.7	CDEF	1122.7-1592.31
36months: Chlorfenapyr-PY LLIN	1325	101.4	DE	1007.21-1642.58
24 months: PBO-PY LLIN	1621	138.29	DEF	1116.51-2126.07
30months: Pyriproxyfen-PY LLIN	1513	147.73	DEF	994.3-2031.84
30 months: PBO-PY LLIN	2000	175.12	EF	1507.85-2492.16
36months: PBO-PY LLIN	2060	162.33	F	1507.07-2612.17

5.3 Multiple comparisons of the mean surface area of the holes in the study nets between net types and age

\*Means sharing a letter in the Bonferroni Groups label is not significantly different at the 5% level.



# 5.4 Mean holes per study net per survey by zones (data from cross-sectional survey)



5.5 The mean height of the study net at t0, t30, and t36

## 5.6 Source of nets in the study area

Variable	12 months	24 months	30 months	36 months
% Trial nets distributed in January 2019 (n)	63.99 (1926)	49.46 (1243)	44.98 (775)	34.39 (1122)
% School Net Program (n)	9.7 (292)	8.4 (211)	12.13 (209)	27.28 (890)
% Antenatal clinic/immunization program (n)	15.51 (467)	29.17 (733)	35.4 (610)	28.65 (935)
% 2015 Universal Campaign (n)	1.1 (33)	1.31 (33)	0.7 (12)	0.34 (11)
% Other faith-based programs (n)	2.29 (69)	8.24 (207)	2.15 (37)	4.72 (154)
% Purchased full price (n)	0.86 (26)	1.39 (35)	2.96 (51)	2.57 (84)
% Received for free by relatives (n)	0.5 (15)	0.96 (24)	0.52 (9)	0.95 (31)
% Don't know the source (n)	6.05 (182)	1.07 (27)	1.16 (20)	1.1 (36)

	Univariable analysis		Multivariable analysis				
Covariate	% infected (N)	Crude OR	95% CI	p- value	Adjusted OR	95% CI	p-value
Condition of net							
Not using any net	46.1 (993)	1 (Ref)			1 (Ref)		
Too-torn study LLINs	28.3 (516)	0.47	0.37-0.61	<0.001	0.60	0.45-0.80	0.001
Damaged study LLINs	25.4 (429)	0.40	0.31-0.53	<0.001	0.56	0.41-0.77	<0.001
Good study LLINs	24.6 (733)	0.33	0.26-0.42	<0.001	0.56	0.42-0.75	<0.001
Study arm							
Pyrethroid (PY) LLIN	40.9 (729)	1 (Ref)			1 (Ref)		
Chlorfenapyr-PY LLIN	23.8 (748)	0.47	0.27-0.79	0.005	0.40	0.24-0.69	0.001
Pyriproxyfen-PY LLIN	35.3 (632)	0.78	0.45-1.30	0.318	0.65	0.38-1.12	0.117
PBO-PY LLIN	34.5 (562)	0.76	0.46-1.32	0.352	0.68	0.40-1.17	0.161
Cross-sectional survey							
12 months post-intervention	20.8 (816)	1 (Ref)			1 (Ref)		
24 months post-intervention	41.4 (865)	2.93	2.32-3.70	<0.001	2.92	2.27-3.75	<0.001
36 months post-intervention	36.9 (990)	2.38	1.89-2.99	<0.001	1.81	1.40-2.34	<0.001
Children age							
0-4 years	17.0 (870)	1 (Ref)			1 (Ref)		
5-10 years	38.8 (1174)	3.26	2.60-4.10	<0.001	3.27	2.57-4.15	<0.001
11-14 years	46.1 (627)	4.67	3.62-6.03	<0.001	4.70	3.58-6.17	<0.001
Socio-economic status							
Lowest	35.5 (901)	1 (Ref)			1 (Ref)		
Middle	35.2 (887)	1.01	0.82-1.26	0.892	0.97	0.76-1.23	0.773
Highest	29.6 (883)	0.79	0.63-0.98	0.034	0.67	0.51-0.88	0.004
Eaves							
Yes	40.0 (893)	1 (Ref)			1 (Ref)		

5.7 Association between sleeping under different net physical conditions and malaria prevalence in children aged 6 months to 14 years in crosssectional surveys

Not	30.2 (1778)	0.65	0.54-0.79	<0.001	0.72	0.58-0.90	0.005
Household study net coverage							
Too few (<=50%)	45.6 (800)	1 (Ref)			1 (Ref)		
Moderate/high (>50%)	27.4 (1775)	0.46	0.38-0.55	<0.001	0.69	0.55-0.88	0.003

\*Household study net coverage= proportion of sleeping spaces in the household used last night covered by study net

5.8 Association between net physical condition and malaria prevalence (in children cohort survey) in children aged 6 months to 10 years at the end of the follow-up period

Condition of the net	Odds Ratio	95%CI	p-values
Good	1 (Ref)		
Damaged	1.09	0.86-1.38	0.4689
Too-torn	1.40	1.13-1.73	0.0022
Net type			
Pyrethroid (PY)-LLIN	1 (Ref)		
Chlorfenapyr-PY LLIN	0.83	0.46-1.52	0.5526
Pyriproxyfen-PY LLIN	0.32	0.17-0.59	0.0002
PBO-PY LLIN	0.63	0.35-1.15	0.1337
Cohort year			
End of year1	1 (Ref)		
End of year2	6.38	5.15-7.91	0.0000
Age group			
0-4yrs	1 (Ref)		

## 5.9 Time people get inside the house and close the main doors

time went to sleep	Chlorfenapyr-PY LLIN	PBO-PY LLIN	Pyriproxyfen-PY LLIN	Pyrethroid (PY) LLIN
% before21hrs (n)	28.82 (441)	27.73 (353)	28.99 (409)	27.06 (417)
% after21hrs (n)	71.18 (1089)	72.27 (920)	71.01 (1002)	72.94 (1124)

### 5.10 Interaction between net physical condition and net type

Covariate	% infected (n/N)	Adjusted OR	95% Cl p-value					
Interaction between net condition and net type								
Good: PY-LLIN	34.05 (79/232)	1 (Ref)						
Damaged: PY-LLIN	31.82 (42/132)	1.01	0.58-1.77 0.9631					
Too-torn: PY-LLIN	35.07 (47/134)	0.99	0.57-1.73 0.9748					
Good: Pyriproxyfen-PY LLIN	23.13 (34/147)	0.63	0.32-1,27 0.2003					
Damaged: Pyriproxyfen-PY LLIN	30.43 (28/92)	0.77	0.37-1.62 0.4961					

Too-torn: Pyriproxyfen-PY LLIN	33.33 (39/117)	0.86	0.43-1.73	0.6762
Good: PBO-PY LLIN	23.81 (30/126)	0.70	0.35-1.42	0.3235
Damaged: PBO-PY LLIN	21.92 (16/73)	0.52	0.23-1.19	0.1209
Too-torn: PBO-PY LLIN	25.64 (30/117)	0.64	0.31-1.31	0.2234
Good: Chlorfenapyr-PY LLIN	16.23 (37/228)	0.45	0.23-0.87	0.0170
Damaged: Chlorfenapyr-PY LLIN	17.42 (23/132)	0.43	0.20-0.89	0.0228
Too-torn: Chlorfenapyr-PY LLIN	20.27 (30/148)	0.47	0.23-0.96	0.0396

### 6.1 Malaria prevalence in non-net users and users (of study nets and other nets)

Study arm	Covariates	12 months	18 months	24 months	30 months	36 months
	Users of other nets	29.3% (78/266)	47.6% (155/326)	40.9% (164/401)	44.5% (138/310)	27.3% (133/488)
group	Users of study nets	29.8% (208/698)	50.0% (333/666)	43.7% (258/591)	50.3% (195/388)	32.8% (110/335)
8.000	Non-net users	41.0% (64/156)	65.3% (154/236)	61.7% (127/206)	67.4% (174/258)	61.9% (164/265)
	Users of other nets	9.2% (21/228)	37.0% (104/281)	19.5% (77/394)	35.3% (122/346)	18.8% (96/510)
group	Users of study nets	14.9% (110/737)	38.4% (260/677)	21.8% (132/607)	34.2% (123/360)	18.9% (60/318)
8.000	Non-net users	28.5% (45/158)	50.2% (144/287)	43.2% (117/271)	56.3% (191/339)	33.2% (105/316)
	Users of other nets	13.7% (40/293)	37.2% (148/398)	34.9% (214/614)	36.1% (181/501)	25.4% (149/587)
piperonyi butoxide group	Users of study nets	19.8% (128/648)	40.4% (199/493)	39.4% (152/386)	50.5% (94/186)	23.6% (33/140)
bacexiae 81 oap	Non-net users	29.9% (38/127)	57.6% (155/269)	56.2% (146/260)	69.8% (213/305)	48.1% (154/320)
. c	Users of other nets	17.8% (44/247)	50.3% (174/346)	33.8% (179/529)	34.9% (139/398)	20.9% (118/565)
group	Users of study nets	19.4% (125/644)	45.5% (250/549)	35.3% (165/468)	36.0% (110/306)	27.6% (53/192)
8.000	Non-net users	35.4% (63/178)	61.9% (159/257)	49.0% (128/261)	59.0% (177/300)	44.7% (131/293)
	Users of other nets	17.7% (183/1034)	43.0% (581/1351)	32.7% (634/1938)	37.3% (580/1555)	23.1% (496/2150)
Overall	Users of study nets	20.9% (571/2727)	43.7% (1042/2385)	34.5% (707/2052)	42.1% (522/1240)	26.0% (256/985)
	Non-net users	33.9% (210/619)	58.3% (612/1049)	51.9% (518/998)	62.8% (755/1202)	46.4% (554/1194)

6.2	Distribution of clusters in each	community usage category	(≤ 40% and > 40%	6) per time point per study arm
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Covariates	12 months	18 months	24 months	30 months	36 months
>40 coverage-pyrethroid-only group	21	19	20	7	2
≤40 coverage- pyrethroid-only group	0	2	1	14	19
>40 coverage- chlorfenapyr group	21	16	15	7	0
≤40 coverage- chlorfenapyr group	0	5	6	14	21
>40 coverage- piperonyl butoxide group	21	11	1	0	0
≤40 coverage- piperonyl butoxide group	0	10	20	21	21
>40 coverage- pyriproxyfen group	20	17	6	1	0
≤40 coverage- pyriproxyfen group	1	4	15	20	21
Total clusters	84	84	84	84	84

6.3 Comparisons of malaria infection between users of pyrethroid-only LLIN and non-users in chlorfenapyr arm by survey timepoint

survey	Non-users in chlorfenapyr group: n/N (%Prevalence)	Users in pyrethroid- only group: n/N (%Prevalence) *	aOR	95% CI	p- value			
12 months	45/158 (28.5%)	286/964 (29.7%)	0.85	0.45-1.59	0.6022			
18 months	144/287 (50.7%)	488/992 (49.2%)	0.92	0.63-1.32	0.6405			
24 months	117/271 (43.2%)	422/993 (42.5%)	0.77	0.48-1.25	0.2902			
30 months	191/339 (56.3%)	333/698 (47.7%)	1.01	0.65-1.58	0.9676			
36 months	105/316 (33.2%)	243/823 (29.5%)	0.83	0.48-1.42	0.4872			
*reference arn	*reference arm/group/variable							

# 7 Additional files for Chapter 7: Acceptability of and preferences for dual-A.I LLINs compared to standard LLINs

		U	<u></u>	<u> </u>		
Mwan za	Misung wi	Olyset Plus	Low (≤40%)	Budutu, Mwajombo, Lukanga, Nyambiti	Low (≤30%)	Mwaholo
			High (>40)	Ibongoya A, Ibongoya B, Ngwa'mazengo, Lubili A	High (>30)	Ibongoya A, Ibongoya B, Lubili A
		Royal Guard	Low (≤40%)	Nya'nghomango, Lubili B, Busongo	Low (≤30%)	Masawe, Busolwa
			High (>40)	Mwagala, Mamaye, Masawe, Gulumungu,	High (>30)	Mwagala, Lubili B, Gulumungu, Busongo
		Intercept or G2	Low (≤40%)	Maganzo, Mbalama, Kifune	Low (≤30%)	Mbela
			High (>40)	Magaka, Mbela, Ngwa'mbola, Ngwa'mazengo	High (>30)	Mbalama, Ngwa'mazengo, Kifune
		Intercept or	Low (≤40%)	Gambajiga, Ngh'amve	Low (≤30%)	Nghamve
			High (>40)	lgongwa , Kwimwa	High (>30)	Gambajiga, Igongwa , Kwimwa, Ilalambogo
	Muleba	Olyset Net	Low (≤40%)	Kakoma, Nyakatanga	Low (≤30%)	Kyanshenge
Kagera			High (>40)	Kabirizi, Kyanshenge	High (>30)	Kakoma, Kabirizi, Nyakatanga
		Olyset Plus	Low (≤40%)	Ngenge, Biija	Low (≤30%)	Biija
			High (>40)	Maigibili	High (>30)	Maigibili, Ngenge,
		Olyset Net + IRS	Low (≤30%)	Rulanda	Low (≤30%)	Rulanda
			High (>40)	Kamatoju	High (>30)	Kamatoju
		Olyset Plus + IRS	Low (≤40%)	Kashanda	Low (≤30%)	Kashanda
			High (>40)	Kyamyorwa, Kangoma,	High (>30)	Kyamyorwa, Kangoma,

# 7.1 Distribution of villages where focus groups and in-depth interviews were conducted: by levels of LLIN usage, and malaria prevalence per study arm

## 7.2 Additional pictures from Eliud lukole's 6.14 km walk







7.3 General perceptions, barriers and drivers to using LLINs, alternative uses, and perceived life span of LLINs (qualitative study in Misungwi)

	Olyset Plus	Royal Guard	Interceptor G2	Interceptor
1	The general perception of the net	The general perception of the net	The general perception of the net	The general perception of the net
	Itchy when still new and mostly when	Itchy	Itchy	Itchy
	[Respondents: Married men, Young men, Married women, School girls]	[School gins, Foung women, Married women, School boys, Married men, Wife]	<i>men, Wife]</i> They are larger in size and they fit perfectly on the bed	They are larger in size and they fit perfectly on the bed
	It does not itch <i>[Wife]</i>	They are larger in size and they fit perfectly on the bed [School girls, Young women,	[Young men, Young women, Married men, Married women, Wife, Husband]	Premade holes (mesh size) are smaller and mosquitoes cannot penetrate
	It is larger in size and fits properly on the beds of various sizes [Young men, School girls, Married	Married women, School boys, Married men, Wife, Husband]	Premade holes (mesh size) are smaller and mosquitoes cannot penetrate	
	women, wije, Husbanaj	not allow mosquitoes to	Married women, School girls,	
	It has bigger premade holes (mesh) [Young men, Housewife, School girls]	penetrate [Husband, School girls, Married men]	Young women, Husband, Wife] The net is soft, easy to wash, and easy to sew [Young men, Married women, Husband, School girls, Young women] The mosquito nets have strong insecticide, which is why mosquitoes do not land on it [School girls, Married men, Young men]	

2	LLIN life span in years	LLIN life span in years	LLIN life span in years	LLIN life span in years
	Between 1-3 years	3 years	4 years (Married men: 77)	5 years
	Married men: 6; School girls: 78;	[Wife]	5 years (Married women: 53)	3 years
	Husband: 39; Married women: 82	6 months to 1.5 years	2 years (Wife: 86)	4 years
		[Married men, Married women,	1 year (Husband: 44)	1 year
	Easy to get torn but if you take good	Young women]		
	care of it can stay longer			
	Young women: 82			
3	What drives net use	What drives net use	What drives net use	What drives net use
	Protect against mosquitoes that	Protect against mosquitoes and	Protect against mosquitoes and	Protect against mosquitoes and
	transmit malaria	malaria	malaria	malaria
	82, 27, 6,		(School girls: 66 (Married	
	85, 82, 39	To protect against other	women: 53 (Young men: 40	To protect against other
		dangerous pests like rodents,	(Young men: 52 (Husband: 44	dangerous pests like scorpions
		scorpions, spiders, dorylus	(Wife: 86)	
		(safari/driver) aunts	We were given education on the	
		(in all FGDs and IDIs)	importance of using mosquito	
		The mosquito net helps people	nets	
		not fall off the bed	(FDG-Young men: 52)	
			It has strong insecticide that	
			protects us	
			(School girls: 66)	
			It provides warmth during rainy	
			seasons	
			(Married women: 53)	
			To protect against other	
			dangerous pests like scorpions,	
			spiders, dorylus (safari/driver)	
			aunts	

			(Young men: 40 & 52 (Married men: 44) The mosquito nets help people especially children not fall off bed (Young women: 40) Because we like it as it has soft threads, it is attractive and good appearance (Young men: 52&40 (Married men: 77 (School girls: 66 (Young women: 52)	
4	Barriers to net use	Barriers to net use	Barriers to net use	Barriers to net use
	Lack of knowledge about the uses of	Lack of knowledge	Lack of education, people do	Lack of knowledge
	net		not know that mosquito nets	Too hot especially in the dry
	Young men: 82	Too hot	protect them from malaria	seasons
	Too hot		(Young men: 40 (School girls:	Indolence and negligence
	Married men: 6	Indolence and negligence	66)	The poor belief that the
	Feel trapped or stuffy for the elderly			insecticide in the net can kill
	and other	Causes bed bugs	It is too hot, especially in dry	sleepers
	Married women: 27;		seasons	No mosquitoes now
	39	Used for alternative purposes	(Husband: 44 (Husband: 77	No proper bed frame
	Affects/lowers male masculinity or		(Young men: 52)	They cause side effects: skin
	male sexual performance or sexual	Can cause impotence, Affects	Indolence and negligence	irritation and facial burning
	drive [poor belief]	men's strength, energy, and	(Married women: 53 (Wife: 86	
	FGD: 6	strong sex drive;	(Young men: 52)	
	39	(Wife: 41)	They cause bed bug	
	We no longer have nets, they are		(Young men: 40)	
	completely damaged	The nets are too torn	Feel closed-up	
	FGD: 6, 78		(Married women: 53)	

	82	They cause side effects: skin irritation and facial burning	They are used as bedding (bed sheets) (Wife: 86 (Wife: 53)	
5	Alternative uses	Alternative uses	Alternative uses	Alternative uses
	Making ropes for tying cows and	Enosing poultry especially	Enosing poultry	Enosing poultry especially
	other objects	chickens and ducks' chicks to	(Young men: 40 (Married	chickens and ducks' chicks to
	FGD: 82, 06, 78	keep away from crows or hawks	women: 53 (Young women-: 52	keep away from crows or hawks
	82, 85	that prey on chicks	(Wife: 86)	that prey on chicks
	Enosing seedlings to avoid pests	Making rope for tying objects	Making ropes: mostly preferred	Making rope for tying objects
	FGD: 82, 78, 06,	Fishing nets	polyethylene nets	Fishing nets
	Building washrooms	Protecting seedlings and	(Married men: 77 (Married	Protecting seedlings and
	FGD: 27	nurseries	women: 53 (Young men:	nurseries
	Used as bed sheets or mattress	Used as bedsheets or bed covers	40&52 (Wife: 86 (Husband:	
	85,	to wrap the mattress	44).	
	FGD: 27		Fishing nets	
	Fishing		(Young men: 40&52 (School	
	FGD: 82		girls: 66 (Wife: 86 (Husband:	
	Used as a bag for carrying recycling		44).	
	plastic bottles		Protecting seedlings and	
	FGD: 06		nurseries	
			(Young men: 40&52 (Married	
			women: 53 (Young women: 52	
			(School girls: 66 (Wife: 86	
			Making bath cloth/washrag	
			(Young men: 52 (Husband: 44).	
			Making toilet/bathroom walls	
			Married women: 52 (Married	
			women: 53 (Husband: 40)	

8 Monitoring of Fabric Integrity and Attrition Rate of Dual-Active Ingredient Long-Lasting Insecticidal Nets in Tanzania: A Prospective Cohort Study Nested in a Cluster **Randomized Controlled Trial** 



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Simple Summary: This study evaluated the physical durability of new types of bed nets with two insecticides incorporated into the fibers (Interceptor G2, Royal Guard, and Olyset Plus) compared to standard nets (Interceptor), which contain a single insecticide (pyrethroid only). These bed nets were distributed in the Misungwi district, Tanzania, in February 2019 and followed up at 6-month intervals up to 36 months post-distribution. During cross-sectional surveys, householders were asked to use the net until the next survey. These nets were supposed to protect the user for three years, but this was not the case in this study. All net types had a life span of much less than three years including the pyrethroid-only ret. In response to the questionnaire, most respondents reported that they discarded their nets due to wear and tear and this was evident from the holes accrued in earlier surveys; this effect was more severe with Olyset Plus nets than with standard Interceptor nets and other dual insecticide nets.

Abstract: Pyrethroid-treated long-lasting insecticidal nets (LLINs) have been the main contributor to the reduction in malaria in the past two decades in sub-Saharan Africa. The development of pyrethroid insecticide resistance threatens the future of LLINs, especially when nets become holed and pyrethroid decays. In this study, three new classes of dual-active ingredient (AI) LLINs were evaluated for their physical durability: (1) Royal Guard, combining pyriproxyfen, which disrupts female fertility, and a pyrethroid, alpha-cypermethrin; (2) Interceptor G2, which combines the pyrrole chlorfenapyr and a pyrethroid (alpha-cypermethrin); (3) Olyset Plus, which incorporates the pyrethroid permethrin and the synergist piperonyl butoxide, to enhance the pyrethroid potency; and Interceptor, a reference net that contains alpha-cypermethrin as the sole active ingredient. About 40,000 nets of each type were distributed in February 2019 to different villages in Misungwi. A total of 3072 LLINs were followed up every 6-12 months up to 36 months to assess survivorship and fabric integrity. The median functional survival was less than three years with Interceptor, Interceptor G2, and Royal Guard showing 1.9 years each and Olyset Plus showing 0.9 years. After 36 months, 90% of Olyset Plus and Royal Guard and 87% of Interceptor G2 were no longer in use (discarded) due to

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### Articles

### Differential impact of dual-active ingredient long-lasting insecticidal nets on primary malaria vectors: a secondary analysis of a 3-year, single-blind, cluster-randomised controlled trial in rural Tanzania

Nancy 5 Matowa, Manisha A Kulkarni, Lavisa A Messenger, Mohamed Jumanne, Jaddine Martin, Elizabeth Mallya, Eliud Lukale, Jaddin F Mosha, Oliva Moshi, Boniface Shirima, Robert Kaaya, Mark Rowland, Alphaxard Manjurana, Franklin W Mosha, Natacha Protopopoff

#### Summary

Background Gains in malaria control are threatened by widespread pyrethroid resistance in malaria vectors across sub-Saharan Africa. New long-lasting insecticidal nets (LLINs) containing two active ingredients (dual activeingredient LLINs) have been developed to interrupt transmission in areas of pyrethroid resistance. We aimed to evaluate the effectiveness of three dual active-ingredient LLINs compared with standard pyrethroid LLINs against pyrethroid-resistant malaria vectors in rural Tanzania.

Methods In this study, we did a secondary analysis of entomological data from a four-group, 3 year, single-blind, cluster-randomised controlled trial carried out between Feb 18, 2019, and Dec 6, 2021. We conducted quarterly indoor mosquito collections using the Centers for Disease Control and Prevention light trap, in eight houses in each of the 84 study clusters in the Misungwi district, northwestern Tanzania. Anopheles vectors were then tested for malaria parasites and identified at species level, to distinguish between sibling species of the Anopheles gambiae and Anopheles finestus groups, using molecular laboratory techniques. The primary outcomes were density of different malaria vector species measured as the number of female Anopheles collected per household per night, the entomological inoculation rate (EIR), an indicator of malaria transmission, and sporozoite rate. Entomological outcomes were assessed on the basis of intention to treat, and the effect of the three dual active-ingredient LLINs was compared with the standard pyrethroid LLINs at household level.

**Findings** Dual active-ingredient LLINs had the greatest effect on *Anophdes functus* sl, the most efficient vector in the study area, with comparatively weak effect on *An arabiensis*. *An functus* density was 3 · 1 per house per night in the pyrethroid LLIN group, 1 · 2 in the chlorfenapyr pyrethroid LLIN group (adjusted density ratio [aDR]–0 · 26, 95% CI 0 · 17–0 · 14, p-0 · 0001], 1 · 4 in the piperonyl-buttacide pyrethroid LLIN group (aDR–0 · 49, 0 · 32–0 · 76, p–0 · 0012), and 3 · 0 in the pyriproxyfen pyrethroid LLIN group (aDR–0 · 72, 0 · 47–1 · 11, p–0 · 15). Malaria transmission intensity was also significantly lower in the chlorfenapyr pyrethroid group, with 0 · 01 versus 0 · 06 infective bites per household per night in the pyrethroid LLIN group (aDR–0 · 21, 0 · 14–0 · 33, p-0 · 0001). Ecological niche models indicated that vector species distribution was stable following LLIN intervention despite the reductions observed in *An functus* sl density.

Interpretation Chlorfenapyr pyrethroid LLINs were the most effective intervention against the main malaria vector An funestus slover 3 years of community use, whereas the effect of piperonyl-butoxide pyrethroid LLIN was sustained for 2 years. The other vector, An arabiensis, was not controlled by any of the dual active-ingredient LLINs. Additional vector control tools and strategies targeted to locally prevalent vector species evading dual active-ingredient LLINs should be deployed to further reduce malaria transmission and achieve elimination.

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#### Introduction

The primary malaria-vector control tools, consisting of pyrethroid long-lasting insecticidal nets (LLINs) and indoor restitual spraying, have substantially reduced malaria morbidity and mortality across sub-Saharan Africa.<sup>1</sup> Among the challenges faced by malaria control strategies, the most important are widespread pyrethroid

resistance in malaria-vector populations' and insufficient funding for malaria control, which have led to intervention prioritisation by national malaria control programmes.

To address the biological challenge of insecticide resistance while sustaining malaria control gains, novel next-generation dual active-ingredient LLINs are under

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#### 10 Studies result dissemination

The results of these studies have been disseminated at local, national, and international levels. Some of the dissemination has been completed but some are still ongoing such as publications in peer-reviewed journals. The following sections list the platforms where the results have been presented and/or submitted.

Studies results were presented by the author at:

- National Institute for Medical Research (NIMR), Mwanza Center-Research Dissemination seminar on 6<sup>th</sup> July 2022
- 2. The Pan-African Mosquito Control Association (PAMCA) conference in Kigali Rwanda in September 2022
- National Institute for Medical Research (NIMR), All centres Research Dissemination seminar in August 2023
- 4. American Society of Tropical Medicine and Hygiene (ASTMH) [abstract for the October 18-22, 2023 was accepted but the author did not attend]
- 5. London School of Hygiene and Tropical Medicine (LSHTM)-Malaria Centre Retreat in April 2024 by the author (online)
- 6. LSHTM PHEG symposium on 14<sup>th</sup> February 2024
- The Multilateral Initiative on Malaria (MIM) conference in Kigali, Rwanda in April 2024
- 8. 32<sup>nd</sup> Annual Joint Scientific Conference (AJSC), Dar-es-Salaam Tanzania, in May 2024