Interpreting durability monitoring data for programmatic action

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# Background

Results from the 12, 24 and 36 months rounds of ITN durability monitoring (DM) are intended to provide information on whether ITN products are performing as expected. These results may demonstrate that nets in given settings are as durable as expected, or that net integrity is lower than expected. These results inform potential next steps, for social and behavior change communication for net care attitudes and practices, or in more extreme cases, for procurement decisions. If physical net durability or insecticidal efficacy is below expectations, PMI teams and others need to identify potential problematic results before the end of the monitoring activities, in order to take appropriate actions.

This document summarizes thresholds for key DM indicators for physical integrity and for insecticidal durability, and provides action steps if results fall below threshold. The goal is to identify whether below-threshold results are due to suboptimal care and handling at the household level, suboptimal storage, or suboptimal manufacturing, or a combination thereof. If multiple causes are affecting LLIN durability, further investigation or data from monitoring activities in other countries may be required to disentangle the most important factors. The standardized approach and reporting templates help to streamline interpretation across different countries.

There are two types of DM activities – those that monitor the same product in different settings, and those that monitor different products in the same setting. When data from multiple monitoring activities are viewed together, across countries, additional patterns may emerge.

# Section 1: Interpreting physical integrity results

The key indicator for ITN durability is the proportion of nets surviving in serviceable condition at a given timepoint. Figure 1 below describes how this indicator is calculated.

Figure : Understanding % of nets surviving in serviceable condition



## Key Indicators

1. Proportion of nets surviving in serviceable condition:
   1. Numerator: the number of cohort nets that are in serviceable condition at the time of the survey (pHI≤642)
   2. Denominator: all cohort nets, including those lost prior to the survey due to wear and tear, but excluding nets given away, used elsewhere or stolen   
      This indicator is the primary outcome on which assessments should be based and its calculation includes two of the other indicators mentioned below, namely physical condition of surviving nets and attrition due to wear and tear.
2. Physical condition of surviving nets: Among only the nets still found in households, the proportion that are in serviceable condition (pHI≤642).  
   As mentioned above this indicator is part of the primary outcome, but can only be interpreted when considered in conjunction with attrition due to wear and tear. If net users tend to retain worn nets rather than throw them away, the condition of the surviving nets can be poor, but attrition due to wear and tear will be very low (and vice versa).
3. Attrition due to wear and tear: the proportion of cohort ITNs (not including nets given away, used elsewhere or stolen) that were reported lost because they were too worn (thrown away, destroyed or used for other purposes). This indicator can only be interpreted correctly in light of the indicator on physical condition of surviving nets (see above).
4. All-cause attrition: the proportion of cohort ITNs lost for any reason, including being given away.  
   This indicator does **NOT** contribute to the primary outcome and is largely driven by the rate of giving nets away, which in turn can vary significantly depending on how many nets household still owned from previous distributions at the time of the last campaign, and how they use old and new nets (e.g. using the new nets and giving away excess older nets, or the other way around).

## Thresholds

### Proportion of all cohort nets surviving in serviceable condition

* Among all cohort nets (including those discarded due to wear and tear in the denominator), the proportion that are still there and in serviceable condition is generally high (>99%) at baseline (<6 months post-distribution) and at 12 months (>93%)
* This indicator is calculated using both the physical condition of cohort nets that are still in the households, as well as information about nets that were lost due to wear and tear. If this key indicator is below threshold, both these factors should be investigated.
* Thresholds apply across the entire monitoring cohort, as well as for each site or product.

Table : Thresholds for % of cohort nets surviving in serviceable condition

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Threshold A** | **Threshold B** | **Threshold C** |
| **Survey round (time since distribution)** | Normal: no action (assuming 3-year median or better) | Potential problem: investigate further (median survival 2.5 years or less) | Significant problem: investigate urgently  (median survival 2.0 years or less) |
| **Baseline (<6 months)** | >=97% | <96% | <93.5% |
| **12 months** | >=93% | <88.5% | <85% |
| **24 months** | >=74% | <62% | <50% |
| **36 months** | >=50% | <36% | <20% |

### All-cause attrition:

* Note that at baseline, it is common to find that 5-20% of campaign nets were given away between the campaign and the baseline survey. This is household redistribution of nets primarily to family members or family members traveling to other locations. This also depends on the scope and scale of previous ITN distributions in the area. After 12 months all-cause attrition can be anywhere between 5% and 40%.
* If more than 5% of campaign nets are reported ‘sold’ at the baseline survey, further investigation into why households are selling nets and to whom should be conducted.

### Attrition due to wear and tear:

* Attrition due to wear and tear normally varies between 0-1% at baseline and 1-5% at 12 months and 3-12% at 24 months

### Physical condition of surviving nets

* Of the cohort nets found in households, the proportion in serviceable condition is generally high (99%) at baseline and at 12 months (97%).
* Note that towards the end of the monitoring, this indicator may remain high as households discard torn nets, keeping only nets still in good condition.

### Product differences

In areas where different products are being monitored in similar settings, there are thresholds of difference between products. These are determined by the power of the study or monitoring exercise. For the PMI recommended sample size the difference in survival in serviceable condition between two brands that can be detected as statistically significant is plus/minus 9-10%-points, which after 36 months translates into a difference in median survival of the brands of about one year. To detect smaller differences, larger sample sizes are needed.

Table : Thresholds for investigating differences in % survival in serviceable condition between two products

|  |  |  |
| --- | --- | --- |
| **Survey round (time since distribution)** | **Threshold A: Normal: no action** | **Threshold B: Potential problem: investigate further** |
| **Baseline (<6 months)** | 0% (no statistical difference) | Any statistically significant difference |
| **12 months** | 0% (no statistical difference) | Any statistically significant difference |
| **24 months** | 0% (no statistical difference) | Any statistically significant difference |
| **36 months** | 0% (no statistical difference) | Any statistically significant difference |

If products are performing at satisfactory durability thresholds, but one product has significantly higher % survival in serviceable condition, further investigation – including triangulation with other monitoring sites - may be useful to determine whether the product specifications or socio-cultural factors are driving the improved durability.

### Use of Cohort ITNs

Note that at baseline, it is common for 50% or more of the cohort ITNs to still be in their packaging, as households save them for when their current ITNs are worn out. This is especially true when the durability monitoring baseline occurs immediately after the campaign distribution. This is not worrisome, but PMI teams should confirm at 12 months that use of cohort nets improves as households transition from older to newer ITNs. If the percent of cohort nets used the previous night does not increase by 12 months or after, check the [ITN Access and Use Report](http://www.vector-works.org/resources/itn-access-and-use/) for behavioral trends in ITN use for the country and region, taking into account seasonal patterns of net use and the timing of the DM data collection. If use is lower than normal trends, strategies for improving ITN use should be discussed with the relevant SBCC partners.

If data indicate that cohort ITNs are not being used but that use of other ITNs (or untreated nets) is high, this may indicate that user preferences for nets are affecting ITN use behaviors.

### Attitudes

Mean attitude scores of at least 1.0 (on a scale from -2.0 to 2.0) are “very positive”). If mean attitude score is less than 1.0, then additional SBCC is recommended to improve net care attitudes, which are demonstrated to be associated with improved ITN lifespan.

## Investigation

There are a variety of reasons why attrition and net condition may be below thresholds. Investigations should be done to identify and/or rule out different reasons, and then to proceed to appropriate action. If attrition, physical durability, or net survival are below Thresholds B or C, the implementing partner for DM should:

1. Analyze the data to identify environmental, socioeconomic, house/sleeping space environment, washing/use practices that may be associated with reduced durability. For similar settings with different products, aim to identify or rule out whether observed product differences are indeed due to the product, or if there may be differences between sites.
2. Rule out any problems training data collectors that may have led to different hole counting practices or data quality issues.
3. If environmental/household factors are not deemed to be important factors, only then should investigation of production issues be done. Production issues can be divided into two categories:
   1. product specification (denier, knitting pattern) is not as durable as expected, or
   2. products are not being manufactured to their specification.

### Product specification is not as durable

Further research would be needed to investigate why product specifications would be more or less durable. Triangulation among at least three different settings would be needed to prompt such an investigation.

### Product not manufactured to specification

If data indicate that the product may not have been manufactured to its specification, there are extended textile tests that can be performed at experienced textile laboratories. For example:

1. Check burst strength at pre-shipment testing was to specification.
2. Confirm denier from samples matches product specifications.

Note that knitting pattern, which has been associated with reduced durability, is not specified in the WHOPES processes, therefore it will be difficult to assess changes in knitting pattern for particular products.

## Action Steps if under Threshold

### Household or environmental factors

If household attitudes or behaviors, or environmental setting are identified as contributing to reduced physical durability, social and behavior change communication should be implemented rapidly to improve net care behaviors. See the [Guide to Net Care SBCC](http://www.vector-works.org/wp-content/uploads/Net-Care-SBCC-GuideV3_23Nov2016.pdf) for further details.

### Product specifications not as durable, or not manufactured to specification

Based on previous research, PMI recommends having data from at least three countries showing the same problem. As most products now have very similar physical durability, the settings themselves have more influence on the physical condition and attrition than product specifications.

If manufacturing issues are identified as the cause of the reduced durability, interim guidance is for PMI teams to:

1. Discuss with PMI ITN Technical and Procurement Teams
2. PMI VMCT Team contacts WHO Pre-Qualification Division and the manufacturer as needed

### Programming

It is important to remember that even very damaged nets are better than no nets, and if ITN coverage is within expectations, reduced physical integrity of those ITNs will still provide some protection. However, if Threshold C issues are identified at 12 months, PMI teams may consider planning to move up the next mass campaign, or increase volumes of nets delivered through continuous channels if coverage is getting too low. Mass campaign timelines are likely not flexible enough to respond quickly to issues identified at 24 months.

# Section 2: Interpreting bioassay results

## Background

PMI recommends monitoring of insecticidal activity on ITNs as part its overall guidelines for ITN durability monitoring (DM). This is done through bioassays at the 12-, 24-, and 36-month[[1]](#footnote-1) assessments on 30 nets per product/site and time point. Bioassays measure how well the ITNs perform at killing susceptible mosquitoes. They do not measure performance against resistant mosquitoes.

WHOPES protocols for bioassays are described in detail the Guidelines for laboratory and field testing of long-lasting insecticidal nets (<http://www.who.int/iris/bitstream/10665/80270/1/9789241505277_eng.pdf>). Recent evidence has indicated that testing protocols should standardize the angle at which the cone is placed on to the ITN sample. Tapping on the cone to ensure mosquitoes are not simply resting on the inside surface of the cone is also recommended but not described in the WHOPES protocol.

The notes on indicators, thresholds and their interpretation as well as action steps described below are intended to help PMI teams identify and/or rule out potential causes of any reduced insecticidal effectiveness results. The goal is to find out whether nets were suboptimally manufactured; suboptimally stored before distribution; excessively washed; or if there is lab error. Note that there could be a combination of factors in some cases.

## Indicators

PMI recommends reporting on the following four indicators.

1. Knock down 60 minutes – mean and/or median of the proportion of mosquitoes that were knocked down within 60 minutes of a three-minute exposure to the ITN among the results from the 30 nets sampled. (Note that the result for each net is itself the mean of multiple cone assays from multiple sites on the net).
2. Mean mortality after 24 hours – mean and/or median of the proportion of mosquitoes that were dead 24 hours after a three-minute exposure to the ITN among the results from the 30 nets sampled (note that the result of each net is itself the mean of multiple cone assays from multiple sites on the net.
3. Optimal effectiveness – proportion of ITNs tested (30) that met WHOPES evaluation criteria of at least 95% KD or 80% mortality.
4. Minimal effectiveness – proportion of ITNs tested (30) that met at least at least 75% KD or 50% mortality.

These indicators are presented in the DM reports as follows:

**Table 1:** Results from bio-assays

|  |  |  |  |
| --- | --- | --- | --- |
| **Variable** | **12 months** | **24 months** | **36 months** |
| **Site A / Product A** | N=30 | N=30 | N=30 |
| Knock down 60 minutes  Mean (95% CI)  Median (IQR) | % ( )  % ( ) | % ( )  % ( ) | % ( )  % ( ) |
| Mortality 24 hours  Mean (95% CI)  Median (IQR) | % ( )  % ( ) | % ( )  % ( ) | % ( )  % ( ) |
| Optimal effectiveness  Estimate (95% CI) | % ( ) | % ( ) | % ( ) |
| Minimal effectiveness  Estimate (95% CI) | % ( ) | % ( ) | % ( ) |
| **Site B / Product B** | N=30 | N=30 | N=30 |
| Knock down 60 minutes  Mean (95% CI)  Median (IQR) | % ( )  % ( ) | % ( )  % ( ) | % ( )  % ( ) |
| Mortality 24 hours  Mean (95% CI)  Median (IQR) | % ( )  % ( ) | % ( )  % ( ) | % ( )  % ( ) |
| Optimal effectiveness  Estimate (95% CI) | % ( ) | % ( ) | % ( ) |
| Minimal effectiveness  Estimate (95% CI) | % ( ) | % ( ) | % ( ) |

## Interpretation and Thresholds

According to WHOPES Phase III evaluation criteria, at least 80% of recommended LLIN brand should achieve optimal effectiveness 36 months post-distribution. For the PMI DM this means that at all timepoints, ≥80% of nets should meet optimal effectiveness criteria (at least 95% KD or 80% mortality). However, this may not be realistic under real-world conditions nor necessary from an epidemiological standpoint.

If less than 80% of nets meet these criteria, then PIs should check whether at least 80% of nets meet minimal effectiveness criteria. This is not an official WHOPES threshold but will give a good assessment by how much the nets are failing. If less than 80% of nets meet minimal criteria, a significant problem with bioefficacy of the nets is very likely and investigation into likely causes should be done.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Threshold A** | **Threshold B** | **Threshold C** |
| **Survey round (time since distribution)** | Normal: no action % of nets that meet optimal effectiveness (95% KD or 80% 24h mortality) | Potential problem: investigate further % of nets that meet minimal effectiveness (75% KD or 50% 24h mortality). | Significant problem: investigate urgently  % of nets that meet minimal effectiveness (75% KD or 50% 24h mortality). |
| **Baseline (<6 months)** | >=80% | >=80% | <80% |
| **12 months** | >=80% | >=80% | <80% |
| **24 months** | >=80% | >=80% | <80% |
| **36 months** | >=80% | >=80% | <80% |

## Investigation Steps

There are a variety of reasons why ITNs may show reduced insecticidal effectiveness during monitoring bioassays.

1. Household causes
   1. Normal washing and drying practices reduce insecticide content within the ITN
   2. Above-normal (more than once every two months) washing and/or drying practices
2. Lab causes
   1. Lab protocols were not strictly followed
   2. Mosquito colony used for bioassays is not fully susceptible
3. Manufacturing or storage causes
   1. ITNs did not contain specified amounts of insecticide at the time of manufacturing
   2. Insecticide content was reduced or lost as a result of extended storage at excessive temperatures between manufacturing and distribution.
   3. Insecticide not available at surface of the net due to other manufacturing processes

PMI teams should request that DM implementing partners take the following actions if bioassay results are below minimal criteria; investigation and its outcomes should be documented separately and included in the subsequent round’s report. Steps below are indicated in order of likely importance, but can be undertaken simultaneously, to the extent feasible.

### Step 1: Behavioral factors

1. Check bioassay net data for any differences between sites. This may indicate behavioral factors.
2. Analyze the DM survey data for above-normal washing frequency or use of bleach/detergent, frequency of net use, or other net handling factors.

### Step 2: Lab factors

If there are no clear behavioral explanations for the low bioassay results, the next step is to confirm the lab tests were done correctly.

1. Check with entomology lab that negative controls (testing against plain untreated netting) had mortality between 0-10% (i.e., that the strain was not weakened or frail).
2. Check with the entomology lab that positive controls (testing against a new ITN of the same product) for the mosquito strain used were available to verify that the results were correct and no pyrethroid resistance in the strain tested
3. Secure additional samples from tested nets for potential chemical residue analysis to be done at CDC or WHO collaborative lab (e.g. Gembleaux)
4. Consider retesting in another lab (consider tunnel test).
5. Confirm with entomology lab that temperature, humidity, age of mosquitoes, angle of cone test were per protocol.

### Step 3: Manufacturing and storage issues

If no behavioral or lab issues are identified, the next step is to check pre-shipment testing and for possible storage under poor conditions.

1. Check pre-shipment data to determine whether ITN batch passed pre-shipment chemical testing and density of yarn.
2. Contact manufacturer to obtain pre-shipment samples for chemical testing and bioassays (or test results if available)
3. Contact implementing partner responsible for storage and/or distribution of ITNs to identify any adverse or extended storage conditions between arrival of ITNs in-country and distribution to beneficiaries. Probe for indications of exposure to temperatures over 54C over extended periods of time.

## Action Items after investigation

1. If funding is available, PMI teams should consider conducting chemical residue testing on the additional samples collected.
2. If investigation is inconclusive, for the monitoring round following a Threshold B or C bioassay result, PMI teams should consider funding chemical residue analysis together with bio-assay.

### Behavioral Issues: Action

If data indicate **washing/handling** as a possible cause of reduced bioefficacy, PMI country teams should engage implementing partner(s) to conduct social and behavior change activities to promote appropriate washing and net care practices.

### Lab Issues: Action

If investigation indicates that any lab issues are responsible for the results, on-the-job training should occur to bring labs back in line with specifications and protocols. If colony is no longer susceptible, then the colony needs to be replaced, and staff should be re-trained on how to maintain and monitor pure colony lines.

### Production Issues: Action

If manufacturing issues are identified as the cause of the reduced bio-efficacy, PMI teams should:

1. Discuss with PMI ITN Technical and Procurement Teams
2. PMI VMCT Team contacts WHO Pre-Qualification Division and the manufacturer as needed

### Storage Issues: Action

If storage issues are identified as a potential cause, PMI teams should document storage conditions to the extent possible, and review storage options with the appropriate implementing partner.

## Programming

It is important to remember that minimally and less-than-minimally effective nets are better than no nets. If severe lack of bioefficacy is identified at 12 months, PMI teams may consider planning to move up the next mass campaign, or increasing continuous distribution channels to deliver additional ITNs. Mass campaign timelines are likely not flexible enough to respond quickly to issues identified at 24 months.

1. Representing time since the ITNs were distributed. [↑](#footnote-ref-1)