Registration of delegates and welcome
## Day 1: Updates from first convening and discussion of post shipment issues

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Introduction and follow up on progress towards Roadmap goals
Welcome to Liverpool!!

We’re happy to bring people together again!

- We hope this meeting will be informative and constructive....
- ... but also allow you all to catch up after so long apart

Please take time to take in the sights.....
Welcome to Liverpool!!

- We’re happy to bring people together again!
- We hope this meeting will be informative and constructive....
- ... but also allow you all to catch up after so long apart

.... Though maybe not all of them
Welcome to Liverpool

Covid measures

▪ Currently no requirement in the UK for wearing masks
▪ However, it is recommended in enclosed spaces with large groups
▪ Essentially a personal choice, so please respect other’s choices
▪ If you develop symptoms please let us know and self-isolate

The Albert Dock
ITN Quality Under Scrutiny

Why we are here
ITN quality has hit the headlines

Anecdotally, other countries have also identified net quality issues, including:
- South Sudan
- Nigeria
- Pakistan
Significant variability in ITN retention has been recorded

“.....the bulk of existing evidence supports the notion that median net retention is commonly lower than 3 years.”

“The primary motivation for discarding a net in these studies was the perception that it was too torn, with even a modest amount of net damage often regarded as unseemly or untidy.”

Nets are not consistently performing as expected - Why?
The first convening focused on pre-shipment aspects.

- **Global Policy Guidelines**
  - Pre-Shipment (covered in first convening)

- **Manufacturing**
  - R&D
  - PQ Evaluation
  - Production Line
  - Quality Control

- **Procurement**
  - Minimum Standards
  - PQ Evaluation
  - QA/QC (Global)
  - Tendering
  - QC (Pre-Delivery)

- **Country Management**
  - Post shipment QC (In-Country)
  - Storage & Distribution
  - Household Use and M&E

- **Post-Shipmnet (to be covered in second convening)**
Emerging Themes from the First Convening

A clear need to distinguish ITN “quality” from “performance”

- Clarity on definitions and roles within the quality space
- Product characteristics that reflect actual performance
- Clearer characteristics to inform value based procurement
- Transparent data to inform on issues
Maintaining a focus on Quality AND Performance of ITNs

**technical definition**
the degree to which nets meet the chemical and physical properties defined by their specifications

**common definition**
whether nets do what we expect under normal usage conditions (remain physically and chemically active for 3 years)

Does meeting the technical definition lead to meeting the performance expected in the common definition?
Extrinsic influences on ITN quality and performance

**Global Policy**
- Are current specs sufficient to determine whether nets will last 3 years?
- How can policies promote continual improvements on quality?
- Is there confidence in current QA processes?

**Data**

**Data generation**
- Do we have the data we need?
- How can data be made more available?

**Data interpretation**
- Are we clear what those data are telling us?
- How can this be more clearly communicated, and with whom?

**Procurement**
- How does price affect quality?
- Is quality/performance incentivized?
- Are quality definitions aligned?
- Are we getting value for money?

**Country Management**
- Are ITNs managed appropriately?
- Are appropriate post-shipment testing processes in place?
- Can we improve ITN care?
- What do DM data tell us?

**Manufacturing**
- Are ITNs being produced to spec?
- Are quality processes sufficient?
- What would ‘better’ cost, and who would pay for it?
This convening to focus on Country Management aspects

**MANUFACTURING**
- R&D
- PQ Evaluation
- Production Line
- Quality Control

**GLOBAL POLICY GUIDELINES**
- Minimum Standards
- PQ Evaluation
- QA/QC (Global)
- Tendering
- QC (Pre-Delivery)

**PROCUREMENT**
- Shipment
- Post shipment QC (In-Country)

**COUNTRY MANAGEMENT**
- Storage & Distribution
- Household Use and M&E

**Post-Shipments**
(to be covered in this convening)

**Pre-Shipments**
(covered in first convening)
Next Steps after the First Convening

Establish the vision for coordination on Raising the Floor of ITNs Q1 2022

- Develop a theory of change that represents the partnership’s vision
- Develop a roadmap to clarify key activities, outputs, and indicators of success
- Develop a communication and engagement strategy including a glossary of terms
- Develop a roles and responsibilities document of the QA process
- Build on Trop Health report of global QA processes and use case studies to identify areas of focus
Next Steps after the First Convening

Continue to push forward with activities already under way and identified as priorities

- Harmonize quality testing guidelines for pre-shipment sampling and testing
- Investigate links between product specifications and eventual performance
- Review product testing and evaluation methods for potential updating
- Develop a case for Return on Investment for improved performance of ITNs and identify potential procurement incentives
- Identify potential additions to ISO 9001 to improve inspection protocols and manufacturing sites
Next Steps after the First Convening

Organise a second convening in Q2 2022

- Update on progress of activities from first convening
- Feedback from countries on ITN procurement, management and quality
- Review of in country data collection approaches and their interpretation
- Evaluation of the testing capabilities and methods of QA laboratories at regional and country level and dissemination routes for best practice methods
## Convening Daily Objectives:

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<tr>
<td><strong>Update</strong> on progress since the first convening &amp; consensus on next steps</td>
<td><strong>Engage in collaborative discussion to agree on issues, discuss tangible solutions and develop a vision of success for post shipment ITN quality &amp; performance</strong></td>
<td><strong>Learn about the latest thinking on measuring surface availability and bioavailability of AIs on ITNs</strong></td>
<td><strong>Establish working groups to lead the way forward on key priorities identified</strong></td>
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<td><strong>Understand</strong> issues experienced during the delivery, distribution and post-distribution phases of ITN life</td>
<td><strong>Gain consensus key activities and agree timelines for implementation</strong></td>
<td><strong>Continue to foster collaboration for timely delivery of activities in the theory of change</strong></td>
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Guiding questions throughout the three days

### Defining the Issue
- What is(are) the issues?
- Do we understand the cause(s)?
- What decisions are affected?

### Understanding the Issue
- What data do we have to inform on these issues?
- What information do we need?
- How do we go about getting this information, sharing it, and making decisions on it?

### Resolving the Issue
- What would a ‘vision of success’ look like?
- What needs to be in place for these solutions to be implemented?
- Who should be responsible and who can play a role?
- What are realistic timelines for solutions?
Guiding Principles for the Convening

To make progress we need a conducive environment for open dialogue.

This is not a detailed review of past performance, but a focus on building for the future.

Dialogue should be constructive and collegial.

Be open to different opinions and experiences.

Focus on specific, achievable solutions and next steps.
What are you most looking forward to discuss during the convening?
What do you hope you’ll get out of the convening?
Thank You

Questions?
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Raising the Floor on Nets
Theory of Change
Save More Lives
Better access to safe, high quality, efficacious vector control tools
Save More Lives
Better access to safe, high quality, efficacious vector control tools

- Quality management system drives continual improvement in ITN quality
- Improved communication and trust among stakeholders
- Countries supported to make informed decisions on quality
- Procurers use data to make value-based decisions
- Quality and innovation are incentivized
- Product specifications represent attributes that correlate with performance
- Methods are standardized and results more consistent
Save More Lives
Better access to safe, high quality, efficacious vector control tools

OUTCOMES
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ACTIVITIES
- Quality and Performance Metrics
  - Link product specifications with performance
  - Revise product testing guidelines
- Robust QA process
  - Develop quality management system standards specific to ITN manufacturing
  - Improve consistency of ITN lab testing results
  - Improve transparency of data and process
- Incentives for Quality and Innovation
  - ITN market analysis to identify drivers of quality and value
  - Enhance procurement model and shape market to reward quality and innovation
- Country Stewardship
  - Harmonize in-country approach to quality & performance management
  - Improve regulatory preparedness for quality changes

Communication, Clarity, Trust, Transparency
Save More Lives
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**OUTPUTS**
- Revised physical and chemical specification requirements
- Fit for purpose methods validated
- Revised product change guidance
- Reports on wash resistance, AI/bioefficacy relationship
- New editions of product testing guidelines
- ISO 9001+ specific for ITN manufacturing
- Data landscaping report
- Database / data sharing platform
- Blueprint for external quality assurance scheme for ITN testing facilities
- ITN testing facility capacity assessments and action plans
- ITN market analysis report
- Manufacturer quality management system risk stratification
- Context-relevant procurement model
- ITN quality guidance for regulators and NMCPs
- Post-distribution data toolkit
- Case studies providing examples success and challenges of QA system

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Communication, Clarity, Trust, Transparency
Insecticide-treated net supplier quality management system assessment

May 2022
Introduction

• Significant reductions in malaria over the past decade are largely due to universal coverage of vector control tools

Challenges

• Insecticide resistance
• Residual transmission of malaria that remains after universal coverage of IRS and ITNs
• Complexity of tools and metrics of their performance
• Lapses in quality assurance mechanisms

Solutions

• Invest in new vector control technologies to ensure robust pipeline of new ITN insecticides
• Development of new tools to mitigate challenges of insecticide resistance
• Identify gaps in current quality assurance framework for ITNs
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Aim and objectives

- Explore and document range of quality assurance (QA) processes and quality control (QC) measures employed by suppliers.
- Gather industry perspective on challenges of current global QA system.
- Develop recommendations for improving evaluation of quality management systems (QMS).
ITN quality lifecycle: focus on manufacturing
Quality Management System (QMS)

• Overall context
  • Set of policies and processes to ensure businesses consistently meet customer requirements
  • Mitigates risk of product not conforming to expectations
  • ISO 9001:2015 specifies requirements of a QMS
  • Process-focused – guidance on leadership, performance evaluation, planning, etc
  • WHO inspects ITN manufacturers based on ISO 9001:2015 criteria

• ITN industry context
  • QMS must consider supply chain management because all physical and chemical components of an ITN must come from a verified source that also implements acceptable quality standards.
  • ITN supplier is ultimately responsible for product development, manufacturing, and supplying the market
  • Production model employed by ITN supplier and appetite for risk determines processes and materials to be considered when implementing a QMS
  • Insecticide is added to ITNs using one of two manufacturing processes: incorporation or impregnation
ITN supply chain (polyester)

1. Raw material network
   - PET Yarn supplier
   - Textile Chemicals (Binders, Dye, Auxiliaries...) supplier
   - Insecticide & other active ingredient Supplier
   - Other supplier (accessories, solvent, bag...)

2. Production Network
   - Knitting
     Input: Yarn > Output: Fabric
   - Heatsetting (Optional)
     I: Fabric > O: Heatset Fabric
   - Impregnation
     I: heatset fabric & insecticide formulation
     O: insecticide – Coated fabric
   - Cut&Sew
     I: Fabric, thread, label > O: Bednet
   - Packaging & Baling /
     Warehouse of finished goods

3. ITN supplier (*)
   - ITN supplier owns production network
   - ITN supplier does not own production network

4. Buyer (UNICEF/Global Fund/PMI...)

5. NMCP/User (Consumer)
Production process

Masterbatches and polymer mixed
Base polymer is mixed with any additives (including active ingredient for polyethylene nets)

Extrusion
Mix is extruded into monofilament yarns

Spinning/drawing
Polyester fibers are spun into multifilament yarns
Polyethylene yarns are drawn out with rollers

Knitting
Yarns are knit to create fabric

Impregnation
Fabric is passed through a bath that includes insecticide, binder, and any additives

Heating setting
Impregnated fabric is cured
Some polyethylene nets use this process, but not all

Cutting and sewing
Fabric is sewn into completed nets

YARN output

FABRIC output

NET output

Only occurs with impregnated nets
Methods

• Developed and distributed questionnaires to ITN suppliers
• Topics included
  • Quality of raw materials
  • Process control
  • During-production product control
  • Final inspections
  • Systems designed to support data in decision-making
• 13 ITN suppliers approached, 7 completed questionnaires
  • Conducted follow-up interviews, including perspectives on WHO prequalification and tendering/procurement processes
The team

Robert Farlow
Entomologist, 26 yrs in chemical industry, product develop expert

Chi Phan
Chemist, 20 yrs in textiles (14 in ITNs), QA expert
Results: Quality assurance practices

- ISO certification
- Raw materials and certificates of analysis
  - CoA available, but unclear if verified
- What is a “lot” of ITNs?
  - = purchase order
  - = from a lot of masterbatch
  - = from a quantity a product where quality can be assumed homogeneous (determined from production processes)
## Summary of ITN supplier responses

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Results: ITN supplier quality perceptions

• Gold standard QMS
  • ISO 9001 sufficient?
  • Role of pre-delivery inspection
• Incentives to improve quality and performance
  • Auditing
  • Focus on WHO PQT/VCP
Recommendations

Support robust ITN supplier QMS
- Develop best practice guidelines/webinar for ITN manufacturer QC
- Review current inspection process to develop tiered auditing approach based on ITN manufacturer risk stratification
- QA of raw materials should be a key component of any enhanced auditing process

Strengthen PDI and post-market surveillance
- Investigate impartiality of PDI and evaluate feasibility of mitigation strategies
- Complete data landscaping exercise across ITN quality lifecycle
- ITN suppliers, procurers, and other stakeholders should discuss how measures of surface availability could become part of the QA process

Enabling mechanisms
- Develop and disseminate clear definitions of ITN quality, durability, and associated terms
- Revise product specifications to be more relevant to performance and reflect intricacies of ITN manufacturing process
- Evaluate how metrics of value beyond unit price could be incorporated into procurement process to incentivize innovation
Conclusions

• Significant variation in ITN supplier QMS systems (QA processes and QC measures/tolerances)
  • Likely indicative of individual ITN supplier risk assessments but may reflect variation in robustness of actual processes
• Current oversight of ITN supplier QMS is heavily reliant on documentary review
• Detailed QA audits may be helpful
  • To elucidate specific areas of strengths and weaknesses
  • To underpin cycle of continual improvement and further incentivization of quality during the procurement stage of the ITN quality lifecycle
• WHO PQT/VCP product review may drive changes in manufacturer QMS – how can this be supported?
ITN quality case studies

Raising the Floor Convening, May 2022
Challenges

Building a cycle for continuous improvement

- Issues with net quality and performance
- Causes unclear
- Unable to learn and improve
Approach

Case study approach and subsequent identification of commonalities

- Document review
- Qualitative interviews with key stakeholders in each case
- External expert review
- Comparison with typical textile supply chain quality management
Background

*ITN quality lifecycle*

- Prequalification
- Defining “quality”
- Defining the spec
- Change notification

- Quality planning
- Supply chain quality management
- Quality control
- Quality assurance

- Pre-shipment inspections
- Resolution of non-compliance

- Activities variable
- Post-shipment inspections
- Performance monitoring
Background

- Prior to 2017, product quality reviewed by WHOPES with specifications set by JMPS and manufacturer
- WHO PQT/VCP established in 2017 with clear dossier requirements & change management process
- Specification setting responsibilities for ITNs being transferred from JMPS
Quality triangle

Specifications

Global quality framework

Performance space

Quality space

Manufacturer QMS and PDI
Recommendations

Three sections

1. Preventative measures
2. Resolution process
3. Fortification
Root cause and subsequent preventative measures – onion layers

- Quality planning
- Management of product changes
Recommendations

1. Preventative measures

- Change management process review (1)
- Ensure specifications are fit-for-purpose, consider variability in the product (2) and reflect performance (1)
- Surface availability measure as part of PDI or bioefficacy measure as part of post-market surveillance (1)
- Guidance on assessment of extreme transport/storage conditions and action (3)
Recommendations

2. Resolution process

- Develop guidance on complaints/resolution processes (all)
- Standardise methods used to measure quality and performance (all)
Recommendations

3. Fortification

- Review of site inspection process/QA audits
  - Focus on elements of concern
- Data landscaping review → Quality data hub
The quality triangle

- Ensure specifications reflect performance
- PDI process review
- QC best practice guidelines
- Testing to performance vs quality
- Change management process review
- Standardise methods used to measure quality and performance
- Review of site inspection process/QA audits
- Data landscaping – quality data hub
Looking forward

• Reflecting on our desire to encourage **sustainability** and **social accountability**

• **Sustainable Apparel Coalition and the Higg Index** is the global framework used in textile supply chain

• Transparent scorecards for Brands, Facilities, and Products
Thank you

www.innovationtoimpact.org
## Day 1: Updates from first convening and discussion of post shipment issues

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What are you most looking forward to discuss during the convening?
What do you hope you’ll get out of the convening?
Day 1: Updates from first convening and discussion of post shipment issues

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Setting the scene for country management issues
Overall objectives of the session

To ensure that the perspective of in-country partners is accounted for in defining priorities

To review key information from previous reviews and presentations

To review the life of an ITN in-country

To agree on what we mean by “stewardship” of ITNs

To discuss data availability, use of data and gaps
Review of key information from previous meetings and presentations
Reports of issues pertaining to the chemical bioefficacy of nets have emerged from several countries in recent years...

**AFGHANISTAN**

“In June 2018, re-testing of two batches of [nets] supplied to Afghanistan found them to be non-compliant with WHO specifications.”

In November, the manufacturer reported to the Global Fund that due to “an unapproved chemical formula” used during manufacture, “[t]he nets had a reduced life span and were outside of the required product specification, due to being underdosed with insecticide...21 countries had received affected nets.” (Global Fund, 2021).

**NIERUGUA**

A 2021 LLIN durability study found that “after 36 months of use, median mortality in cone bioassays was 2% compared to 16% at 6 months.” (Villalta, et al., 2021)

**APUA NEW GUINEA**

Results of study showed that in 17% (n = 167) of LLINs tested that were manufactured after 2013 fulfilled the required WHO bioefficacy standards of ≥ 80% 24 h mortality. (Vinit, et al., 2020)

**ANZAI**

In 2013, the Ethiopian National laboratory tested a particular ITN and found that the nets “were impregnated with suboptimum concentrations of insecticide and thereby failed to meet WHO-required bioefficacy standards.” (Binagwaho & Karema, 2015)

Note: This is not a comprehensive review of quality concerns, only a few examples of reports that have emerged.
...while durability data has shown that nets are not lasting the expected three years in the field.

A recent analysis of nearly 4,700 nets in Mozambique, DRC, Nigeria, and Zanzibar showed massive variability in net durability, even within the same brand. Median survival ranged from 1.6 to 5.3 years. Usable nets at ~3 years ranged from 17 to 80%.

Bioefficacy

Physical durability

Manufacturing

User behavior
Nets do not have to be totally destroyed before they are disposed

“.....the bulk of existing evidence supports the notion that median net retention is commonly lower than 3 years.”

“The primary motivation for discarding a net in these studies was the perception that it was too torn, with even a modest amount of net damage often regarded as unseemly or untidy.”
Extrinsic influences on ITN quality and performance

Global Policy
- Are current specs sufficient to determine whether nets will last 3 years?
- How can policies promote continual improvements on quality?
- Is there confidence in current QA processes?

Data
- Data generation
  - Do we have the data we need?
  - How can data be made more available?
- Data interpretation
  - Are we clear what those data are telling us?
  - How can this be more clearly communicated, and with whom?

Procurement
- How does price affect quality?
- Is quality/performance incentivized?
- Are quality definitions aligned?
- Are we getting value for money?

Manufacturing
- Are ITNs being produced to spec?
- Are quality processes sufficient?
- What would ‘better’ cost, and who would pay for it?

Country Management
- Are ITNs managed appropriately?
- Are appropriate post-shipment testing processes in place?
- Can we improve ITN care?
- What do DM data tell us?
Critical stages which may impact ITN durability quality

<table>
<thead>
<tr>
<th>Design/data generation</th>
<th>Pre-market evaluation</th>
<th>Production</th>
<th>Storage and distribution</th>
<th>End user</th>
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</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>NRA/WHO</td>
<td>Manufacturer</td>
<td>Manufacturer, Procurer, Transport Service, Storage Authority, Distributors</td>
<td>User</td>
</tr>
<tr>
<td>• R&amp;D</td>
<td>• Evaluation of dossier to support quality, safety and efficacy, and/or other parameters</td>
<td>• Scale up to commercial production</td>
<td>• QC</td>
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<tr>
<td>• Optimization</td>
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<td>• QA/QC procedures</td>
<td>• Storage and transport in variable conditions</td>
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<td>• Pilot production</td>
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<td>• Packaging</td>
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<td>• Data generation</td>
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<td>• Proper and consistent use of the product</td>
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Maximising Impact: Effectiveness of ITNs

Product backed by WHO policy / recommendation confirming public health value

Product pre-qualified by WHO confirming safety, efficacy, and quality

Procurement policies and procedures: Governments, TGF, PMI, others

Product specification published by WHO/FAO and sufficiently defines product characteristics essential to impact

Quality assurance sampling and testing is sufficient to confirm products are in specification

Context of use: ento and epi setting, including IR profile regularity of use, durability, attrition

Supply chain from manufacturer to point of distribution: under conditions specified by the manufacturer according to product characteristics

Figure: End-to-end analysis of factors influencing potential for impact from an ITN
Over 2 billion ITNs have been delivered to malaria-endemic countries since 2004

AFR total since 2004; other regions’ totals since 2009. AMP Net Mapping Project
Assumptions along the product lifecycle

<table>
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<tr>
<th>Assumption</th>
<th>Pre-shipment quality control testing of chemical content is a relevant measure of product against its specifications and thus intended impact in the field</th>
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<tbody>
<tr>
<td>PQ dossier compiled and reviewed against relevant criteria and thresholds</td>
<td>Shipping and storage conditions en route to destination do not impact bioefficacy</td>
</tr>
<tr>
<td>Product developed and evaluated against relevant criteria and thresholds</td>
<td>At sea</td>
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<tr>
<td>Product specifications published by WHO/FAO are sufficient to define essential product characteristics</td>
<td>On land</td>
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<tr>
<td>Chemical content testing is a valid proxy for bioefficacy</td>
<td>Nets arrive at households fully effective and will remain so for 20 washes</td>
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<tr>
<td>(Cone/tunnel) bioassays are relevant proxies for ITN performance</td>
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<tr>
<td>SOPs exist and are sufficient to ensure that bioassays are consistent and reproducible across locations, mosquito strains, and laboratories</td>
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<tr>
<td>Products are tested against appropriate strains of mosquitoes; strains remain consistent over time</td>
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<td>Post-market surveillance processes sufficient to identify product quality and efficacy issues and respond appropriately, feeding into future tendering and production</td>
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ISO 9001:2015 is sufficient to ensure quality production systems
Efforts to reduce costs to remain competitive in the market do not impact bioefficacy
QA/QC agents are not unduly influenced in their work

12 Nov 2021

GLOBAL FUND ITN BIOEFFICACY LANDSCAPING
Assumptions along the product lifecycle

Transport

Strengths

A. Most countries have appropriate storage facilities for ITNs at central level; storage at lower levels generally limited to several weeks.

B. Temperature and humidity aboard cargo ships is relatively well-characterized from other sectors; at-sea max temperatures are relatively stable around 30-36°C and are unlikely to pose significant threats for ITN bioefficacy.

Weaknesses

A. On land, daily max temperatures inside a container can reach 60°C when ambient temperatures are 40°C and container is not shaded; this may occur during customs clearance and land transport depending on conditions. Max temperatures may only be reached for 1-2 hours each day, but the cumulative impact on bioefficacy over periods of weeks or months is not well understood.

B. Deltamethrin may convert to R-isomer particularly above 50°C. This conversion reduces the bioavailability of deltamethrin to mosquitoes.

Challenges

A. The correlation between storage stability tests, intended to approximate extended shelf life under normal conditions, and ITN bioefficacy after repeated exposure to high temperatures, is not clear.

Opportunities

A. Conduct research to characterize temperatures encountered and duration during clearance, land transport.

B. Conduct research assessing impact of above temperature fluctuations and duration on bioefficacy across ITN products.
Assumptions along the product lifecycle

Post-market surveillance

Strengths

A. PQT-VC includes post-market requirements in their guidance, including change notification, 3 yearly manufacturing site inspections, product review, and complaints.

B. PQT-VC may issue notifications of concern regarding products, suspend them pending investigation, or delist.

Challenges

A. Unlike medicines or vaccines, there are no robust systems in place for reporting issues. ITNs are not used in a clinical setting and do not have the same types of adverse events.

B. Due to testing variations (next slide) confirmatory testing required when results are inconclusive. Triangulation of results across different settings (as in durability monitoring) is challenging given many confounding factors.

C. Post-shipment inspection approaches are not harmonized across countries and rarely include bioefficacy testing.

D. Funding is currently a barrier for post-shipment bioefficacy testing at country level. Decision to reject a shipment at post-shipment stage was felt to be too late by Northern stakeholders; in-country stakeholders felt it was important to maintain this accountability step despite cost and time implications.

E. Process for submitting complaints to PQT is not clear. Some stakeholders were concerned that complaints could be made by competitors.

F. Limited complaint investigation resources within PQT.

Weaknesses

A. Post-market surveillance guidance for countries and NRAs yet to be developed

B. Surveillance currently limited to durability monitoring and post-shipment inspection. Post-shipment inspection procedures do not typically include bioefficacy testing due to cost and time constraints.

C. No formalized mechanism or clear mandate for pulling together bioefficacy data across post-market surveillance activities

Opportunities

A. Develop consensus approach for post-shipment testing at country level.

B. Build in relevant post-market surveillance activities (post-shipment testing; durability monitoring) into the cost of ITN delivery systems

C. Strengthen role of NRAs and local research institutions to conduct post-market surveillance

D. Clarify complaints submission and investigation process for broader stakeholders, particularly its link with OOS results and procurer investigations
Risk ratings along the product lifecycle

- **Product developed and evaluated against relevant criteria and thresholds**
  - PQ dossier compiled and reviewed against relevant criteria and thresholds

- **Product specifications published by WHO/FAO are sufficient to define essential product characteristics**
  - Chemical content testing is a valid proxy for bioefficacy
  - (Cone/tunnel) bioassays are relevant proxies for ITN performance

- **Product specifications published by WHO/FAO are sufficient to define essential product characteristics**
  - SOPs exist and are sufficient to ensure that bioassays are consistent and reproducible across locations, mosquito strains, and laboratories

- **Tendering criteria and allocation algorithms incentivize quality and reduce risk of procuring substandard products**
  - Products are tested against appropriate strains of mosquitoes; strains remain consistent over time

- **ISO 9001:2015 is sufficient to ensure quality production systems**
  - Post-market surveillance processes sufficient to identify product quality and efficacy issues and respond appropriately, feeding into future tendering and production

- **Efforts to reduce costs to remain competitive in the market do not impact bioefficacy**
  - Manufacturer maintains sufficient control over production processes to identify production problems

- **QA/QC agents are not unduly influenced in their work**
  - Manufacturer maintains production approach and source materials over time; all changes are assessed for potential impact on bioefficacy
  - ITNs are consistent within the manufacturer-defined batch size

- **Pre-shipment quality control testing of chemical content is a relevant measure of product against its specifications and thus intended impact in the field**
  - Pre-shipment quality assurance sampling is sufficiently representative of the shipment

- **Shipping and storage conditions on route to destination do not impact bioefficacy**
  - Shipping and storage conditions on route to destination do not impact bioefficacy

- **Nets arrive at households fully effective and will remain so for 20 washes**

Risk ratings:
- **Lower risk**
- **Moderate risk**
- **Higher risk**

12 Nov 2021

GLOBAL FUND ITN BIOEFFICACY LANDSCAPING
Variability inherent in biological assays across labs contributes to confusion

Tunnel test seldom conducted on deltamethrin/alphacypermethrin products when they fail cone bioassay, in contrast to Guidelines – as tunnel tests are seen as less relevant for these products which lack a strong repellent effect

Clear need for updated Guidelines for laboratory and field-testing of ITNs, reflecting diversity of ITN modes of action

ISO-9001 standard necessary but not sufficient to identify key ITN production challenges essential for ensuring bioefficacy

Potential for cost-cutting measures to impact bioefficacy

Variability in batch/lot size and implications for representativeness of samples taken

Concerns of collusion between in-country inspectors/sampling agents and staff at contracted manufacturing sites

Insufficient financial resources to conduct desired levels of bioefficacy testing during ITN lifecycle

Uncertainty whether product drift, if it has occurred, has impacted malaria control efforts

Periodic re-evaluation of product bioefficacy has not occurred

Concerns that product specifications, particularly chemical content, are not sufficient to ensure and confirm bioefficacy

Limited understanding of frequency, duration, and impact on bioefficacy of extreme temperature fluctuations encountered in some environments – primarily on land – during ITN transport and storage
Recommendations:
Specifications

- Conduct a review of chemical content and bioefficacy correlations
- Conduct a review of the wash resistance index specification
- Wider impact (i.e., beyond ITN bioefficacy prior distribution): potential for positive impact on other ITN stakeholders. Suppliers, research institutions are relevant and specific enough to ensure quality and bioefficacy.

Proposed lead: WHO PQT/VCP, WHO-GMP
Recommendations: Transport

- **Fund and publish operational research** subjecting ITNs to extreme transport and storage conditions encountered.

- **Why?** To better understand the impact (if any) of such conditions on bioefficacy. Such work may help to improve transport and storage guidance and/or to rule out this element as an area of significant risk.

- **Proposed lead:** Key funder(s) with mechanisms for this type of research

- **Proposed stakeholders:** WHO PQT/VCP, Suppliers, procurement agencies, research institutions, NMC/EPs, national standards bodies, WHO-GMP.

- **Wider impact (i.e. beyond ITN bioefficacy prior to distribution):** potential to impact all ITN characteristics related to quality, including durability, safety, and ecological impact
Recommendations: Post-shipment testing

- **Develop guidelines on effective use of resources for post-shipment testing.**

- **Why?** Approaches to post-shipment testing vary considerably across countries and cost and time pressure are a significant barrier. Recommendations on effective approaches for post-shipment testing as well as the expected use of all data are needed. Work could also be done to identify the most critical points for evaluating bioefficacy across the ITN lifecycle, leading to recommendations around its use in post-shipment testing.

- **Proposed lead:** WHO ERG

- **Proposed stakeholders:** WHO PQT/VCP, WHO-GMP, Suppliers, funders, procurement agencies, research institutions, NCM/EPs, national standards bodies.

- **Wider impact (i.e. beyond ITN bioefficacy prior to distribution):** potential to impact all ITN characteristics related to quality, including durability, safety, and ecological impact; potential to stimulate development of post-shipment testing guidelines for other vector control products
  - While outside the scope of the present landscaping, further work is needed to review and assess the factors that influence product bioefficacy post-distribution, as products are used by households, and the duration of bioefficacy under field conditions.
Q&A / Discussion
The in-country life of an ITN
ITN arrives at port and clearing area

- ITN arrives at port. ITN is packaged individually or not and in bale wrapping.
- ITN sits in bale in container during offloading from ship, customs clearance
  - Time for clearing from port
  - Status of the container during the clearing process (e.g. shaded or in full sun)
ITN transported to initial delivery point

Transport in container:
• ITN sits in bale in container during loading at port to truck
• Time for container to move to delivery warehouse
• Inter-country movement and second clearing at country
• Time for transport
• Status of container during the transport process (e.g. shaded or in full sun)

Offload from container and transport in bale:
• ITN is offloaded in bale to truck for transport
• Time for offloading and loading
• Status of bales during the offloading and loading process (e.g. shaded or in full sun)
• Transport quality and type (e.g. covered, etc.)
ITN received at initial storage point

ITN received at initial storage point:
- ITN is offloaded in bale to identified storage
- Time for offloading into stores
- Status of bales during the offloading process (e.g. shaded or in full sun)
- Storage infrastructure and quality

ITNs remain stored in containers placed at delivery point:
- Status of containers during storage (quality, shade or sun, etc.)
- Duration of storage in container at initial storage point
Countries should prioritize other more permanent and controllable storage options before considering containers

Given the potential risks of distributing ITNs that may have become sub-standard as a result of exposure to high temperatures and/or humidity and in the absence of data to support this storage option for longer duration, current operational recommendations from the World Health Organization (WHO) and AMP does not recommend storage of ITNs in containers for more than two weeks after delivery to final destination in-country.
ITN transported from delivery to distribution location
ITN transported from delivery to distribution location – 2

ITN is still in bale in most cases; some cases bales opened before last delivery point

Multiple types of transport used, potentially multiple levels of the supply chain → handling

Quality of transport, status of bales during transport, status of individual nets during transport
ITN stored at various levels and distribution location

- ITN is still in bale in most cases; some cases bales opened before last delivery point
- Multiple types of storage used, potentially multiple levels of the supply chain handling
- Quality of storage, status of bales during storage, status of individual nets during storage
To this point, the ITN is (in principle) protected from significant risks of physical damage.
Nearly all nets meet optimal effectiveness at baseline (standard pyrethroids).

Baseline results largely fine!

*Caveat: limited data*

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ITN distributed to recipient

- ITN is now out of bale and may be individually packaged or naked
- ITN handling at distribution
- ITN removal from individual packaging (inconsistent)
- Instructions to recipient on ITN care
ITN transported to its forever home!

- Transport of unpackaged nets from distribution point (campaign or HF) to HH → loose or put in second carrying option, time to HH, conditions en route and means of transport (foot versus moto)
ITN spends up to six months stored

- Families ‘use up’ older nets first
- ITN may be individually packaged or naked
- ITN handling at household and storage
- Instructions to recipient on ITN care, including appropriate storage

Figure 1: Data from six durability monitoring activities on proportions of campaign nets hanging (blue) vs. stored in their package (tan) over time\(^{7,8,10}\)

Percent

Time (months) since distribution

predicted % hanging predicted % still in package % nets hanging
ITN airing

ITN is aired in the shade for 24 hours before use (or more or less or sun or other) before hanging.
Management of leftover campaign ITNs

- ITN is either loose (individually packaged or naked) or still in bale
- Time that ITN stays at DP or PPS before transport to health facility, conditions for storage, management of individual nets, entry into routine/community system and procedures (e.g. LIFO for unpackaged nets), tracking and accountability
Gets hung and taken down (frequency, care)

ITN lives in house...

Gets washed (frequency, materials, drying)
ITN hopefully gets tied up during the day
ITN gives up on life as a malaria prevention tool and tries to find use in old age
Points for discussion

Does this represent the full life of an ITN? If no, what is missing?

What are the additional risks at each point in the life of the ITN?

What data is available to assess the importance of these factors for quality?
Day 1: Updates from first convening and discussion of post shipment issues

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<td>Registration of delegates and welcome</td>
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<td>9.30</td>
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<td>Introduction and follow up on progress towards Roadmap goals</td>
<td>Angus Spiers</td>
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<tr>
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<tr>
<td>11.15</td>
<td>1 hour 15 min</td>
<td>Panel discussion - progress since first convening</td>
<td>Angus Spiers (chair)</td>
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<td>• Marion Law</td>
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<td>• Grit Thierfelder</td>
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<td>Hannah Koenker (chair)</td>
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<td>• The in-country life of an ITN</td>
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<td>• Findings from country interviews</td>
<td>Nandita Jaitly</td>
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<td>• Data availability and gaps</td>
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<td>• Discussion</td>
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<tr>
<td>4.45</td>
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<td>Wrap up and next steps</td>
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<td>Close of day and cocktail reception</td>
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Findings from country interviews
Raising the Floor on Nets

Findings from Country Interviews

May 2022
ITNs have played a major role in malaria prevention. However, ITN performance issues have been raised by several countries recently.

**Afghanistan**
- Received ITNs in 2018 manufactured using unapproved methods.

**Nicaragua**
- A 2021 LLIN durability study revealed rapid loss of chemical bioefficacy. Mosquito mortality was 16% at 6mo after arrival, and 2% after 3yrs.

**Papua New Guinea**
- A 2015 study identified bioefficacy issues with ITNs manufactured after 2013. Only 17% of ITNs tested met WHO bioefficacy standard of ≥80% mosquito mortality after 24 hours.

**Rwanda**
- An increase in malaria cases revealed that a PQ ITN in use in country had low bioefficacy. The ITN was removed from circulation and eventually from PQ list.
ITN quality and performance are affected by the policies and processes of different actors involved in the manufacture, evaluation, procurement and distribution of ITNs. This session focuses on post-shipment issues.

CHAI conducted an informal country questionnaire across several NMCPs to better understand current country activities and concerns around ITN quality.
Informal interviews were conducted with NMCPs to understand in-country processes regarding ITN quality and performance.

NMCPs of 10 countries from West Africa, East Africa, Southern Africa, Central America and Southeast Asia were interviewed.

The interviews were conducted both in-person and remotely with national malaria program managers and/or vector control focal persons between Q3 2021 and Q4 2021. Some additional questionnaires were directly shared over email with country malaria programs in Q2 2022.

During the interview, CHAI made a presentation and proceeded to a brief questionnaire that consisted of both multiple-choice and open-ended questions.

Responses were transcribed and then analysed.
The meeting was structured to understand perceived issues affecting ITN quality and performance, as well as potential solutions.

**Focus of the Questionnaire***

- Whether guidelines and SOPs exist to support ITN Quality Assurance/Quality Control (QA/QC) in country
- Whether country has access to ITN QC test results conducted by procurers
- Information on ITN QC testing conducted in country
- Satisfaction with ITNs distributed during last campaign
- Information on capacity available to conduct QC testing and monitoring in country

*See Appendix for complete list of questions

**Key Objectives**

- Understand guidelines and SOPs available in-country for ITN QA/QC
- Understand program’s interest in, and capacity available, for ITN QA/QC
- Understand what types of QC are conducted
- Understand what QA/QC data is available and how that data is used to make decisions
- Understand barriers to QC testing and data use
- Determine concerns about the quality of nets used in-country and changes in ITN QC process they would like to see
Limitations of the interview process

Not all interviews were conducted in English as some malaria program managers requested the interview to be conducted in their local language. There is a likelihood of potential loss in translation of some technicalities of QC testing methods.

Some program managers did not have answers to all the questions and requested to provide answers after consultation with their team post completion of the interview or sent their responses via email. Not all countries responded to every single question posed to them.

In some instances, countries requested to have the interview and discussions together with ITN partners. This could have influenced some responses.

In situations where we received different responses for a question, for instance one from a malaria program manager vs partner, we used the response from the malaria program manager. Between a malaria program manager and program staff responsible for ITNs, we used the response from the program staff (ITN focal person).
3 of 10 programmes reported that they have guidelines to support in-country ITN QA/QC.

5 of 10 programmes reported that they have SOPs detailing how to perform QC procedures on ITNs.

Only 3 of the 5 programmes that reported the existence of SOPs or guidelines reported that these were being followed.

3 of the 5 programmes without policy structures reported that establishing in-country ITN QA/QC guidelines and policies would improve quality monitoring.
QC being conducted on arrival

- None of the programmes interviewed conducted the exact same QC tests on ITNs upon arrival in country.

- In 3/10 countries, the programme did not conduct any QC tests upon arrival in country. 2 out of these 3 programmes reported that they did not have the capacity to conduct QC upon arrival.

- 6 programmes reported having access to the results of ITN QC tests from procurers before the nets arrived in country.

- The programmes reported different barriers to QC testing upon arrival, including lack of funding, staff and infrastructure, lack of policy guidance, lack of adherence to QC protocols, donor restrictions, strong lobby of manufacturers and tight timelines between delivery and distribution.

- Note: Where respondents from the same country provided conflicting responses, the answers provided by the individual most directly involved in quality monitoring upon arrival were used.

### QC tests conducted on arrival

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<th>QC test</th>
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</tr>
<tr>
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<td>Bioefficacy on arrival</td>
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</tr>
<tr>
<td>Fabric integrity</td>
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Quality monitoring being conducted post distribution

- None of the programmes interviewed provided the same suite of monitoring tests on ITNs after distribution.

- In 2/10 countries the programme did not conduct any quality or performance testing on ITNs after distribution.

- Bioefficacy after use was the most reported test conducted by programmes.

- 4 programmes definitively stated they currently had capacity to monitor the quality of ITNs while in use in the field.

- The programmes reported different barriers to quality testing in the field. Funding was the most common barrier reported, with lack of capacity and defined roles, and monitoring not being a routine programmatic activity also being reported.

- Note: *Where respondents from the same country provided conflicting responses, the answers provided by the individual most directly involved in quality monitoring post-distribution were used.*

### Quality monitoring post distribution that would be useful for decision-making

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<tr>
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</tr>
<tr>
<td>Bioefficacy</td>
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</tr>
<tr>
<td>Chemical content after use</td>
<td>5</td>
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Countries cited capacity issues in conducting pre and post shipment QC

A. The country has the human, infrastructural, and technical capacity to conduct QC tests upon the arrival of ITNs in-country to ensure product quality reflects what was tested before shipment?

B. The country has the human, infrastructural, and technical capacity to monitor the quality of ITNs while in use in the field.
Reported uses of QC data in-country for decision-making

- Justifying the acquisition of new generation LLINs
- Determining the optimal period between two consecutive bed net distribution campaigns
- Defining the messages for creating targeted IEC in order to improve the utilization of ITNs
- Decision taken to conduct independent durability studies
Areas of improvement for in-country QC of ITNs

Representatives from 3 programmes definitively stated they were unsatisfied with the quality of the ITNs distributed during the last campaign. Respondents from 3 countries held off on reporting satisfaction pending results from ongoing durability studies or due to lack of evidence to formulate an opinion.

Concerns included: Lack of details about ITNs procured, and that ITNs did not match specifications on labels.

Only 3 programmes gave examples of how QC data is used for decision-making. One country used the data to define minimum acceptable attributes for ITNs to be approved on inspection.

Representatives from 6 programmes suggested that establishing and adhering to policies and protocols, infrastructure and capacity to drive locally-owned QC efforts would help improve the quality of ITNs in-country.
No standardized process exists for QC upon net arrival in country. Is there a need for a standardized process given the QC challenges reported by countries? What does the post-shipment QC entail?

How can countries be best supported with optimal net storage?

Countries reported currently using or wanting to use post-distribution quality data to help inform the selection/deselection of nets.

Lack of coordination, structures, and time pressures were cited as challenges to conducting robust QA/QC. What are the potential solutions to these challenges?
Appendix
Interview Questions

1. National policies/guidelines exist to support ITN QA/QC (yes/no)
2. SOPs exist that detail how to perform QC procedures on ITNs (yes/no)
3. If yes to 1 or 2, national policies/guidelines and/or SOPs are followed.
4. What QC ITN testing is currently done in the country?
5. What QC ITN tests would be useful to inform decision-making that are not currently being done in the country?
6. I am satisfied with the quality of nets distributed and used in my country from the last ITN campaign. (yes/no)
7. Why were you satisfied/dissatisfied?
8. The country has access to the data from ITN QC tests from procurers (e.g., GF, PMI, UNICEF, etc.) before ITNs are shipped to the country.
9. The country has the human, infrastructural, and technical capacity to conduct QC tests upon the arrival of ITNs in-country to ensure product quality reflects what was tested before pre-shipment?
10. The country has the human, infrastructural, and technical capacity to monitor the quality of ITNs while in use in the field.
11. What are the key barriers in-country hampering the process of conducting QC tests upon arrival of ITNs in-country?
12. What are the key barriers in-country hampering the process of monitoring the quality of ITNs while in use in the field?
13. Can you share an example of how the country has used QC data to inform decision-making?
14. What needs to be done to improve the quality of nets delivered/distributed in your country?
Thank You

For more details contact:

Munashe Madinga - mmadinga@clintonhealthaccess.org
Nandita Jaitly - njaitly@clintonhealthaccess.org
Discussion on data
WHO PQT/VCP – Product review report

Some language could be applied to in-country stewardship and process for identifying gaps to be addressed

Product review process to identify and address any gaps in the data supporting these products... intended to address an issue which impacts a group of products sharing certain attributes. The process includes:

- Identification of a need for a review of information across multiple products sharing similar characteristics or a class of products
- Identification of the relevant products based on the issue
- Review of existing information
- Identification of new information/data gaps to be addressed
Product review report – considerations for ITN in-country stewardship

Do you have recommendations on how your ITNs are stored upon delivery to the recipient? [10 responses]

- Yes: 90%
- No: 10%

Requirement of a statement of approved storage conditions and maximum storage period for inclusion in the listing or decision document. This may require the addition of appropriate studies to the data requirements and validation of accelerated storage methods.
Knowing whether adherence to recommended storage conditions is okay...

Please describe your storage recommendations by type of product.

• Cool (as possible), dry and out of direct sunlight.
• No exposure to light, high humidity or very elevated temperatures.
• All ITNs should be stored in a normal condition temperatures and not high temperatures.
• Store in cool and dry place.
• Out of direct sunlight. To be stored in a dry ventilated place under normal indoor temperature; bales should be stacked on pallets.
• As per our safety data sheet: Store in ambient temperature and at atmospheric pressure in original packaging. Do not store near highly flammable materials. Store product in closed packing in a cool area away from direct sunlight.
• We recommend not to have container storage. For standard storage: always keep the product in the shade and also dry.

Requires standards, tools to measure and data to take decisions.
Product review report – considerations for ITN in-country stewardship

• A process must be implemented which allows for the flexibility to generate data which are linked directly to the intended use of the product and thereby used to substantiate product claims

• Previous system did not incorporate a life-cycle approach – What does this mean for the in-country part of the ITN life-cycle beyond post-distribution data collection?

• ITNs are subjected to extremes in conditions before and during their extended useful life. Therefore, the directions for handling and use, often overlooked or considered as inconsequential/uncontrollable, are actually critical. For ITNs to perform as intended, for the duration intended, improved directions for handling and use of ITNs must be considered by the entire stakeholder community to maximize the potential impact of current products and inform the development of ITNs of the future. – Improved directions for handling and use are important, but how is adherence to them measured? What data should be collected in-country to establish policies for in-country ITN management pre-distribution?
In many countries, at least some data (e.g. durability, behaviour) exist related to post-distribution ITN in-country stewardship.

Questions:

• What are the primary uses of these data?
• Are these data being used effectively for decision-making?
• If no, what are the key bottlenecks beyond funding?

NOTE: for the purposes of discussion, it is assumed that funding is needed across areas.
Facilitated discussion – 2

Questions:

1. What data are missing for improvements to ITN in-country stewardship?
2. Is it possible to set indicators and standards for different points of ITN in-country stewardship?
3. Is data collected timely for decision-making?
<table>
<thead>
<tr>
<th>Point in in-country life</th>
<th>Types of data</th>
<th>Standard data collection method exists</th>
<th>Data available</th>
<th>Policies available</th>
<th>Structures in place to collect data / assess adherence to policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrival and clearing from customs</td>
<td>Post arrival inspection, temperature, humidity, delay tracking</td>
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<tr>
<td>Storage</td>
<td>Warehouse condition, temperature, humidity</td>
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<td></td>
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<tr>
<td>Transport</td>
<td>Transport condition, temperature, humidity, delay tracking</td>
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<tr>
<td>Handling after distribution - MOH</td>
<td>Unpackaged nets from campaigns, storage and issuing conditions, damage tracking</td>
<td></td>
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</tr>
<tr>
<td>Handling after distribution – HH</td>
<td>Bioefficacy, durability, acceptance, Malaria Behavior Surveys</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>End of life</td>
<td>Durability, qualitative</td>
<td></td>
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</tr>
</tbody>
</table>
What is the biggest challenge in country management related to ITN quality/performance that we need to address?
Are there policies in place that set standards for warehousing and transport of ITNs?

- Yes: 9
- No: 14
- Under development: 1
Are there policies in place that set standards for distributor ITN handling up to recipient?

- Yes: 10
- No: 10
- Under development: 1

Total: 21
Are there policies in place that set standards for recipient ITN handling?

- Yes: 7
- No: 13
Are there policies in place for end of life nets?

- Yes: 6
- No: 15
How important is it that we have the policies mentioned in the previous slides?

- High: 19
- Medium: 11
- Low: 1
- Not a priority: 0
What are the priorities for in-country stewardship of ITNs moving forward?

- measuring performance
- standards setting
- capacity building
- quality check
- funding
- testing
- fifty percent
- efficacy
- data for decision
- better control on storage
Final discussion points, wrap up and closing
Wrap up and next steps