

Monitoring entomological, epidemiological and operational indicators to assess outcomes and impacts of an insecticide-treated net campaign in Ondo State, Nigeria

CONCEPT NOTE

Malaria Consortium

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Background

The last insecticide-treated net (ITN) replacement campaign in Ondo State was conducted in October and November 2017 [1]. More than 2.4 million pyrethroid ITNs were distributed in all 18 Local Government Areas (LGAs), covering population of nearly 5 million. The Nigerian Demographic and Health Survey (DHS) 2018 found that 80% of the households in Ondo State owned at least one ITN approximately one year after the campaign, well above the national average of 61% [2]. In 2015, only 50% of households in the state had at least one ITN, far below the national average of 69% [3].

A universal coverage ITN replacement campaign is planned for implementation in October and November 2021, using an ITN containing a pyrethroid insecticide and the synergist piperonyl butoxide (PBO) based on recommendations of a stratification report developed by the World Health Organization (WHO) and Nigeria's National Malaria Elimination Programme (NMEP) [4]. DuraNet Plus® containing alpha-cypermethrin and PBO will be distributed by the NMEP and Malaria Consortium.

This concept note was developed to gather comprehensive monitoring and evaluation (M&E) data to assess the outcomes and impacts of the campaign.

Indicators

Impact indicator

The main indicator to assess the epidemiological impact of the ITN campaign will be malaria incidence rates in children aged 6-59 months estimated from outpatient data collected longitudinally from a sample of health facilities (primary health centers or equivalent), by comparing changes during post-campaign compared with a baseline period.

Additional indicators

The following additional indicators will be measured at various intervals to assess the outcome of the campaign and other associated variables, some of which will be used to explain results of the impact assessment.

- Insecticide susceptibility levels at baseline and two years after the campaign in six sites across the state
- ITN ownership and use rates at base line, 3–4 months after the campaign, and after one, two and three years
- Durability of the distributed ITNs at various intervals up to three years after the campaign, including attrition rates, physical durability, and duration of bio-efficacy
- Indoor and outdoor biting habits of the main vectors
- Meteorological indicators (rainfall, temperature and relative humidity) across the state

- Total costs of the campaign

Methods

There will be five study components:

- Malaria incidence studies
- ITN durability monitoring, including household data collection
- Entomological studies
- Meteorological data monitoring
- Costing and cost-effectiveness studies

There are 18 LGAs and 203 wards in Ondo State. The estimated total population projected for 2021 is 5.4 million.

For most of the study components, a stratified sampling will be used to ensure that samples will be representative at state level, as well as for urban/rural residence and two major ecological strata—humid forest and derived savanna. Four strata will include:

- A1 Forest and urban
- A2 Forest and rural
- B1 Savanna and urban
- B2 Savanna and rural

Malaria incidence studies

Incidence data

Monthly malaria incidence rates will be calculated based on number of RDT-confirmed cases, clinically diagnosed (presumptive cases), test positivity rates, treatment-seeking behaviour and catchment populations of the sampled health facilities. The malaria data will be compiled directly from patient registers, by age, gender and residence for the period 1 November 2018 – 31 October 2024. This will provide three years of baseline for comparison with data the post-campaign period. A stringent data compilation quality control system will be put in place through frequent supervisory visits from the LGA level.

Sampling design

Only publicly owned primary health centers or equivalent facilities that have been reporting malaria data regularly during the past few years will be included in the sampling frame, to ensure similarity of the sampling units and representative coverage.

Due to expected differences in malaria transmission intensity and/or ownership and use of ITNs among urban and rural residents and the two ecological strata, stratified two-stage cluster sampling will be used to select health facilities.

The primary sampling units for the health facility sampling will be wards. All wards with eligible health facilities will be included in the sampling frame. In the first-stage sampling, wards will be selected based on probability proportional to size (PPS), with size denoting populations per ward. Within each ward, primary health centers will be selected using simple random sampling, in the unlikely situation where a ward has more than one eligible health facility.

Sample size and data analysis approach

Health facility sampling will be done independently in each of the four strata. A total of 32 primary health centers or equivalent facilities will be selected across the state. The sample

size determination was based on the type of expected analysis of incidence trends as well as feasibility of quality control and budget. The primary statistical method to assess changes in malaria incidence rates will be interrupted time series analysis with 72 time points per health facility for monthly data. There is no standard method of determining minimum number of individual time series for such analysis (that we are aware of), but the generally recommended number of data points is a minimum of 50 per series. Approximately 8 health facilities representing a stratum each with 72 time points was deemed sufficient to analyze post-campaign incidence trends compared with the baseline trends. The overall sample size of 32 health facilities will be sufficient to carry out additional statistical analyses to assess pre- and post-campaign differences in incidence rates at least at the state level and for urban/rural strata. These additional analyses will include regression analysis taking into account autocorrelation in the data. Incidence rates will be calculated by using health facility catchment populations as denominators.

Household surveys

Survey rounds

Cross-sectional household surveys will include interviews with household heads (and in some of the survey rounds, women of reproductive age). There will be five rounds of household interviews (Table 1).

Table 1. Durability monitoring (DM) and household survey rounds.

Survey rounds	Time relative to ITN campaign	Activities	Note
1	1 month before campaign	Baseline ITN ownership and use survey	Stand-alone household survey
	Campaign month (= month 0)	ITN distribution	
2	Month 3	Post-campaign evaluation of retention, ownership and use; DM (baseline)	Post-campaign evaluation will be integrated with DM
3	Month 12	DM	
4	Month 24	DM	
5	Month 36	DM	

All durability monitoring household interviews in cohort households will be also used to collect data on ITN ownership and use.

Sampling design

We will use a stratified multi-stage cluster sampling of households. The first-stage sampling of wards will use PPS, followed by the second-stage sampling of households. Households within selected wards will be sampled using simple random sampling. Wards and households will be re-sampled during each survey round.

All households in selected wards will be visited and numbered consecutively. The numbers and names of household heads will be recorded. The list will be sent to Abuja and London for sampling to avoid bias. Simple random sampling will be done using computer-generated

random numbers. Large wards will be divided into segments before selecting one segment randomly for listing of households to save costs of listing and numbering.

Sample size

We will decide on sample allocation strategy to each stratum after stratification of the wards and when ward-level population data is obtained. Expected changes in ITN use rates before and after the ITN campaign will be used to determine sample size in terms number of households. The total sample size is sufficient for ITN durability monitoring as well as ITN use rates.

An independent two-stage sampling procedure will be carried out in each stratum based on the following assumptions:

- Design effect = 2.5
- Significance level = 95%
- Power = 80%
- Non-response rate = 10%
- ITN use rates before and after the campaign: see Table 2. An increase in use rates by 20 percentage points is assumed in each stratum three months after the campaign.

Table 2. ITN use rate assumptions used in sample size calculations.

ITN use rates assumed	Strata			
	A1	A2	B1	B2
Before campaign (%)	25	38	19	32
Three months after campaign (%)	45	58	39	52

Based on the above assumptions, a total of 775 households in 49 clusters (wards) will be required for estimation of ITN ownership, access and use rates as well as studies related to durability.

The same sample size will be used for the baseline household survey and post-campaign evaluation (and baseline durability monitoring). However, the clusters and households in the post-campaign evaluation survey will be independently selected and will not be the same as in the baseline survey. Subsequent household interviews for durability monitoring will be conducted in the same cohort households selected during the post-campaign survey at the baseline durability monitoring round. The integration of the post-campaign evaluation and durability monitoring baseline will save costs.

Data collection

Structured interviews will be used to gather information from selected households. Interviewers will be assigned to clusters based on language abilities. Interviewers will use mobile phones to collect data. Tools based on the Open Data Kit (ODK) will be used for data collection. Electronic equipment for all surveys will be borrowed from the ITN distribution campaign.

Survey staff will record names, sex and age of each household member, whether they stayed in the house the previous night, and whether they slept under a mosquito net. Data on each mosquito net found in sampled households will be gathered, including: type, brand, identity of persons who slept under the net, and where and when the net was obtained.

Data analysis

The household data will be used for estimation of campaign ITN retention, ownership rates, proportion of the population with access to ITNs in their households, ITN use rates by gender and age groups, socio-economic status, and variables related to ITNs owned. The data will be analyzed in relation to other datasets related to ITN durability and malaria incidence trends.

ITN durability monitoring

Durability of the campaign nets will be studied over three years using standard procedures. The study includes collection of data on attrition (due to loss of nets), physical durability (measured by number and size of holes), and insecticide effectiveness (measured by cone bioassay using susceptible mosquitoes and chemical analysis).

Durability monitoring will include identification of a cohort of campaign nets and following them up longitudinally during annual surveys, and additional bioassays of a sample of campaign nets outside the main cohort in each location. The nets for this specific campaign are labelled at the manufacturing stage for ease of identification, with additional unique labelling of the cohort nets¹. At the end of the third year, a sample of surviving nets from the main cohort will be used for bioassay and chemical analysis. Standard procedures will be used to study ITN durability, including attrition, calculations of the hole index, bio-efficacy, and chemical contents over time.

Entomological studies

The main objectives of entomological studies are:

- To monitor changes in indoor and outdoor biting habits in relation to patterns of sleeping times or night-time duration of exposure to mosquito bites of local communities
- To assess levels of insecticide resistance at baseline (at least one month before the campaign) and two years after the campaign

Additional entomological data will be gathered using mosquito samples collected for the purpose of the main objectives, including determination of sporozoite rates and resistance markers.

Human biting rates will be estimated using Centers for Disease Control and Prevention (CDC) light traps installed in and around two houses indoors and outdoors at each of the two entomological surveillance sites, over three nights, twice a year. The traps will be installed by a bed or sleeping place where a volunteer (household member) will sleep under an ITN at the indoor and outdoor locations. Mosquitoes will be collected hourly by entomology assistants.

Collected mosquitoes will be stored dry on silica gel (after morphological identification) for subsequent laboratory analyses to determine species, sporozoite infection, and resistance markers.

Insecticide susceptibility studies will be conducted in six sites at baseline and two years after the campaign, to understand changes in resistance levels and make recommendations on

¹ An agent has been contracted for a pre-shipment quality control, including inspection of manufactured nets, and physical and chemical tests of samples at an independent laboratory.

the types of ITNs for the subsequent replacement campaign. The WHO and/or CDC bottle bioassays, resistance intensity tests, synergist assays, and molecular analysis (target-site resistance markers and other mechanisms as necessary) will be carried out.

The proportions of vectors biting outdoors versus indoors and the peak biting times will be determined from the CDC light trap collections to understand any changes in biting habits as the result of the intervention. The data will also provide estimates of human biting rates per night, estimated from biting patterns and night time habits of local residents. The length of time villagers spend outdoors and indoors during the night will be observed to understand exposure to mosquito bites and use the information for human-vector contact and biting rate calculations.

Other entomological data such as changes in insecticide resistance will be assessed using standard WHO procedures for interpretation of vector mortality rates. Sporozoite rates in resistant and susceptible mosquitoes will be compared to study impact of resistance.

Meteorological data monitoring

Monthly rainfall, minimum and maximum temperatures, and relative humidity data will be collected from all functional weather stations in Ondo State, for up to 10 years before the ITN campaign and during the three years period post-campaign. The data will be analyzed in conjunction with selected indicators.

Time series methods will be used to study seasonal and annual trends in meteorological variables in conjunction with trends in malaria morbidity (incidence rates), entomological variables, and data related to ITN use rates and durability data. The meteorological data will be used to explain some of the trends in the other variables and for deeper understanding of the impacts of the intervention.

Costing studies

Financial and economic costs associated with the ITN campaign will be collected and used for cost-effectiveness analysis. The costing analysis will involve review of financial cost data obtained from various partners involved in the ITN campaign, and use of multiple sources to estimate economic costs incurred by each partner. Both desk-based studies and field visits will be required. Consultants (health economists) will be recruited to undertake the work, assisted by Malaria Consortium staff, national and state malaria programme staff and field assistants. The costing data and the epidemiological impact assessment results will be used alongside appropriate models and other relevant results to estimate cost-effectiveness of the campaign.

All costs of the campaign will be calculated and used in the cost-effectiveness analysis. Cost-effectiveness analysis is beyond the scope of the studies covered in this concept note although the generated data will be used by GiveWell for that purpose.

Budget

A total of US\$ 2,051,853 will be required to implement the studies in Ondo State (Table 3). Details of the budget and the associated assumptions are provided in the accompanying spreadsheet. The M&E costs for the post-campaign evaluation survey included in the separate ITN campaign budget will be used for developing or customizing the ODK-based electronic data collection tools and management of the data for both the baseline and subsequent household interviews, and other costs related to the campaign M&E.

Table 3. Budget estimates by year and study component.

Category		Baseline	Year 1	Year 2	Year 3	Total (USD)
MC staff costs	MC staff salary	152,495	253,844	259,837	275,980	942,156
	MC office recharge	14,459	25,579	26,347	27,674	94,059
	MC staff travel	18,099	12,170	11,784	20,228	62,282
Study components	Household survey	53,192	0	0	0	53,192
	Durability monitoring	49,297	33,384	34,310	35,264	152,255
	Entomology	112,726	18,220	91,539	19,329	241,814
	Meteorology	8,640	720	720	720	10,800
	Incidence study	72,833	45,699	33,878	34,846	187,256
	Costing study	0	15,898	0	0	15,898
	Miscellaneous	19,500	7,000	16,800	29,000	72,300
Sub-total		501,241	412,513	475,215	443,042	1,832,011
Management fee		12%	60,149	49,502	57,026	53,165
Total (USD)		561,390	462,015	532,241	496,207	2,051,853

References

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