**LLIN durability monitoring guidelines**

Introduction

LLIN monitoring aims to provide programs with information needed to optimize their procurement, delivery and effectiveness. Monitoring allows programs to identify products that perform below expectations; it also provides useful feedback to manufacturers in their efforts to improve their products. While a rule of thumb that nets should be replaced every three years is commonly followed, field studies have shown that the durability of LLINs varies within and among countries, and that the durability of different types of nets may also vary. This variation is attributed to various behavioral, mechanical and chemical elements so country-specific information is thus useful for guiding procurement and programmatic decisions made by NMCPs and PMI.

Similar to monitoring of drug efficacy and insecticide sensitivity, LLIN monitoring must compromise between cost and optimal sampling. The diversity of LLIN types, environmental circumstances, and cultural practices make exhaustive sampling impractical; however, it is possible and cost-effective to obtain representative data on the major types of LLINs distributed. This document provides guidance on how the monitoring can be done. It also aims to provide a framework to decide whether monitoring should be carried out and under what circumstances it might be terminated. Programmatic context drives the decision making process; it does not matter whether PMI, the GFATM, or other funds have been used to purchase the nets.

LLIN monitoring measures the effect of normal daily use on four outcomes: 1. Attrition (survivorship), as measured by the loss of nets from households, 2. Physical durability, as measured by the number and size of holes in the net, 3. Insecticide effectiveness, as measured directly but imprecisely by bioassay, and 4. Insecticide content analysis, as measured accurately by chromatography. These are best monitored in a prospective design linked to a mass LLIN distribution campaign. In the following, we provide a decision matrix for deciding whether to carry out LLIN monitoring and provide guidance for sample sizes for each outcome.

Should LLIN monitoring be carried out?

Factors affecting whether LLIN monitoring might be undertaken include:

1. Stage of malaria control. LLIN monitoring is most valuable for countries whose programs are in control phase and distribute large of numbers of LLINs. It is less useful for a program in pre-elimination or elimination phase which distributes fewer numbers of LLINs.

2. Size and diversity of the country. The larger the country and the more diverse it is culturally and environmentally, the more useful LLIN monitoring is likely to be. A small country with limited diversity might carry out monitoring in one site, while a larger country with greater environmental or cultural diversity might monitor LLINs at two sites. Monitoring at more than two sites is not recommended.

3. Numbers of types of LLINs distributed. Programs that rely heavily on one brand or type of LLIN might carry out durability monitoring on that brand only, while a country distributing large numbers of several types of nets might wish to carry out durability monitoring on the two major types of nets used. Monitoring more than two net types concurrently is not recommended.

4. Availability of data. Countries with data available on the durability of specific brands of nets distributed in the country do not need to carry out further monitoring on those brands. Countries with no data should consider carrying out LLIN monitoring. Programs that distribute nets that have not previously been subjected to routine monitoring in other countries should also be given priority. This is particularly true for next generation nets for which no durability data yet exist. When considering beginning a new three-year monitoring activity, countries that have previously conducted durability monitoring should review whether previously monitored sites are very different, socio-culturally or geographically, from new sites. They should also review whether ongoing monitoring of cultural/behavioral factors is needed to inform programming.

5. Programmatic context. Programs have multiple priorities. It is possible that other priorities such as diagnosis, treatment, or surveillance might take precedence, depending upon country context. Initiation of a mass LLIN distribution campaign is, in contrast, an opportunity to begin prospective monitoring should other factors support this.

Clearly, the above factors are best weighed by PMI country teams in consultation with NMCPs, with a view towards extracting maximally useful data with the least expenditure. Some extreme cases have clear outcomes. A small country with existing data on the type or types of LLIN to be distributed in the future can discontinue monitoring. A country that is distributing small numbers of LLINs in the context of malaria elimination has no urgent need to carry out LLIN monitoring, even if data on LLIN durability are unavailable. In contrast, a large country distributing large numbers of several types of LLINs with no country-specific data should make LLIN monitoring a priority. A country introducing a new type of LLIN into its program should also begin monitoring its durability. Most countries will fall between these extremes and should exercise judgement in deciding upon whether or not to initiate monitoring.

If LLIN monitoring is done, which outcomes should be measured and with what sample size?

LLIN durability monitoring consists of four outcomes: attrition, physical integrity, insecticidal activity and insecticide content. Depending upon the country context, it may be necessary to limit which outcomes are measured. At a minimum, all countries should have the capacity to measure attrition and physical integrity. These outcomes do not require any special equipment or expertise. Further, recent evaluations suggest that these factors may be the most important limiting factor in LLIN durability. Attrition and physical durability can be reasonably measured in a cohort sample of 250 marked nets followed longitudinally and examined yearly for three years. With this sample size, using 15 clusters of 10 households each, countries will be able to detect approximately 20% variation in performance among products over a three year period, equivalent to approximately plus/minus 6-7 months of median net lifespan.

Insecticidal activity is measured by exposing LLINs to susceptible mosquitoes in WHO cones. Because the purpose of the activity is to measure insecticidal activity, any susceptible species of mosquito may be used for the bioassay. This activity requires specialized facilities and staff, in particular an insectary with a susceptible colony of mosquitoes and lab staff with the ability to consistently generate large numbers of mosquitoes of uniform quality required for bioassays. If an insectary is not available, net samples may be sent to an outside laboratory for analysis. Measurement of insecticidal activity at baseline, 12 and 24 months should be done on nets from outside the main cohort and at 36 months from the main cohort, whereby 30 nets are taken from the field for laboratory testing each year for three years. Nets collected at the 12 and 24 months may be identified through one of two methodologies, either: a) random selection from outside the study cohort; or b) tagging a separate bioassay net cohort at baseline. Each methodology has pros and cons and should be selected based on what is most appropriate within the country specific context. The nets taken from the field will need to be replaced by new nets. Where deltamethrin ITNs are being monitored, and capacity exists to do testing, the CDC colorimetric field test (CFT) may be considered in addition to bioassays, on discussion with the VMCT team.

The measurement of insecticidal content is a supplementary tool for the monitoring of insecticidal activity that may be done on the same cohort of nets sampled for bioassays. Content testing should not be done independently of bioassays. Determination of insecticidal content can be used to confirm the bioassays and estimate insecticide retention rates across different settings and in different LLIN products. However, measurement of insecticidal content requires highly specialized capacity that is likely limited or absent in nearly all PMI countries. Therefore, this must be done either at CDC or at a WHO collaborating center where the cost of analysis is approximately $150 - $350 per sample. Furthermore, in some cases there is a poor correlation between insecticidal content and insecticidal activity, particularly for some LLINs made of polyethylene with insecticide directly incorporated into the fiber. We do not generally recommend carrying out content testing for nets types which incorporate insecticide in solution in the net fiber[[1]](#footnote-1).

Measurement of insecticidal content is done by PMI at baseline for all PMI-procured LLINs. The GFATM has put in a place an analogous program so there is no need for PMI to fund pre-shipment measurement of insecticide content in GFATM-procured nets. Insecticidal content testing may be done on samples of the same 30 nets taken from the field for bioassays. If bioassays are being performed, the marginal cost of performing insecticidal content analysis is determined by the cost of the laboratory analysis; for 30 samples this cost will range from 4,500 – 10,500 USD. Such analysis should be given priority where there are no existing data or where new compounds or new net technologies are in use. It may also be useful to carry out content testing on an ad hoc basis should bioassay data demonstrate a loss of effectiveness.

Interpretation and use of the results of LLIN monitoring

The WHO Prequalification Team has provided clear cut-off points for WHO cone tests. Nets are considered optimally effective if they cause >80% mortality or >95% knockdown in the WHO cone test while nets are considered minimally effective if they cause >50% mortality or >75% knockdown.

Criteria for attrition and physical durability are less established but recent guidelines have been presented by the WHO Vector Control Advisory Group and the WHO Malaria Policy Advisory Committee. PMI recommends that nets be considered in need of replacement if they have a proportionate hole index (pHI) of at least 642 (equivalent to at least 1000cm2 of damage, regardless of assumptions of shape of the hole). Population level survivorship curves can then be fitted to estimate an optimal replacement cycle.

Results of LLIN monitoring can be used:

1. To determine the median LLIN life in a country and understand factors affecting attrition and LLIN performance;
2. To inform improved procurement practices to ensure that LLINs bought provide as optimal performance as can be expected;
3. To inform countries on how to develop their LLIN distribution strategies to ensure nets are available when needed, depending on median life;
4. To inform countries to develop effective BCC messages on the care of LLINs;
5. To provide information to WHO Prequalification and manufacturers on the durability of different LLINs under different conditions to improve products and their specifications.

LLIN Durability Operational Research

There may be occasions where PMI country teams seek additional data points to answer an expanded set of programmatic and/or operational questions related to the national LLIN program. Expanding beyond the parameters outlined in these guidelines will likely shift this investment from a standard monitoring activity to one more closely aligned with operational research. In those circumstances, these guidelines are no longer applicable and PMI country teams must develop and submit a concept note to the PMI Operational Research Committee to explain, justify and seek approval for the proposed operational research study.

1. [↑](#footnote-ref-1)