

(1) Household Surveys

1. Will you be able to blind campaign planners and distributors to the areas selected for monitoring? We'd like to ensure that those wards are representative of distribution quality across the study area.
 - o "The selected wards will be kept the same throughout the study."

Distributors can be blinded if they are not involved in both the distribution and the surveys. Ward-level community leaders whose support will be needed during the distribution as well as the surveys cannot be blinded. We may not be able to completely blind LGA level health staff but all others (national and state level planners and supervisors) can be.

2. How will you do simple random sampling of households within selected wards, and how will you ensure the interviewed households match up with those selected?

All households in the 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 or 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. Selected households visited by the interview team will be given a card with the household number and names of children 6-59 months. The household head will be asked to take the card and all eligible children to the biomarker collection team's station at a central position in the village to take blood samples.

3. Among the various malaria tests planned (microscopy, serology, RDTs, and PCR), is there a primary outcome that you expect to be most reliable? What's the rationale for including multiple test metrics? Should we interpret these markers as capturing malaria prevalence?

The primary outcome will be prevalence as determined by microscopy by an expert technician at an appropriate laboratory. RDT tests are used for comparison and for on-the-spot tests and treatment. PCR is used for assessment of sub-microscopic parasitemia especially in low endemicity situations. Serological studies detect human antibody responses and will be used to assess both current and past exposure to infection, and therefore can provide a picture of longer-term transmission intensity and changes over time as opposed to the cross-sectional point prevalence estimates from the other methods.

4. What do you know about the cultural acceptability of collecting blood biomarkers in this part of Nigeria? How will you engage with communities to ensure acceptability and high consent rates?

[REDACTED]

9. Would the planned durability monitoring meet the qualifications for a Phase III trial of the DuraNet Plus?

Our planned durability study will meet the requirements of Phase III tests but not necessarily as part of the manufacturer's planned trial as mentioned above.

[REDACTED]

11. Will the durability studies be cross-sectional or longitudinal?

The studies are based on identification of a cohort of nets and following them up longitudinally during surveys at the indicated intervals, and additional annual bioassays of a sample of campaign nets outside the main cohort in each location.

12. How will you identify nets from this campaign (versus other sources) for durability monitoring?

The nets will be labeled at the manufacturing stage, with additional unique labeling of the cohort nets.

13. Will you use standard WHO proportionate hole index measurements and thresholds to classify net condition?

Yes.

(3) Entomological studies

14. Our initial inclination is to skip this piece, given high costs and limited direct value for improving our cost-effectiveness model. The part we're most excited about is a one-time measurement of resistance and PBO synergist bioassays to confirm net choice for these areas. However, we'd be happy to discuss further if you want to expand on the case for this piece. Do you want to discuss?

The suggested entomological indicators are important to monitor especially as new types of nets are being introduced and that entomological and epidemiological impacts are both necessary for a complete understanding of the effectiveness. (1) In nearly all states supported by PMI and the Global Fund, similar entomological surveillance activities are ongoing; such data on effectiveness of PBO nets could be compared directly with similar data from other states especially those with standard (pyrethroid-only) nets. (2) The chosen entomological parameters such as parity rates (to estimate changes in vector longevity in relation to the nets), vector infection rates and biting rates (to estimate entomological inoculation rates) would provide information on the “mass effect” of the nets on the vector population, to allow additional parameters for estimating changes in transmission intensity; and (3) the design allows monitoring of any potential changes in vector species composition and habits following the intervention.

(4) Malaria incidence studies

15. How will you select the two sentinel sites for incidence monitoring?

These will be one each from southern (the forest areas) and northern parts (lowland forest and savanna areas) of Ondo State, among the wards to be selected for entomological monitoring. Availability of a functional laboratory including trained laboratory technicians, quality of record keeping, and overall health facility management will be considered during selection.

How representative will results from the two sites be?

The aim of the incidence data monitoring is not spatial representation, but assessment of temporal trends following the ITN campaign, and linking of entomological, household survey, and malaria prevalence data with number of cases seen at health facilities.

16. How will you monitor data quality from the two surveillance sites? Is there evidence that the plans to support these locations in diagnosis and record keeping lead to reliable data?

- “The health facilities will be equipped with diagnostic supplies and staff trained in diagnosis, case management, and quality record keeping. The facilities will be also supervised quarterly to maintain the required quality of data collection.”

Studies in other countries in which selected sentinel sites have received regular supervision combined with a system of record quality control have demonstrated that clinical data record keeping and compilation accuracy can be substantially improved (e.g. [Jones et al 2008](#)).