

**Study protocol**

**Durability Monitoring of Long-Lasting Insecticidal Nets in (*Country and/or locations)***

*Date*

Table of Contents

[1 Background 3](#_Toc464487242)

[1.1 Objectives 3](#_Toc464487243)

[1.2 Expected Benefits and Value 4](#_Toc464487244)

[2 Methods 4](#_Toc464487245)

[2.1 Study Sites 4](#_Toc464487246)

[2.2 Study design 5](#_Toc464487247)

[2.3 Sample size 5](#_Toc464487248)

[2.3.1 Physical durability 6](#_Toc464487249)

[2.3.2 Insecticidal durability 6](#_Toc464487250)

[2.4 Sampling procedures 6](#_Toc464487251)

[2.4.1 Stage one: selection of clusters 6](#_Toc464487252)

[2.4.2 Stage two: selection of households and study nets 7](#_Toc464487253)

[2.4.3 Stage three: selection of sub-samples of nets 7](#_Toc464487254)

[2.5 Field procedures 8](#_Toc464487255)

[2.5.1 Preparatory phase 8](#_Toc464487256)

[2.5.2 Field work 9](#_Toc464487257)

[2.6 Laboratory analyses 12](#_Toc464487258)

[2.6.1 Bio-assays: 12](#_Toc464487259)

[2.6.2 (*Optional … delete following if not applicable)* Chemical residue: 12](#_Toc464487260)

[2.7 Outcome measures 13](#_Toc464487261)

[2.7.1 Net attrition rate due to wear and tear: 13](#_Toc464487262)

[2.7.2 Net integrity: 13](#_Toc464487263)

[2.7.3 Net survival: 13](#_Toc464487264)

[2.7.4 Median net survival: 13](#_Toc464487265)

[2.7.5 Chemical residue: 14](#_Toc464487266)

[2.7.6 Bio-assay: 14](#_Toc464487267)

[2.8 Data analysis and reporting 14](#_Toc464487268)

[3 Ethical Considerations 15](#_Toc464487269)

[3.1 Informed consent 15](#_Toc464487270)

[3.2 Maximum benefit - Minimum harm 15](#_Toc464487271)

[3.3 Confidentiality 15](#_Toc464487272)

[3.4 Conflict of interest 15](#_Toc464487273)

[4 Implementation and time plan 16](#_Toc464487274)

[4.1 Roles and Responsibilities 16](#_Toc464487275)

[4.2 Timeline 16](#_Toc464487276)

[5 Personnel 17](#_Toc464487277)

[6 References 17](#_Toc464487278)

# Background

Malaria prevention with long-lasting insecticidal mosquito nets (LLIN) has seen a tremendous scale-up in sub-Saharan Africa in recent years. As many countries have now achieved high ownership coverage with LLIN and are approaching the universal coverage target of one net for every two people of the population at risk as recommended by WHO, the question of how these successes can be sustained, i.e. high coverage levels be maintained, becomes the focus of discussion. In this context the importance of net durability and the “average useful life” of a net is increasingly recognized as one of the critical factors a malaria program needs to know as it determines the frequency at which nets need to be replaced and the type of net to be procured. This is reflected in the WHO guideline for the monitoring of LLIN in the field which recommends that countries routinely monitor net durability [1].

In 2013 WHO released additional technical guidance outlining how the actual physical survival can be estimated and the median survival time calculated from multiple data points [2-3]. This has facilitated a number of studies that apply this new methodology measuring performance of different LLIN in different areas [4-8]. The results suggest that the physical durability of similar products may vary significantly between less than two and four or more years and differences are largely driven by environmental and behavioral factors. This has been further confirmed by a study in Nigeria where Behavior Change Communication was able to significantly improve household’s attitude towards care and repair which resulted in better physical condition of nets in these households [9]. Additionally, in Mozambique, a first comparative study on the durability of two types of LLIN was undertaken between 2008 and 2011 in Nampula [10] and showed a significantly better performance of a 100 denier polyester LLIN compared to a 150 denier polyethylene LLIN, but also a better performance of nets in households away from the coast (inland) compared to the coastal area.

## Objectives

The primary objectives of the study are:

1. To assess the physical durability of a (*provide specifications of brand or brands to be monitored such as material, denier, insecticide etc.)* LLIN in (*single or multiple as applicable)* locations over a three-year period and estimate median LLIN survival.
2. (*If applicable)* To compare the durability across the different locations and identify major determinants of field performance.

Secondary objectives are:

1. To describe major behavioral aspects of net care and repair and their impact on physical durability
2. *(Delete if not possible)* To assess the insecticidal effectiveness (residue and bio-assay) over a three-year period of field use
3. (*Optional … delete if not applicable)* To analyze the damage on the nets after three years to establish the prevalence of specific damage mechanisms and compare these against ex-factory textile tests of the product (Resistance to Damage Index)

## Expected Benefits and Value

The results of the proposed study will

* Provide the National Malaria Control Program, RBM partners, and PMI with valuable information regarding the performance and estimated “useful life” of (*add specifications of brand(s)* LLIN distributed during the mass campaign (*delete following statement if not applicable)* and whether and if how it varies between eco-geographical areas within the country.
* (*Optional … delete if not applicable)* Contribute to the international data base on insecticidal and physical LLIN durability and its relationship to ex-factory textile testing results.

# Methods

## Study Sites

The study will be carried out in at least [insert number] locations with differing malaria epidemiology and socio-ecological profiles. Ideally, sites should represent areas with high, moderate, and low malaria transmission potential and/or areas with significantly different climatic or socio-demographic characteristics.

The specific sites within each location will be selected from all (*add administrative unit equivalent to district)* that undertake the mass campaign distributions within the six months preceding start of the monitoring activities. If more than one district qualifies, a selection will be made purposively after consultations between the NMCP, local administration (e.g. Province), PMI and the study implementation team.

## Study design

The principle study design is that of a prospective study of a cohort of nets distributed through a mass campaign (refer to Figure).

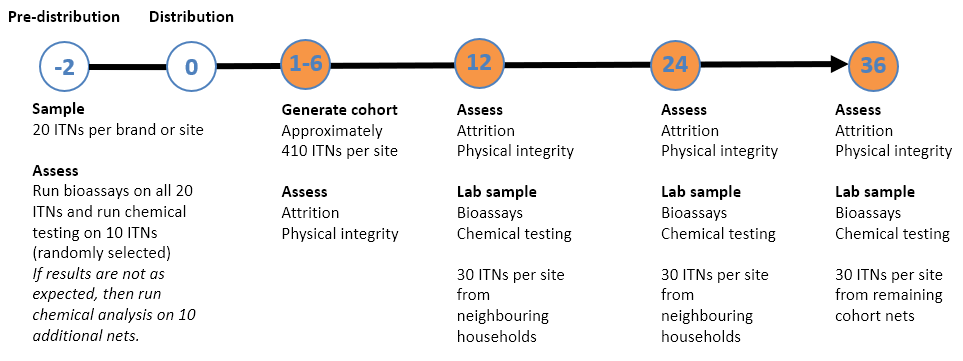
**Pre-distribution**

Once ITNs have landed in country and before the ITN mass distribution campaign begins, 20 ITNs per brand (or per site if samples for each site will be taken from different storage locations) will be sampled from the central stores to undergo bioassay and chemical residue testing. All 20 ITNs will undergo bioassays and chemical testing will be conducted on a random selection of 10 out of the same 20 nets. If results are as expected for the brand, then no further tests will be conducted. However, if results are not as expected – for example, they do not meet manufacturer specifications – then chemical analysis will be conducted on the remaining 10 nets.

**Post-distribution**

Within a few months (ideally 1-3, but not more than six) following the mass campaign, a representative sample of campaign nets from the study location will be identified through a cluster household survey with all campaign nets from consenting households forming the study cohort. These nets will then be labelled with a unique identifier and their presence and physical condition assessed at this baseline and in three additional annual surveys together with household characteristics and use, care and repair behavior for the net. During follow-up assessments at 12-, 24- and 36-months after the campaign (but not at baseline), sub-samples of 30 campaign nets per site are withdrawn and replaced for insecticide effectiveness testing (bioassays and chemical residue). Pre-distribution samples of nets will undergo bioassay and chemical content testing assessment as described above to form routine post-procurement quality control (QAQC). Results from these tests will form the pre-distribution time point against which annual study results will be compared. (*Optional … delete following if not applicable)* In addition, samples will be taken at the end of the study for laboratory textile testing.

**Figure:** Overview of study design



## Sample size

The following assumptions are underlying the calculations of sample size and precision using standard formulas:

* Confidence interval (alpha-error) 95%
* Power (beta-error) 80%
* Design effect of 2.50
* Household loss to follow-up 5%
* (*Adjust according to campaign allocation strategy and average household size) x*.x campaign LLIN per households at baseline (assuming an average household size of y.y) and a loss of 0.2 nets/household between campaign and baseline survey
* Total attrition rate for campaign nets of 35% over three years and an attrition rate due to wear and tear of 20%, i.e. loss due to giving away nets to others of 15% over three years.
* Estimated median net survival of three years, i.e. survival of 50% after three years.

### Physical durability

Based on calculations using the *sampsi* command of Stata and using the assumptions above, a sample of 15 clusters with 10 households each is considered to be sufficient per study location. This will result in an initial cohort of 345 campaign nets from 150 households per location or 790 nets from 300 households. After three years – considering loss to follow-up and attrition rates as outlined above – there will be 279 nets with complete data for evaluation per location (557 nets in total). This sample size with the assumed design effect will allow detection of a 10-11%-points difference between locations if the assumed median survival is three years: e.g. 39% or less or 61% or more estimated survival compared to 50%. This translates into approximately a 0.5 median survival difference that can be detected as statistically significant.

### Insecticidal durability

Following the recommendation of WHO for phase III testing of LLIN [11], random samples of 30 campaign nets per site (total 60) will be selected at each annual assessment (from outside the main cohort at 12- and 24 months, and 30 nets from the main cohort at 36 months) for insecticidal effectiveness (bioassay and chemical residue) analysis. If the proportion of nets with at least minimal insecticidal effectiveness (see section 7) in the bio-assay is around 80% after three years, the overall sample under the assumptions mentioned above will provide a precision of ±10.0%-points in a one-sided analysis. A similar precision will be achieved for chemical residue for the outcome of “proportion of nets with at least (*add cut-off level for specific insecticide in mg/m2 or g/kg)* of (*add name of insecticide)*”.

## Sampling procedures

### Stage one: selection of clusters

For the selection of clusters the campaign LLIN distribution registers by District will be used provided by the (*add sub-national administrative level)* or National Malaria Control Program. A cluster will be defined as a community and the selection will be done with probability proportionate to size (PPS) with number of LLIN distributed per community as the measure of size.

### Stage two: selection of households and study nets

Within each selected community, 10 households will be selected using the following methodology: if the community is small (less than 200 households) the field team will map the whole village (i.e. list all inhabited houses where people live) and from the compiled list of eligible households the supervisor will randomly select 10 households with equal probability for each household using random number lists. These random number lists provide 10 random numbers for each possible total of listed households. In addition 6 replacement households will be sampled, which will be used if a sampled household reports never to have received any nets from the campaign.

Following the household definition used in the LLIN distribution campaign, the definition of a household will be “people eating from the same pot”. If the community is large, i.e. exceeding 200 households, the equal size section-approach will be used. With the help of local authorities the community will be divided in sections of approximately equal size (40-60 compounds each). One of these sections will be randomly selected by the supervisor using a pre-prepared random number sheet and within this section all households will be mapped and households selected as above. The number of sections used in such clusters will be recorded by the supervisor.

Sampled households will be visited and initially screened whether or not they had participated in the LLIN distribution campaign. If this is not the case the household will be dropped and one of the replacement households will be visited. If a household confirms participation in the campaign, information on the study will be given and oral consent sought using the consent script in the local language. If the household does not give consent, it will be dropped, and one of the replacement households will be visited until the total of 10 households is reached.

For each consenting household the GPS coordinates will be recorded and together with the name of the head of household entered into the household master list which will be used to identify the household for the annual assessment visits.

Within each household, all campaign nets will be identified by the field team based on the label of the net and on the interview with the household respondents. Each campaign net will be labeled with a unique identifying number that will be used to create a master net list.

### Stage three: selection of sub-samples of nets

The nets for the 12- and 24-month follow-up effectiveness assessment (bioassay and chemical residue) will be randomly selected from outside the study cohort (as these nets will have to be cut up for the tests), as follows: In each cluster two campaign nets will be selected by randomly selecting one of the 10 sampled households, and visiting the next house to the left of this household to find a verified campaign net (verifying source and age of net as campaign net). This is repeated (visiting houses to the left) until the 2 nets are obtained. For 36-month sample, 30 nets will be selected from the main cohort master list using simple random sampling. Households will be given a new LLIN as replacement. The collected nets will be labeled and stored in separate plastic bags for transport. A one-page questionnaire confirming the net is a campaign net and obtaining basic information on its use and washing patterns is administered at this time and packed with each net. For the pre-distribution effectiveness assessment, nets will be sampled at random from the general or central stores.

**[Alternate option to tag a separate bioassay net cohort at baseline, for sampling at the 12 and 24-month follow-ups:**

At baseline, a separate cohort of 6 nets per cluster are tagged for eventual follow-up and removal at the 12 and 24 month assessments. Using a separate group of two-digit tags (A1-A6; B1-B6, etc), households are selected randomly from outside the main net cohort. This can be done by two different methods: 1) by randomly selecting one of the 10 sampled study households, and visiting the next house to the left to find a verified campaign net that is hanging and being used, continuing until 6 nets from different households are obtained, or 2) by randomly selecting 6 households plus 2 replacements from the remaining unsampled households within the cluster, and visiting them to confirm and tag campaign nets hanging and being used. One net in each household is tagged for follow-up at 12 or at 24 months, GPS location is recorded, and the one-page questionnaire is administered at baseline. At the 12 and 24 month assessments, 2 nets per cluster are selected for bioassay testing from the master list of bioassay households using simple random sampling, using the replacement households as needed.]

## Field procedures

### Preparatory phase

During the preparatory phase the following activities will be undertaken:

An initial visit by one of the co-investigators to establish all necessary local partnerships (*add list of partners and stakeholders to be involved*).

For the interviewer training a detailed guide will be prepared that will support the field team in the interviews. The questionnaire will be in (*add language to be used*), however, adequate translations of questions into local languages will be agreed upon during interviewer training. The questionnaire will comprise of the following sections:

* Household characteristics (composition, assets, factors potentially associated with net damage etc.)
* Nets received from campaign and any new nets obtained from any source since the campaign
* Exposure to care and repair messages
* Net care and repair behavior and attitude and perceptions towards care and repair (assessed using a series of Likert score questions)
* Campaign net presence or absence and reasons for loss if applicable
* Assessment of existing campaign nets which will include use pattern (location, type of sleeping place, users of the net), recalled damage mechanisms, washing and drying habits and a physical assessment of holes and repairs on each net
* Assessment of any other net in the household’s possession (nets not from the campaign)

A visual aid for LLIN brand identification will be prepared in advance. This will be a plasticized sheet with photographs of the campaign brand of LLIN as well as other net brands common in the area with one photograph of the label and one of the net.

Visual aids and plasticized tally sheets for the hole assessment will also be prepared in advance.

After careful assessment of the local conditions (cellular network connectivity etc.) and costs involved, a decision will be made whether or not a paper-based or electronic data collection will be used and if the latter which digital device (phone, tablet) will be most suited to collect the data in the field including the recording of GPS coordinates. This will include the selection of the most adequate software platform for the programming of the questionnaires and data transfer and storage (final databases). Once this decision is made, programming of a beta version will begin and be tested repeatedly in order to ensure a fully functional version is available at the start of the field work. This work will be carried out by a consultant (local, regional or international depending on available capacity).

Working with (*add local implementing partners as adequate)* job descriptions for the different positions will be developed and a pool of potential staff identified from which the field staff will be selected.

### Field work

#### Teams and training

Each location will have its own implementation team with one overall site coordinator and two field teams of one supervisor and three interviewers each. It is estimated that the time needed for the 15 clusters per location will be one day per cluster, therefore the estimated time for the field work per site is 15 working days, so that each assessment round can be completed within four weeks.

Interviewers and supervisors will be carefully selected so that they are culturally acceptable, have good knowledge of the local languages and experience in household surveys. Just prior to each round of field work there will be one five-day training that will include the following components:

* Understanding the study design and sampling procedures
* General approach to ethics of field work (consent and interview)
* Detailed study of interview with role play
* Introduction to and practice of use of the data entry device
* Physical assessment of holes and repairs in nets with practical exercises

The first training will be given by a team of local, regional and international experts in the field of durability testing and will be attended by all provincial coordinators and the consultants for technology. Training in the other locations will then be done by a smaller team so that they can be carried out in parallel.

Before each annual round of data collections the training will be repeated.

#### Logistics and administration

The field teams will be supported by one administrative support staff and one logistician in charge of ensuring all transport arrangements are in place.

#### Sensitization

As soon as clusters are selected the local authorities and chiefs will be informed of the purpose and expected time of the survey and their support sought. Communities will then be sensitized and mobilized in order to obtain maximum cooperation for the surveys.

#### Household consent and interviews

After the selection of the household (see above) each selected family will be visited and the head of household or his/her spouse will be interviewed if it qualifies for the study. In case no adequate respondent is found at the house, a new visit will be scheduled later that day. At least three attempts will be made to reach a respondent, but if this is unsuccessful the household will be dropped and one of the sampled replacements used instead. Before the interview the head of household or respondent will be informed about the purpose of the study and this information will be given in the local language. The respondents will be specifically informed that participation is voluntary and that he/she may refuse at any time. Once consent is obtained the interview will be carried out. Each interviewed household will receive a unique identification number consisting of the cluster and the household’s number. Questionnaires will be pre-coded with these ID numbers to avoid issue of double numbers. The main respondent will be the head of household or his/her spouse.

#### Campaign net identification and labelling of study nets

In order to identify the LLIN from the last campaign the interviewers will inspect each net and compare the brand label with the visual aids previously prepared. If the label matches the campaign net brand respondents will be asked about the source and time of obtaining the net and if this information confirms the net as one of the campaign, a label with a unique identifying number (previously prepared) written in wash resistant ink will be solidly fixed to that net. Nets that cannot be verified as campaign nets are recorded but not included in the study cohort. Separate groups of tags are used to identify study nets and bioassay nets.

#### Net hole assessment

Each registered campaign net still in possession of the household at the time of the survey will be assessed for physical condition and signs of repair. If possible each net will be taken outside or to a well-lit location. Two team members will hold the net by its four corners while the third does the hole assessment. Separately inspecting each side and roof of the net, existing holes will be counted categorized into four different sizes based on the WHO guidelines [1]: 0.5-2 cm, 2-10cm, 10-25 cm and larger than 25 cm in diameter using the size templates and tally sheets provided. The number of holes of each size category will be summarized in the questionnaire separately for the sides and the roof. The presence and number of repaired holes will be noted, but these will not be counted as holes.

#### Bioassay net removal and replacement

For households sampled for bioassay net collection, the team members will administer a one-page questionnaire, remove the net, and pack it in a separate plastic bag with the completed one-page questionnaire for transport to the lab. A replacement net is then given to the household.

#### Data collection, management and safety

For data collection, electronic devices will be used that allow a detailed programming of skip patterns and internal controls to ensure that all necessary data is collected and consistent. Depending on local conditions, data from each interviewer will be uploaded to the web-based database on a daily basis or collected on a local storage device (laptop or USB drive) by the supervisor until it can be transferred.

From the data three types of data files will be created and updated after each assessment round:

* The household master list
* The net master list
* The annual household and net data files
* The master bioassay household list

The household master list will include the GPS coordinates and name of head of household as this information will be needed to track the household in subsequent surveys. However, between surveys, this list will be safely kept on a fixed and secure data storage device (e.g. server) with adequate protection (encryption and password) and access only by the core PI and co-investigators. Immediately following the final data collection this information (name and GPS coordinates) will be deleted.

Other personal identifiers will be the first names of household members needed to identify the net users in the household surveys. Following data cleaning these will be removed so that analytical data files will have no household or personal identifiers remaining.

#### Supervision and field support

At the end of each day the team supervisor will review all collected data and discuss with the team the performance in the field with respect to strengths and weaknesses. Daily reports will be made to the location coordinator and is any problems arise this will be reported to the co-investigators or principle investigator for discussion and finding solutions. For technical issues with the electronic data collection devices consultants will be on stand-by for field support throughout the field activities.

## Laboratory analyses

### Bio-assays:

From each of the sampled nets for insecticidal effectiveness (see 2.4.3 for sampling methodology) a piece of 30x30cm will be cut from the mid-section of one of the long sides of the net by the study team. The samples will be labeled with the net ID number and sent to the National Institute of Health (INS) for bio-assay tests according to WHO guidelines [11]. The primary test used will be the cone assay. For the tests insectary-raised, 2-5 day old, unfed females of a pyrethroid sensitive strain will be used (ideally *Anopheles gambiae s.s*. Kisumu strain but other species such as Aedes can also be used). No wild-caught mosquitoes should be used. Five mosquitoes at a time will be introduced into WHO cones and four cones applied simultaneously onto the net sample with a three-minute exposure of the vectors. After exposure, females will be grouped into batches of 10 or 20 in 200 mL plastic cups and maintained at 28°C ± 2°C and 80% ± 10% relative humidity with honey solution provided. For each sample this procedure will be repeated twice, i.e. a total of 40 mosquitoes will be used. For each series a control will run with no exposure and results will only be used if control mortality is less than 5%. Numbers of mosquitoes knocked down will be recorded at 30 and 60 minutes and knock down rate at 60 minutes (KD60) calculated. Percentage mortalities will be recorded after 24 hours using immediate and delayed mortality as defined by WHO guidelines. Samples that score less than 95% KD60 or less than 80% mortality the cone assay will be tested with the tunnel test [11].

### Chemical residue:

For the analysis of insecticidal content five 10x10cm samples will be cut from each sampled net, one from the roof and one from each side. These will be labeled with net ID number, packed in aluminum foils per net and shipped to Wallon Agricultural Research Centre (CRA-W), Gembloux, Belgium (WHO Collaborating Centre for Quality Control of Pesticides) for further testing using the ISO 17025 accredited analytical method RESMM002. The samples will be measured and weighed and then introduced into a 100 mL Erlenmeyer flask. Alphacypermethrin will be extracted from the sample by heating under reflux for 60 minutes with 40 mL xylene. The final extract will be analysed for determination of alphacypermethrin by Capillary Gas Chromatography with 63Ni Electron Capture Detection (GC-ECD) using an external standard calibration. For each sample two chromatographic injections will be performed and the mean reported as g/kg and mg/m² of alphacypermethin.

## Outcome measures

There will be four primary outcome measures applied for the physical durability measurement.

### Net attrition rate due to wear and tear:

Thisis defined as the proportion of originally received nets (based on registers) which have been lost due to wear and tear (thrown away, destroyed or used for other purposes) at the time of assessment. Nets received but given away for use by others or stolen are excluded from the denominator.

### Net integrity:

This will be measured first by the proportionate Hole Index (pHI) as recommended by WHO [1]. Data from the net hole assessment will be transformed into the proportionate Hole Index (pHI) for each net in the following way:

*pHI= # size 1 holes + (# size 2 holes x 23) + (# size 3 holes x 196) + (# size 4 holes x 576)*

Based on the pHI each net is then categorized as “good”, “serviceable” or “torn” as follows [2,3]:

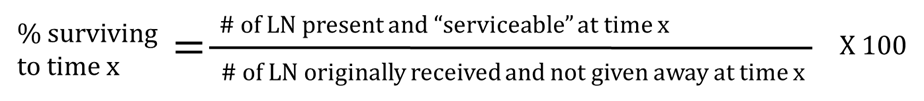
Good: total hole surface area <0.01m² or pHI<64

Serviceable: total hole surface area <=0.1 m² or pHI<=642

Torn: total hole surface area >0.1m² or pHI>642

### Net survival:

This is the combination of the two previous measures, i.e. the proportion of received nets not given away for use by others that are still present and in “serviceable” condition. It is calculated for each time point as follows:



### Median net survival:

Median estimated net survival was calculated from at least two time points, the lowest of which was below 85% using the following formula:

where tm is the median survival time, t1 and t2 the first and second time points in years and p1 and p2 the proportion surviving to first and second time point respectively in percent.

Secondary outcome measures will include the following:

### Chemical residue:

Here two metrics will be used

1. The geometric mean insecticide content across the overall sample and for each location

### Bio-assay:

The primary outcome of net effectiveness for standard ITNs will be based on the bio-assay results using the following criteria:

Optimal effectiveness: KD60 ≥ 95% or functional mortality ≥ 80%

Minimal effectiveness: KD60 ≥ 75% or functional mortality ≥ 50%

## Data analysis and reporting

In case of paper-based data collection the field-checked questionnaires will be double entered using a suitable software (e.g. EpiData), validated and inconsistencies corrected before the data is transferred to a statistical software. In case of digital data collection, the data will be transferred from the digital devises to the central data base (e.g. MS Access). Once data collection for each assessment round has been completed and data verified, the data sets will be transferred to statistical software package (e.g. Stata, SPSS or R) for further consistency checks and preparation for analysis. This process will be documented using e.g. Stata do-files (macros) so that any interested partner can repeat the steps on their own copy of the data set.

Final analysis will follow the previously defined outcome measures (see above). Since sampling probability proportionate to size is used at the first stage the sample can be considered as roughly unbiased and does not need sampling weights. This assumes however, that size of clusters (communities) is also roughly similar. Should this not be the case sampling weights will be calculated. For calculation of confidence intervals around estimates the intra-cluster correlation will be taken into account (design effect). In addition to descriptive uni-variable analysis multi-variable analysis will be performed to assess determinants of physical durability. Data on household attitudes towards care and repair from the Likert score questions will be summarized by recoding the four-level Likert scale to have a value of -2 for “strongly disagree”, -1 for “disagree”, +1 for “agree” and +2 for “strongly agree”. These attitude scores for each respondent will then be summed and divided by the number of statements to calculate an overall attitude score.

A wealth index will be computed at the household level using principal component analysis (PCA). The variables for household amenities, assets, livestock, and other characteristics that are related to a household’s socioeconomic status will be used for the computation. All variables will be dichotomized except those of animal ownership where the total number owned will be used. The first component of the PCA will be used as the wealth index. Households will then be classified according to their index value into quintiles within each study location and time point.

Initial results will be shared and discussed among all partners after each round of assessments and a preliminary report issued. Once the final report is completed a dissemination meeting will be organized to present findings and recommendations to all stakeholders and partners. The report as well as data set will be made publicly available on a website dedicated to LLIN durability monitoring ([www.durabilitymonitoring.org](http://www.durabilitymonitoring.org)).

# Ethical Considerations

The proposed study will be conducted according to the principles of the Declaration of Helsinki and the International Guidelines for Ethical Review of Epidemiological Studies.

Particularly the following principles are being observed:

## Informed consent

All persons in selected households will be informed about the purpose and nature of the study, what participation in the study requires and possible risks and benefits and verbal consent will be obtained. It will be stressed that any person may retreat from the study without negative consequences.

## Maximum benefit - Minimum harm

Since this is an exclusive interview survey without taking of samples of any kind no harm is expected to the participants.

## Confidentiality

None of the information registered is sensitive. Upon entry of data into the computer database, all names will be omitted and each household will only be identified by the ID-number. The exception will be the master list of households which will include the GPS location and the name of the head of household. This will be an electronic data file only and will be kept in a secure location with password protection and access only by the PI and co-investigators. This data base will be destroyed after the final assessment round. All results of the study will be reported anonymously.

## Conflict of interest

There is no potential conflict of interest.

Ethical clearance will be obtained from a local ethics review board, as well as from the Institutional Review Board (IRB) at the (*add relevant partner university or institution)*.

# Implementation and time plan

## Roles and Responsibilities

Implementation of the study will be jointly done by all partners, namely

* + 1. National and Provincial Malaria Control Programs
    2. (*local implementing partner)*
    3. (*project through which PMI funds and support are channeled)*

While all partners will give input into the questionnaires and tools (*project name)* with technical support from other partners will be responsible for all aspects of the field work, data entry and data management and cleaning.

## Timeline

Anticipated time line for the first round of surveys in [YEAR]:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Month 1** | | | | **Month 2** | | | | **Month 3** | | | | **Month 4** | | | | **Month 5** | | | |
| **Activity** | **1** | **2** | **3** | **4** | **1** | **2** | **3** | **4** | **1** | **2** | **3** | **4** | **1** | **2** | **3** | **4** | **1** | **2** | **3** | **4** |
| **Preparatory Phase** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Obtain ethical clearance |  | x | x | x | x | x | x | x | x | x |  |  |  |  |  |  |  |  |  |  |
| Set-up visit |  |  |  |  |  |  |  | x | x |  |  |  |  |  |  |  |  |  |  |  |
| Identify survey team |  |  |  |  |  |  |  |  | X | x |  |  |  |  |  |  |  |  |  |  |
| Prepare training guide |  |  |  |  |  | x | x | x | x | x | x |  |  |  |  |  |  |  |  |  |
| Prepare data entry system |  |  |  |  |  | x | x | x | x | x | x |  |  |  |  |  |  |  |  |  |
| **Field work** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Training and field work location 1 |  |  |  |  |  |  |  |  |  |  |  | x | x | x | x |  |  |  |  |  |
| Training and field work location 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | x | x | x | x |  |

# Personnel

Principle Investigator: Dr. TBD

Co-investigator: Dr. TBD

Co-investigator: Dr. TBD

# References

1. WHOPES: **Guidelines for monitoring the durability of long-lasting insecticidal mosquito nets under operational conditions**, WHO/HTM/NTD/WHOPES/2011.5 <http://whqlibdoc.who.int/publications/2011/9789241501705_eng.pdf>
2. World Health Organization: **WHO guidance note for estimating the longevity of Long-lasting Insecticidal nets in Malaria Control.** Geneva: 2013. <http://www.who.int/entity/malaria/publications/atoz/who_guidance_longevity_llins/en/index.html>.
3. World Health Organization: **Estimating functional survival of long-lasting insecticidal nets from field data**. Vector Control Technical Expert Group Report to MPAC September 2013. <http://www.who.int/malaria/mpac/mpac_sep13_vcteg_llin_survival_report.pdf>.
4. Kilian A, Byamukama W, Pigeon O, Gimnig J, Atieli F, Koekemoer L, Ptotopopoff N: **Evidence for a useful life of more than three years for a polyester-based long-lasting insecticidal mosquito net in Western Uganda**. *Malar J* 2011, **10**:299.
5. Mejía P, Teklehaimanot HD, Tesfaye Y, Teklehaimanot A: **Physical condition of Olyset nets after five years of utilization in rural western Kenya.** *Malar J* 2013, **12:**158.
6. Gnanguenon V, Azondekon R, Oke-Agbo F, Beach R, Akogbeto M: **Durability assessment results suggest a serviceable life of two, rather than three years for the current long-lasting insecticidal (mosquito) net (LLIN) intervention in Benin.** *Malar J* 2014, **14:**69.
7. Hakizimana E, Cyubahiro B, Rukundo A, Kabayiza A, Mutabazi A, Beach R, Patel R, Tongren JE, Karema C: **Monitoring long-lasting insecticidal net (LLIN) durability to validate net serviceable life assumptions, in Rwanda.** *Malar J* 2014, **13:**344.
8. Van Roey K, Sovannaroth S, Sochanta T, Touch MS, Pigeon O, Sluydts V, Durnez L, Coosemans M: **A phase III trial to evaluate the efficacy, fabric integrity and community acceptance of Netprotect using a recommended insecticidal net as positive control.**  *Malar J* 2014, **13:**256.
9. Koenker H, Kilian A, Hunter G, Acosta A, Scandurra L, Fagbemi B, Onyefunafoa EO, Fotheringham M, Lynch M: **Impact of a behaviour change intervention on long-lasting insecticidal net care and repair behaviour and net condition in Nasarawa State, Nigeria**. *Malaria Journal*, 2015,**14:**18
10. Morgan J, Abílio AP, do Rosario Pondja M, Marrenjo D, Luciano J, Fernandes G, Sabindy S, Wolkon A, Ponce de Leon G, Chan A, Vanden Eng J: **Physical durability of two types of long-lasting insecticidal nets (LLINs) three years after a mass LLIN distribution campaign in Mozambique, 2008-2011.** *Am J Trop Med Hyg* 2014, doi:10.4269/ajtmh.14-0023.
11. WHO: **Guidelines for laboratory and field testing of long‐lasting insecticidal nets.** Geneva 2013, WHO/HTM/NTD/WHOPES/2013.3 <http://www.who.int/iris/bitstream/10665/80270/1/9789241505277_eng.pdf?ua=1>