Registration of delegates and welcome

Day 1: Updates from first convening and discussion of post shipment issues

Time	Duration	Topic	Presenters
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5.00	Close of day and cocktail reception		

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

Malaria Journal

Home About Articles Submission Guidelines

Research | Open Access | Published: 19 February 2021

Evaluation of the durability and use of long-lasting insecticidal nets in Nicaragua

Emperatriz Lugo Villalta, Aida Mercedes Soto Bravo, Lucrecia Vizcaino, Nicole Dzuris, Marco Delgado, Michael Green, Stephen C. Smith, Audrey Lenhart & Alexandre Macedo de Oliveira

Malaria Journal **20**, Article number: 106 (2021) | Cite this article

151 Accesses | **5** Altmetric | Metrics

nature communications

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nature > nature communications > articles > article

Article | Open Access | Published: 20 July 2020

Decreased bioefficacy of long-lasting insecticidal nets and the resurgence of malaria in Papua New Guinea

Rebecca Vinit, Lincoln Timinao, Nakei Bubun, Michelle Katusele, Leanne J. Robinson, Peter Kaman, Muker Sakur, Leo Makita, Lisa Reimer, Louis Schofield, William Pomat, Ivo Mueller, Moses Laman, Tim Freeman & Stephan Karl

Nature Communications **11**, Article number: 3646 (2020) | Cite

3818 Accesses | **7** Citations | **82** Altmetric | Metrics

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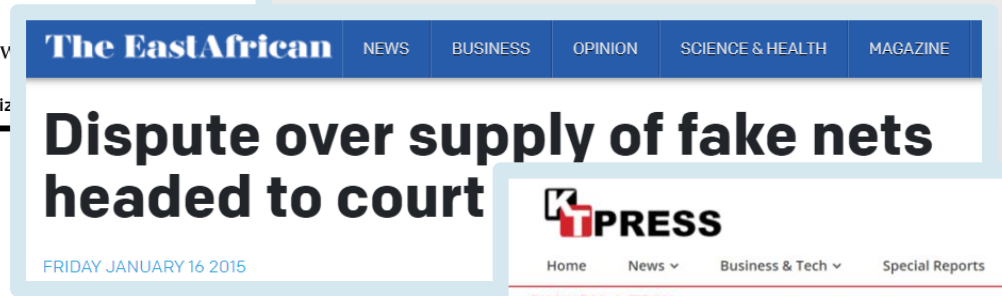
NEWS

Malaria increase blamed on substandard bed nets

The Ministry of Health has blamed the rising rate of malaria incidences in the country on substandard bed nets.



The EastAfrican NEWS BUSINESS OPINION SCIENCE & HEALTH MAGAZINE

Dispute over supply of fake nets headed to court

FRIDAY JANUARY 16 2015

PRESS

Home News Business & Tech Special Reports Voices Sports Society

BUSINESS & TECH

Rwanda To Halt Importing Mosquito Nets

By Daniel Sabiiti March 04, 2019 at 5:44 pm 0

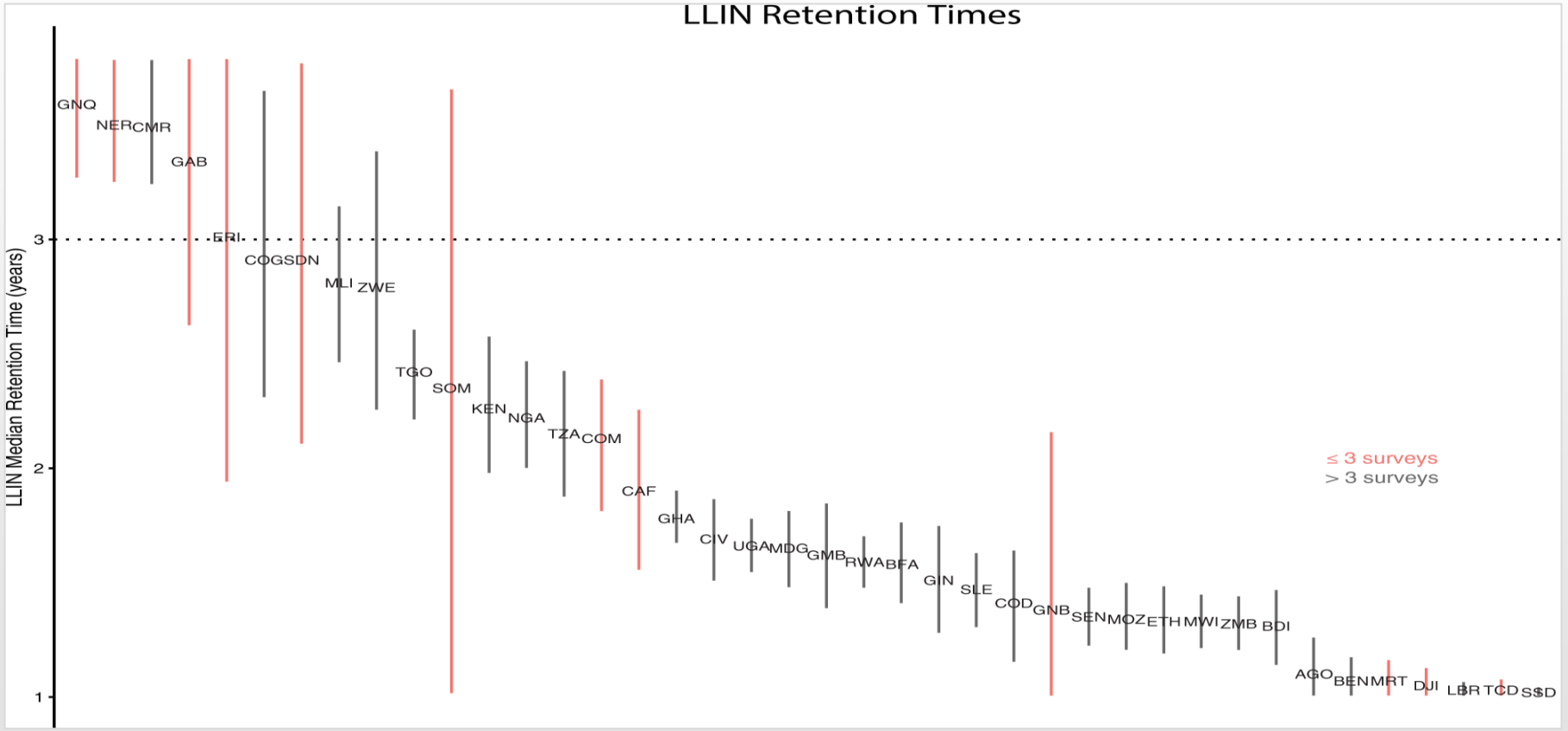
Anecdotally, other countries have also identified net quality issues, including:

- 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."

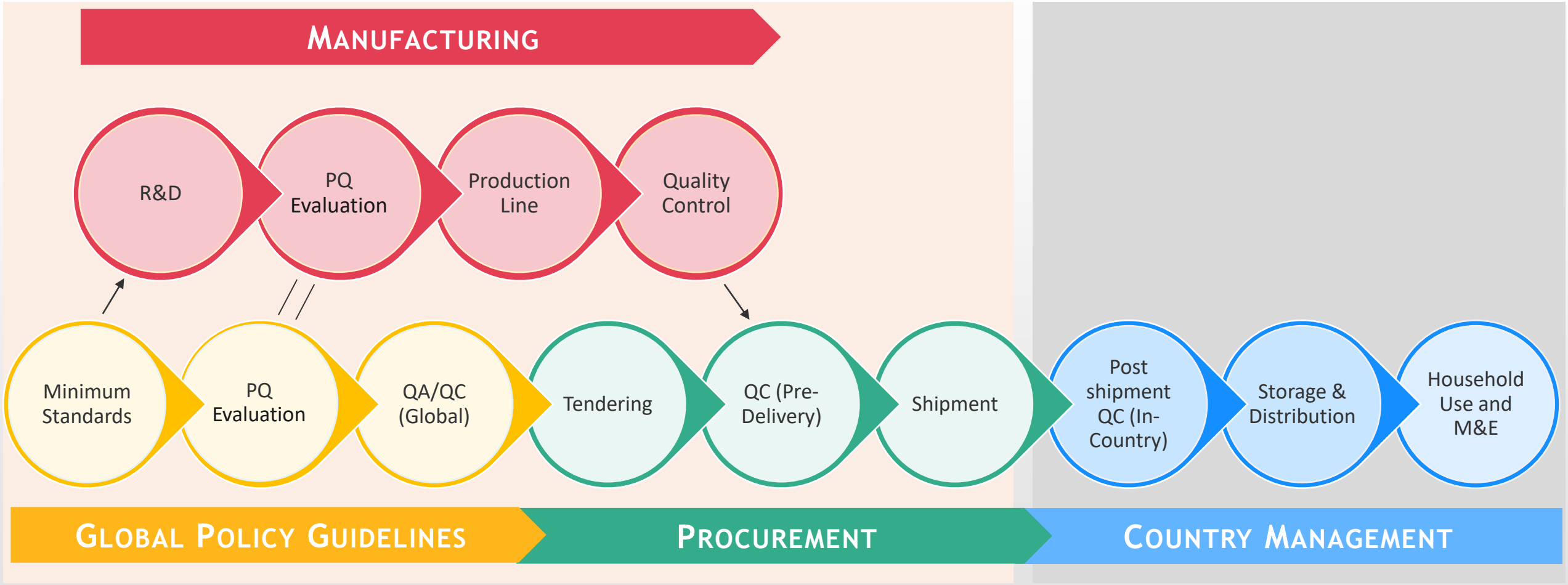
"The primary motivation for discarding a net in these studies was the perception that it was too torn, with even a modest amount of net damage often regarded as unseemly or untidy."



Bertozzi-Villa, A., Bever, C.A., Koenker, H. *et al.* Maps and metrics of insecticide-treated net access, use, and nets-per-capita in Africa from 2000-2020. *Nat Commun* **12**, 3589 (2021).

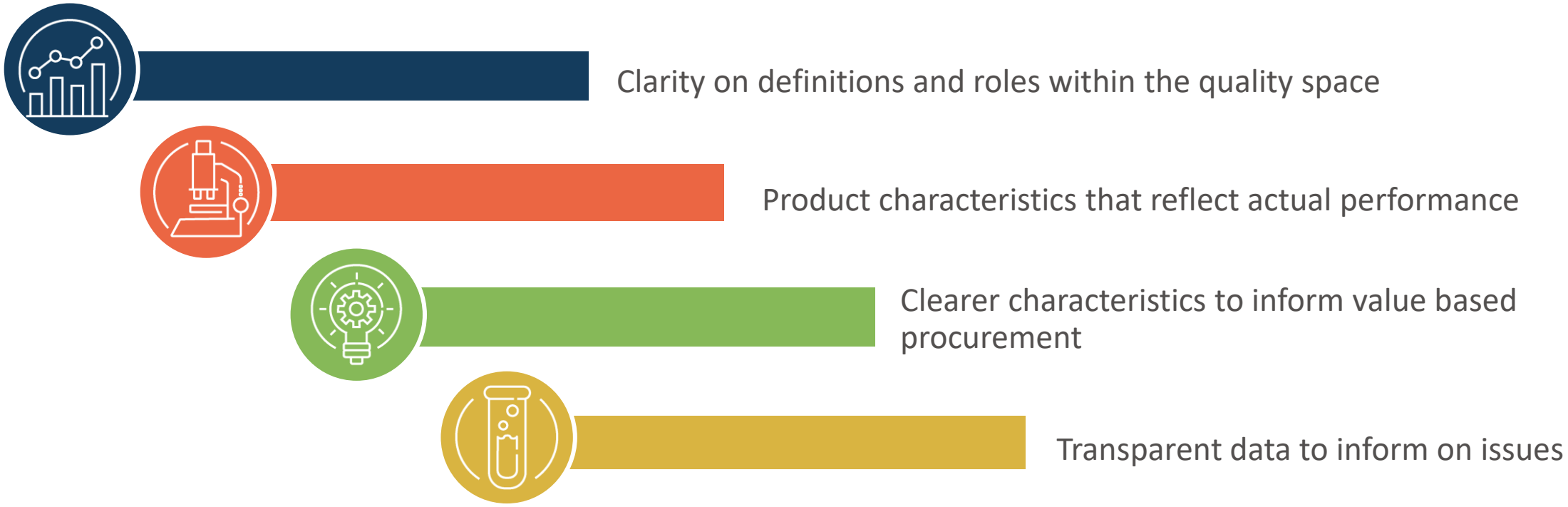
Nets are not consistently performing as expected - Why?

The first convening focused on pre-shipment aspects

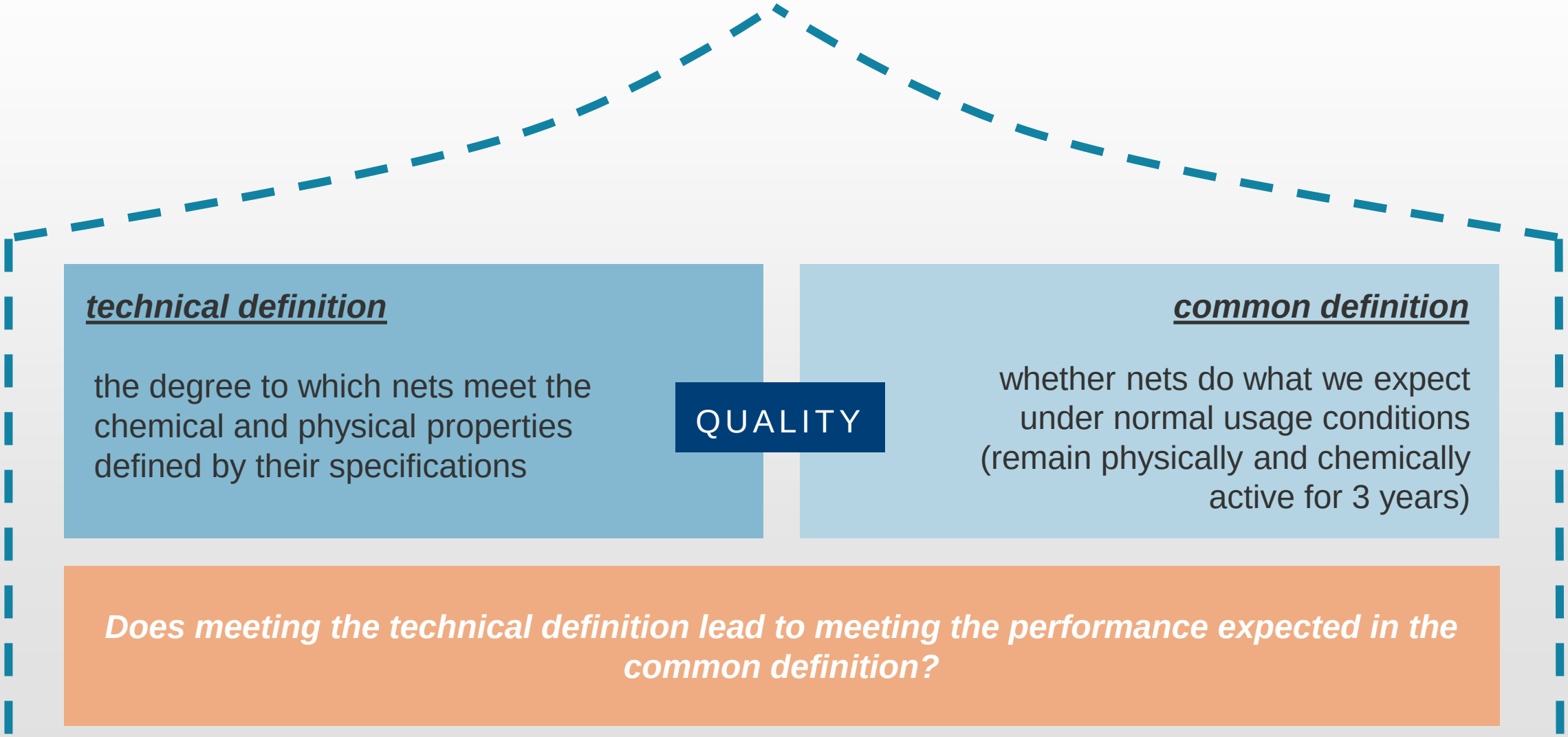


Emerging Themes from the First Convening

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



Maintaining a focus on Quality AND Performance of ITNs



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?

Procurement

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

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?

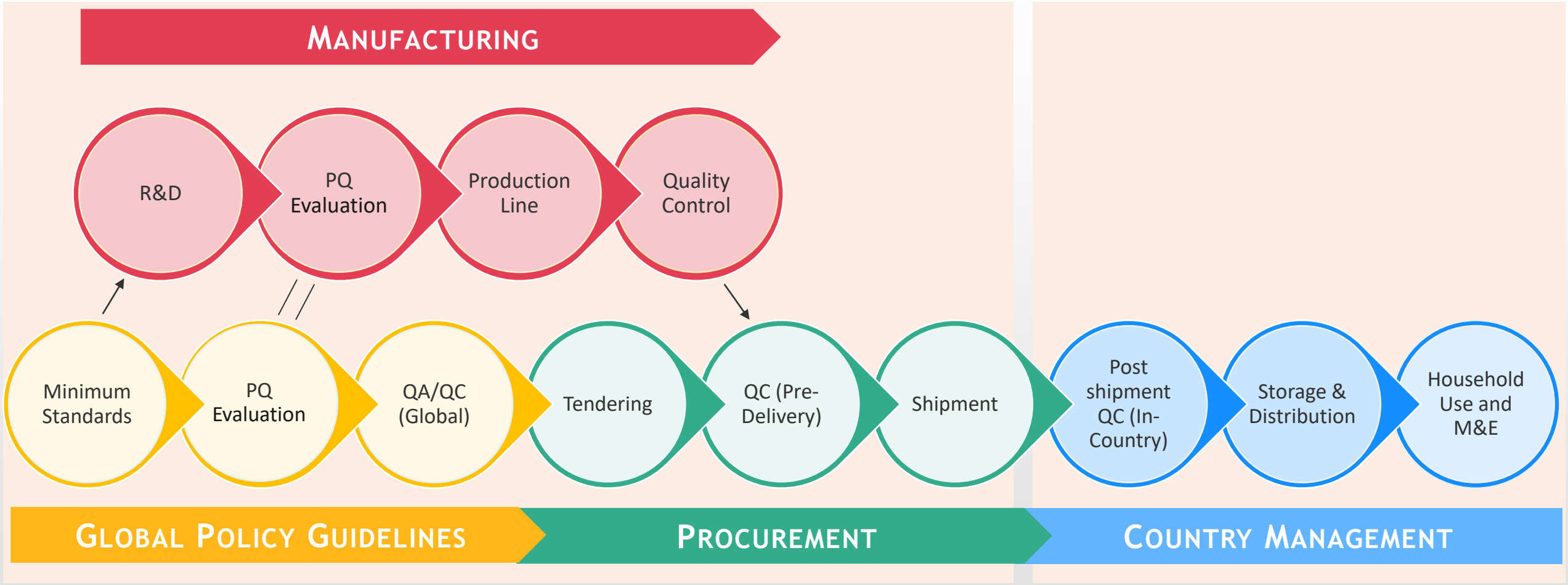
Manufacturing

- 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?

This convening to focus on Country Management aspects



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

Outline for the next three days

Convening Daily Objectives:

Day 1

- **Update** on progress since the first convening & consensus on next steps
- **Understand** issues experienced during the delivery, distribution and post-distribution phases of ITN life

Day 2

- Engage in collaborative discussion to **agree on issues, discuss tangible solutions** and **develop a vision of success** for post shipment ITN quality & performance

Day 3

- **Learn** about the latest thinking on measuring surface availability and bioavailability of AIs on ITNs
- **Gain consensus key activities** and agree timelines for implementation

And Beyond

- **Establish working groups** to lead the way forward on key priorities identified
- Continue to **foster collaboration** for timely delivery of activities in the theory of change

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?

Day 1: Updates from first convening and discussion of post shipment issues

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Key updates:

- Theory of change
- Manufacturer QA
- Case Studies

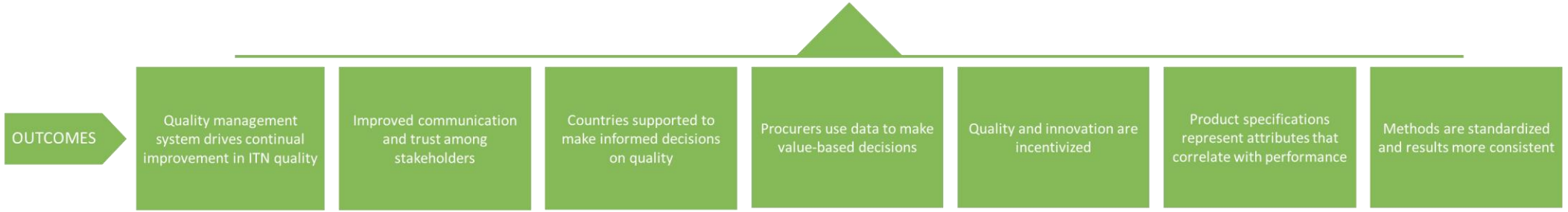
Raising the Floor on Nets Theory of Change

Save More Lives

Better access to safe, high quality, efficacious vector control tools

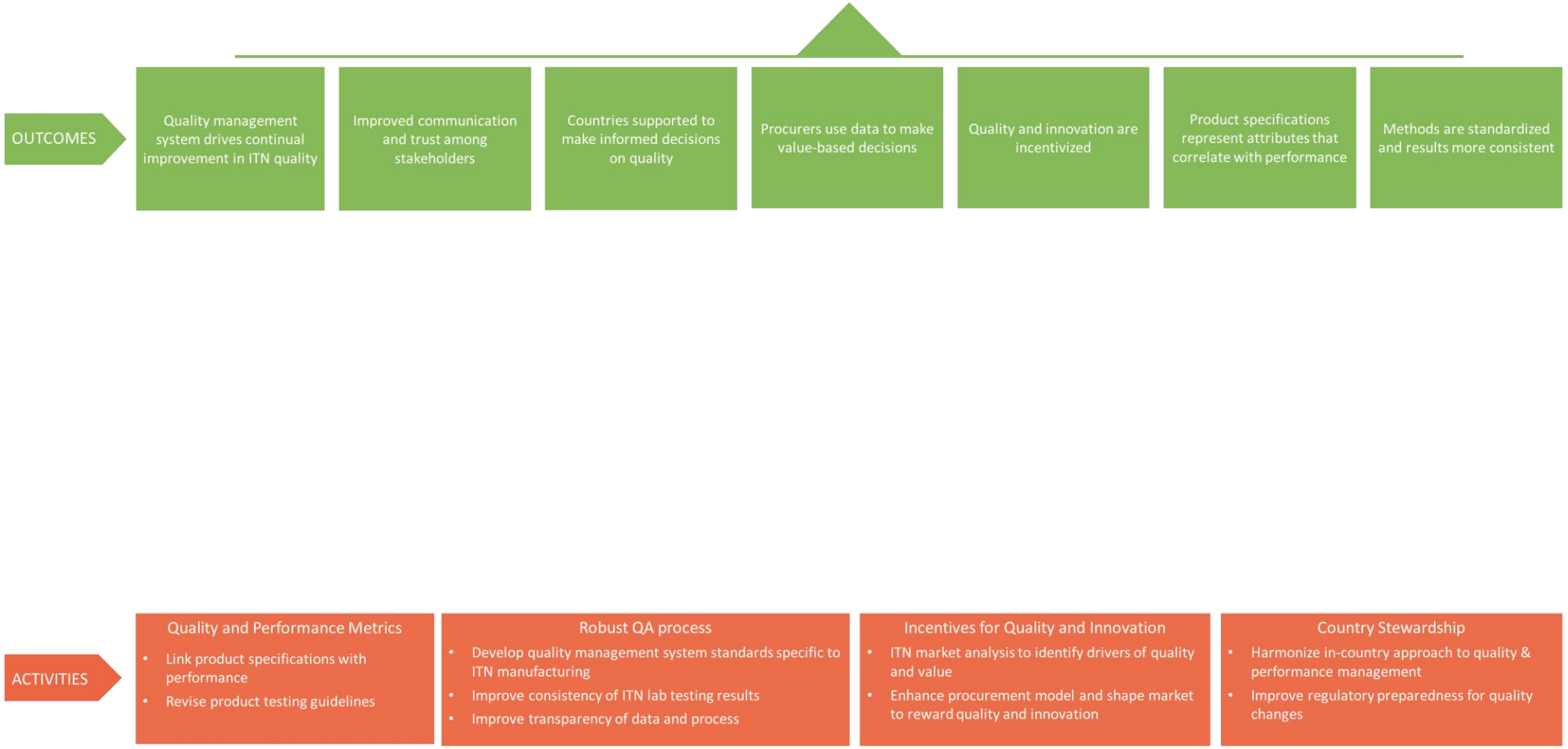
Save More Lives

Better access to safe, high quality, efficacious vector control tools



Save More Lives

Better access to safe, high quality, efficacious vector control tools



Communication, Clarity, Trust, Transparency

Save More Lives

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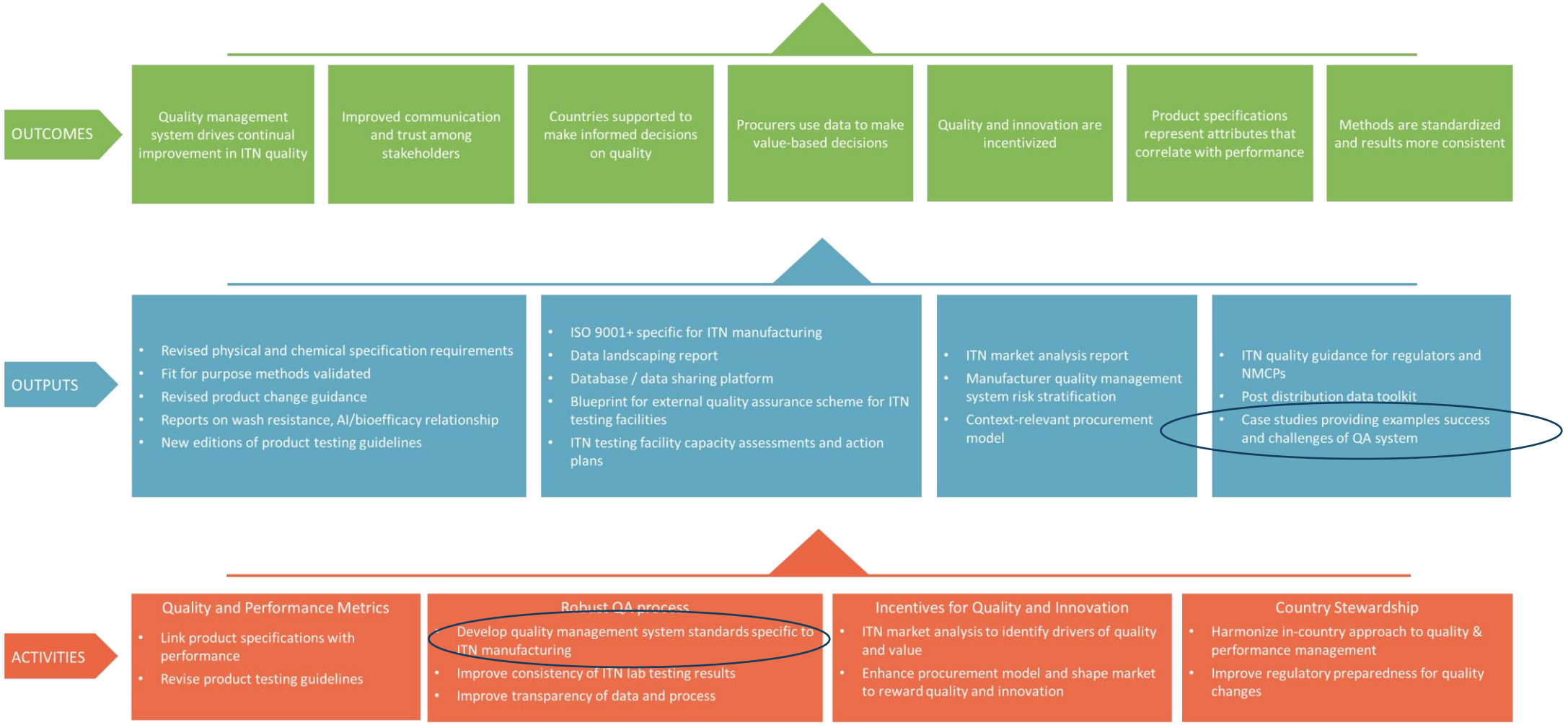


Communication, Clarity, Trust, Transparency

Insecticide-treated net supplier quality management system assessment

May 2022

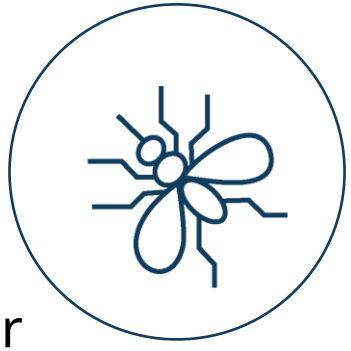
BILL & MELINDA GATES foundation

LSTM
LIVERPOOL SCHOOL OF TROPICAL MEDICINE
Since 1898

Introduction

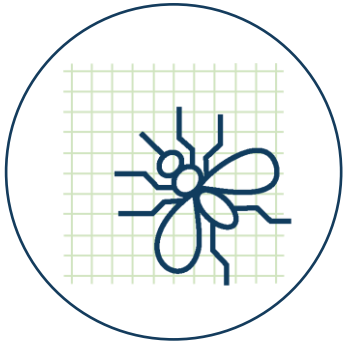
- Significant reductions in malaria over the past decade are largely due to **universal coverage of vector control tools**

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

Introduction

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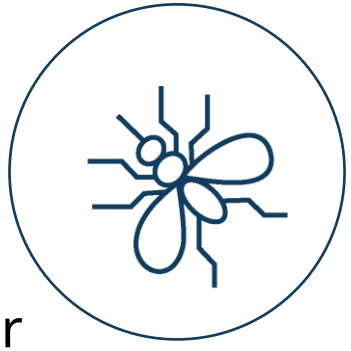
Challenges



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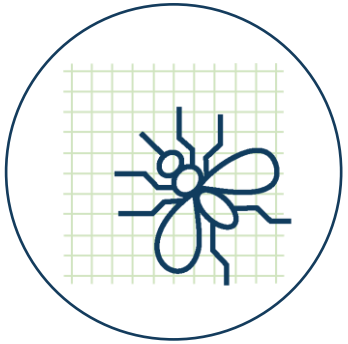

- Invest in new vector control technologies to ensure robust pipeline of new ITN insecticides
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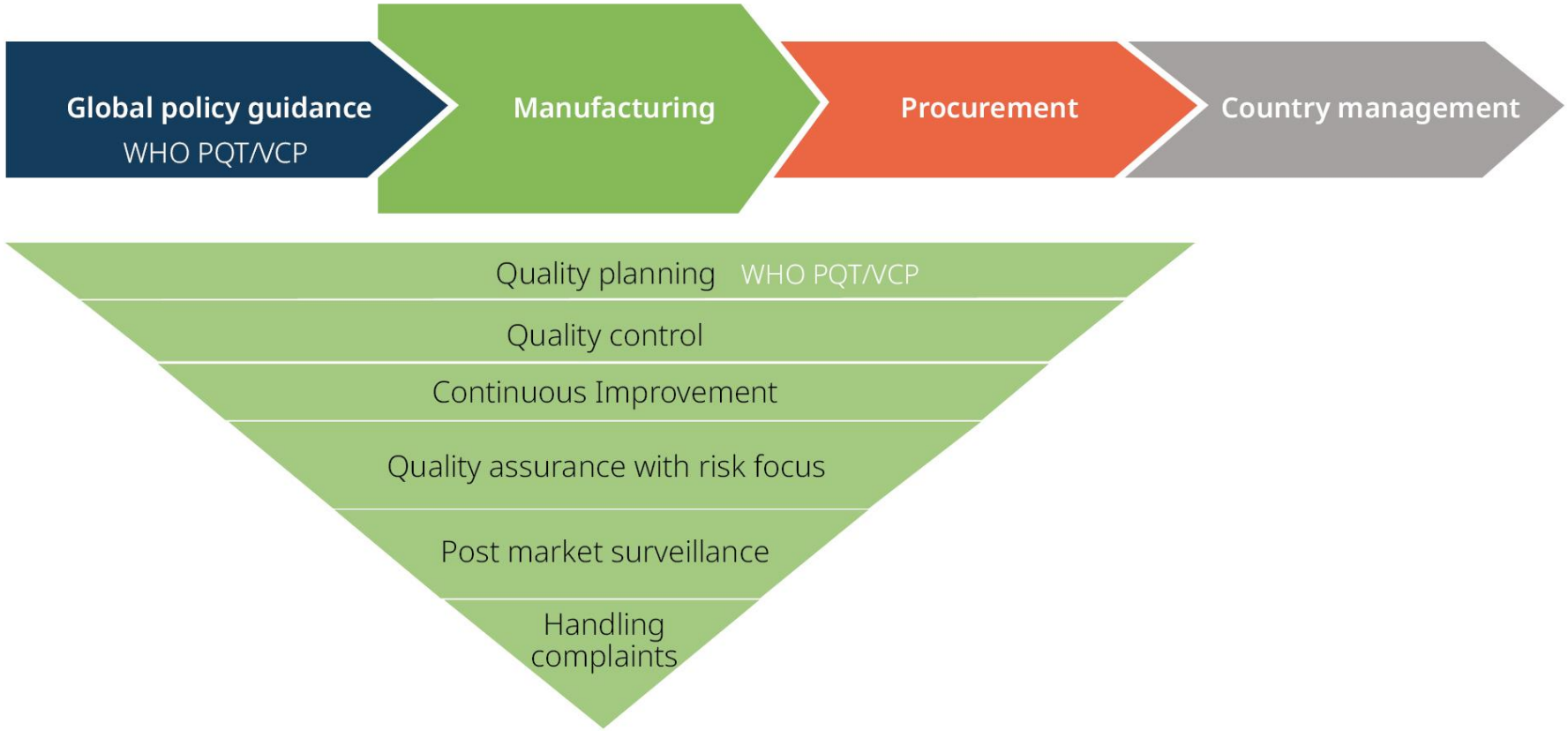
Aim and objectives

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)

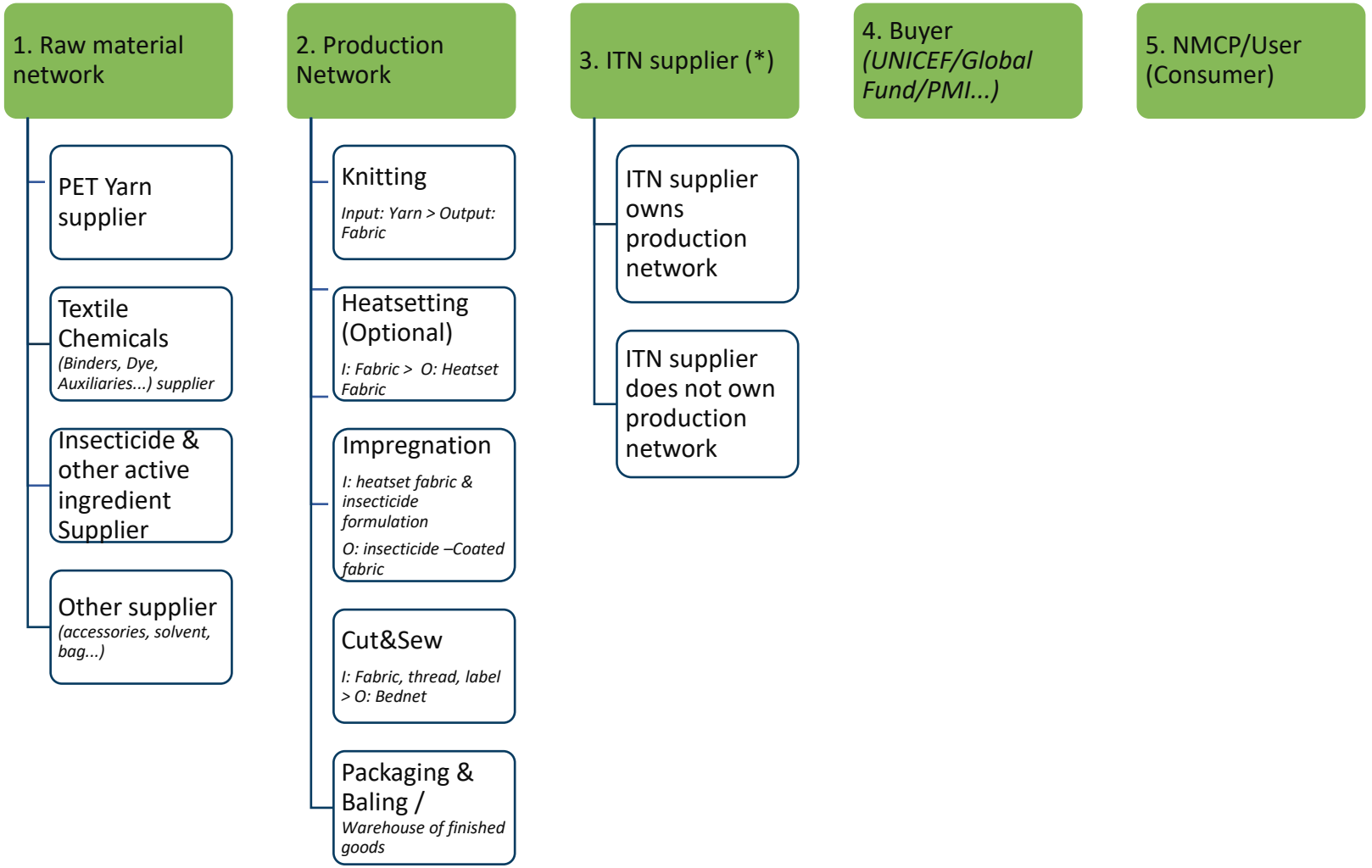
ITN quality lifecycle: focus on manufacturing



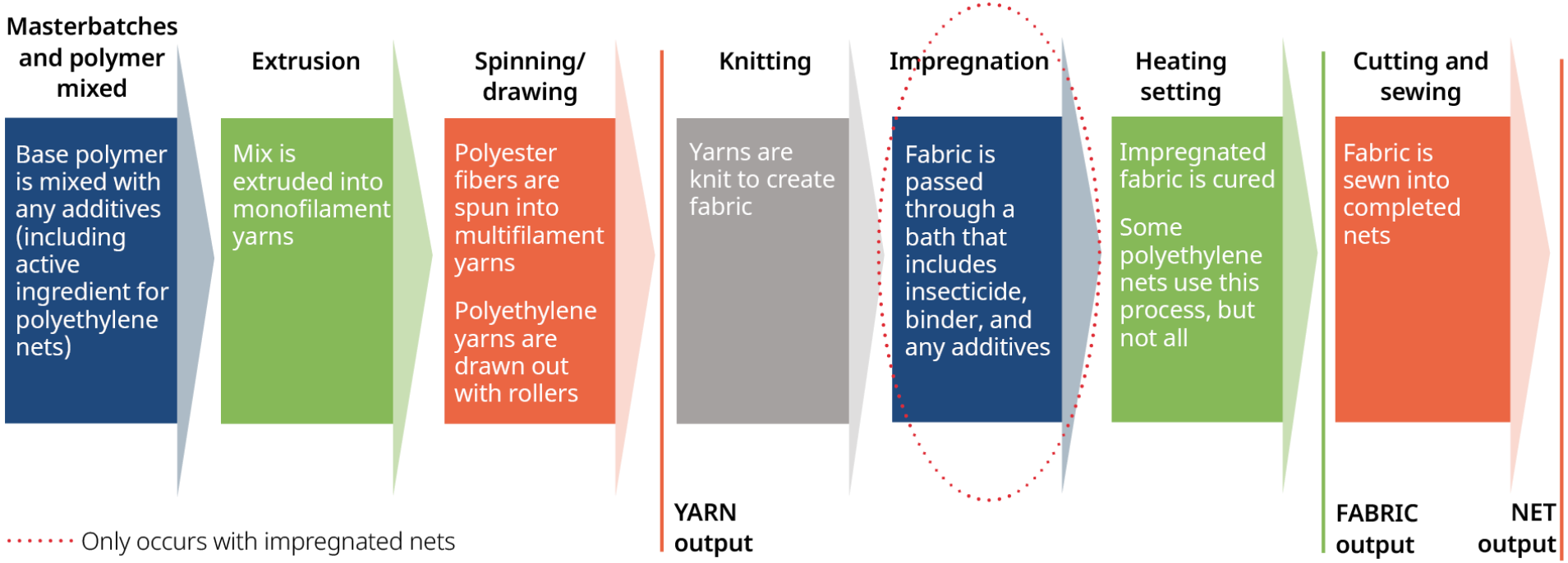
Quality Management System (QMS)

- 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)



Production process



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

			ITN supplier						
			A	B	C	D	E	F	G
Manufacturer of incorporated polyethylene ITNs				✓	✓		✓	✓	✓
Manufacturer of impregnated polyester ITNs			✓	✓	✓	✓			
Quality control area	Material/process/product	Parameter							
Raw material specification	Polymer	Crystallinity			✓				
		Solubility			✓				
		Density					✓		
		Molecular weight distribution					✓		
		Melt flow index		✓	✓		✓	✓	✓
Process control parameters	Extrusion	Draw ratio		✓	✓		✓		
		Extrustion temperature		✓	✓		✓	✓	✓
		Extrusion speed		✓	✓		✓		✓
		Yarn annealing temperature/ time		✓	✓				
	Impregnation	Chemical mixing ratios/ time/speed		✓		✓			
		Nip roller pressure				✓			
		Moisture content			✓				
	Heat setting	Stenter temperature	✓	✓	✓	✓			
		Stenter speed	✓	✓	✓	✓		✓	
Material control parameters (during production or final inspection)	Yarn/Netting/Net	AI content	✓	✓	✓	✓	✓	✓	✓
	Yarn	Elongation		✓	✓			✓	
		Tenacity		✓	✓	✓		✓	
		Denier		✓	✓		✓	✓	✓
	Netting	Bursting strength		✓	✓	✓	✓	✓	✓
		Knitting pattern/quality		✓	✓		✓		✓
		GSM			✓				
	Net	Seam quality/strength	✓	✓	✓	✓	✓	✓	✓
		As per ITN specification	✓	✓	✓	✓	✓	✓	✓
		Bioefficacy		✓		✓			

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

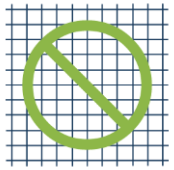
- Significant variation in ITN supplier QMS systems (QA processes and QC measures/tolerances)
  - Likely indicative of individual ITN supplier risk assessments but may reflect variation in robustness of actual processes
- Current oversight of ITN supplier QMS is heavily reliant on documentary review
- 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

Guidance document February 2021

WHO Prequalification of Vector Control Products

World Health Organization

Post-prequalification change application

The manufacturer of any vector control product (VCP) included in the World Health Organization's (WHO) list of prequalified VCPs is required to report all changes related to the quality, safety or efficacy of the prequalified product – including, but not limited to, changes to its formulation, source ingredients, process/site(s) of manufacturing, specification(s) or labelling – to the WHO Prequalification Unit Vector Control Product Assessment Team (PQT/VCP).

The intent to change a prequalified VCP must be communicated to PQT/VCP before any change is made, to allow sufficient time for WHO to assess the change before its implementation. **WHO will not approve any changes without assessment.**

For all proposed changes to a prequalified product, the manufacturer must submit a Post-Prequalification Change Application (PPQC) including the supporting information/data, as applicable, to pqvectorcontrol@who.int.

NOTE:

- Depending upon the significance of proposed change(s) and if a change has been made prior to notifying WHO, PQT/VCP may determine that it is necessary to issue a suspension of the prequalification until an assessment of the information/data submitted to support the change has been assessed.

Failure to submit a PPQC which may impact the quality, safety and/or efficacy of a prequalified product, may lead to suspension of the prequalification, or delisting of the product(s) from the list of prequalified VCPs.

The PPQC requires information on:

- updated/current authorized contacts;
- the product(s) for which the changes are being proposed;
- details of the proposed change(s);
- acknowledgement of the roles and responsibilities accepted in PPQC assessment process.

Once the PPQC application is received by PQT/VCP, it will be screened for completeness and, provided all the required information has been supplied, will undergo assessment by WHO.

- If any aspect of the supporting documentation is incomplete, the manufacturer will be informed in writing and requested to address the deficiencies.
- Depending on the type of change, the assessment may also include an inspection of the manufacturing site(s). The manufacturer will be notified in writing if this is required.
- Depending on the significance of change, a new product application may be necessary. The manufacturer will be notified in writing of this and the reason for the requirement of a new product application.

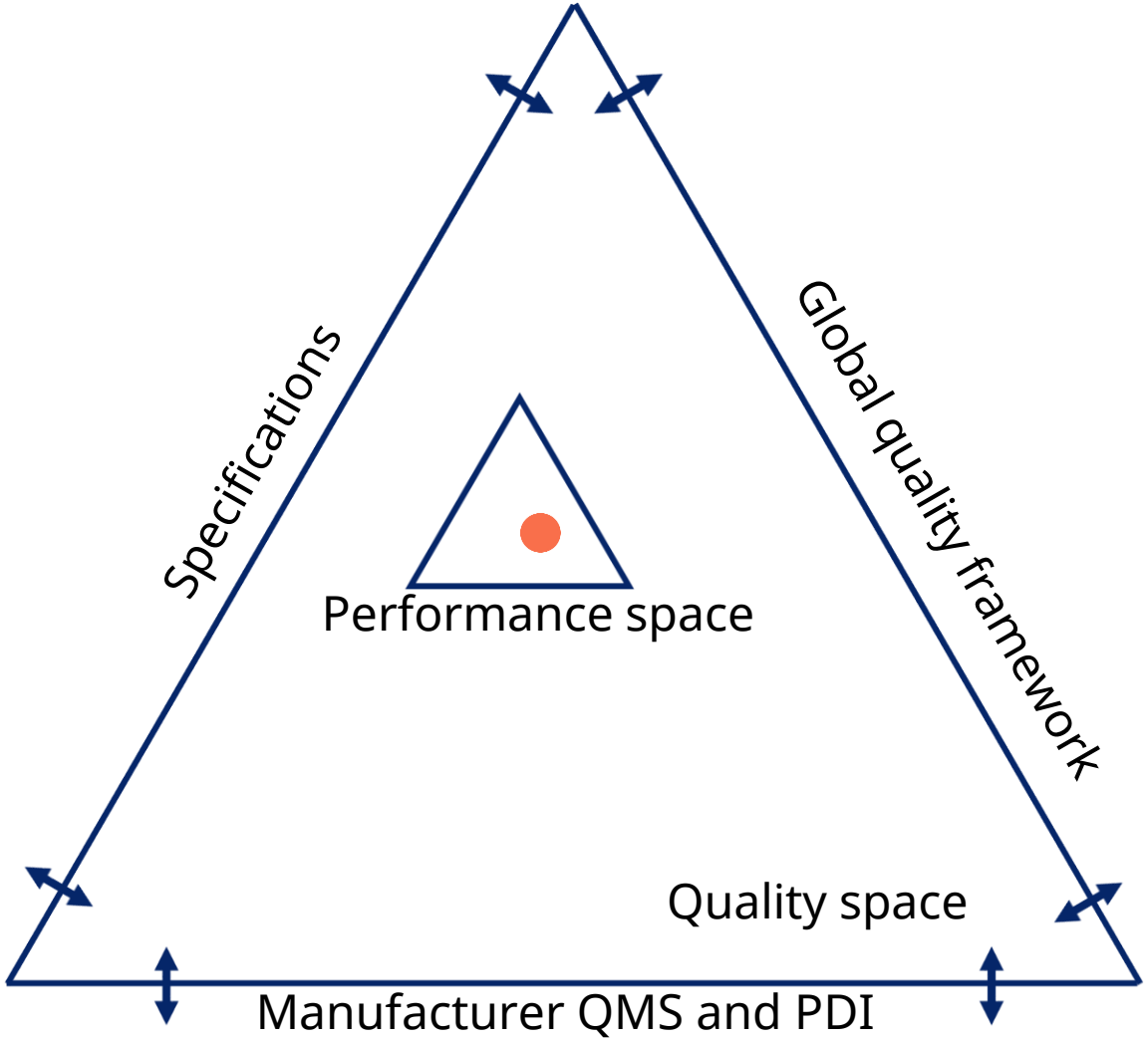
Once WHO is satisfied that the prequalification change assessment of a product is complete, the manufacturer will be informed and the WHO list of prequalified VCPs will be updated, as necessary, to reflect the relevant change accepted by WHO, provided that the overall findings demonstrate, as determined by WHO, that the product continues to meet all WHO prequalification requirements.

If the submitted documentation supporting the change does not meet WHO prequalification requirements or if all the requested information is not provided by the manufacturer within the specified deadline, WHO will reject the change and will the inform the manufacturer in writing of the outcome of its assessment of the change and of the impact of such a decision on the prequalification status of the prequalified VCP.

WHO Prequalification of Vector Control Products
Avenue Appia 20
1211 Geneva 27
Switzerland

For further information, contact:
pqvectorcontrol@who.int
https://extranet.who.int/pqweb/vector-control-products

Quality triangle



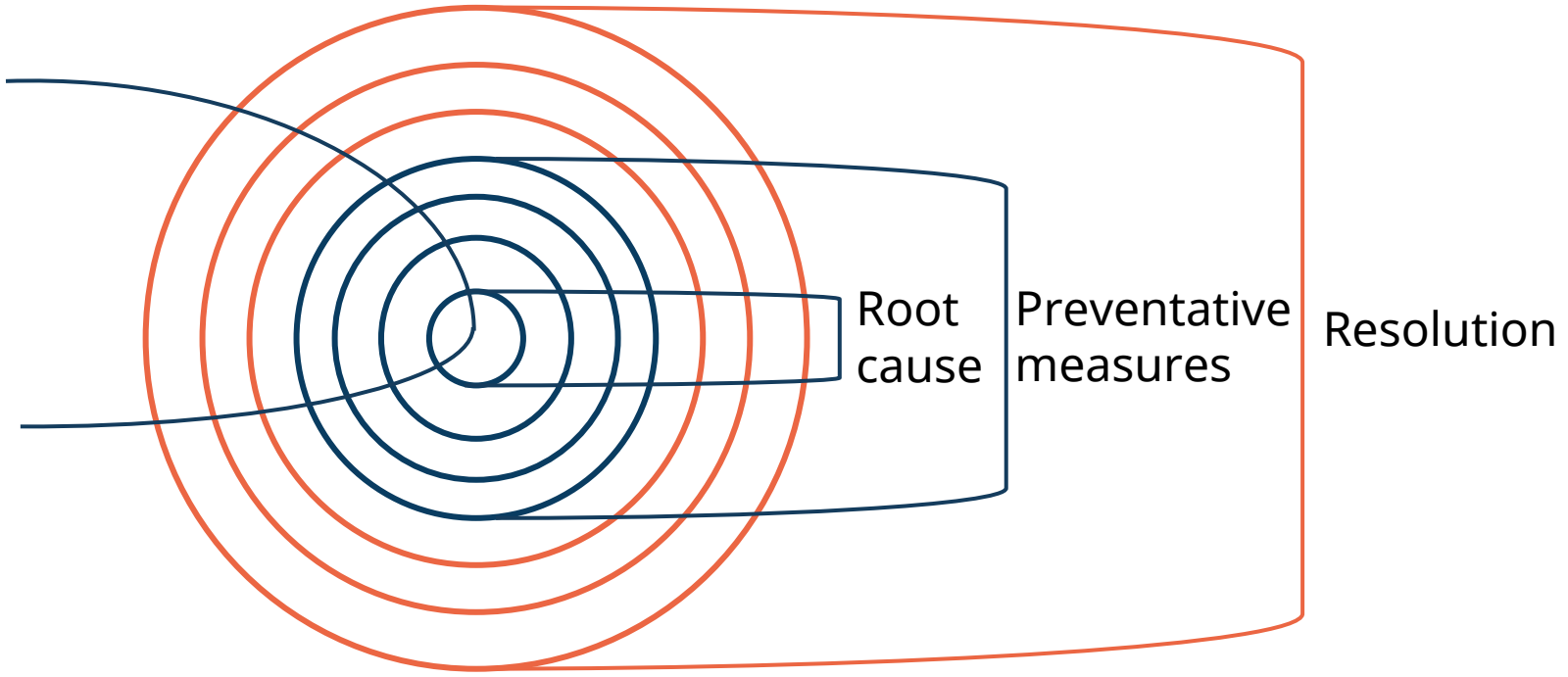
Recommendations

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

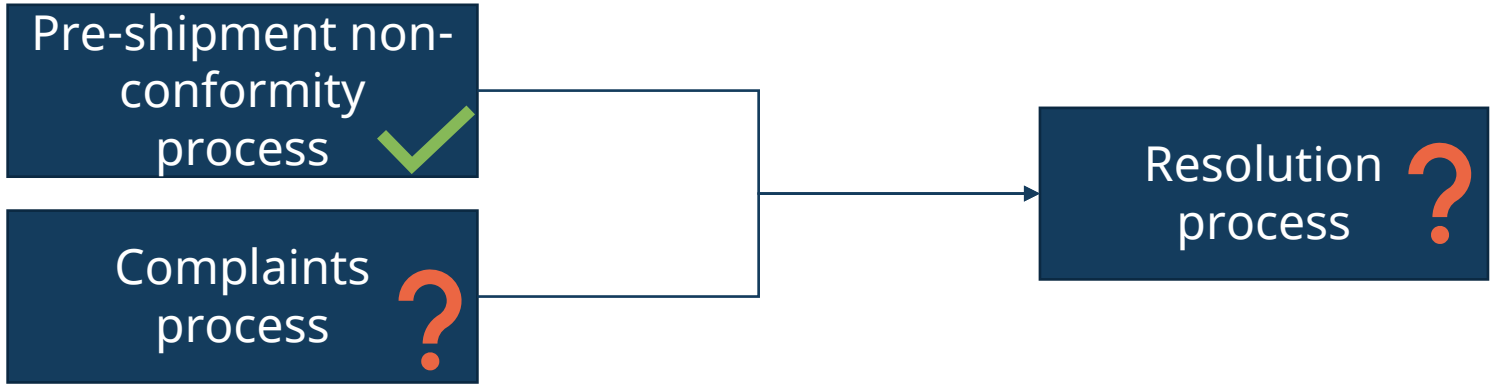
1 Preventative measures

- 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)

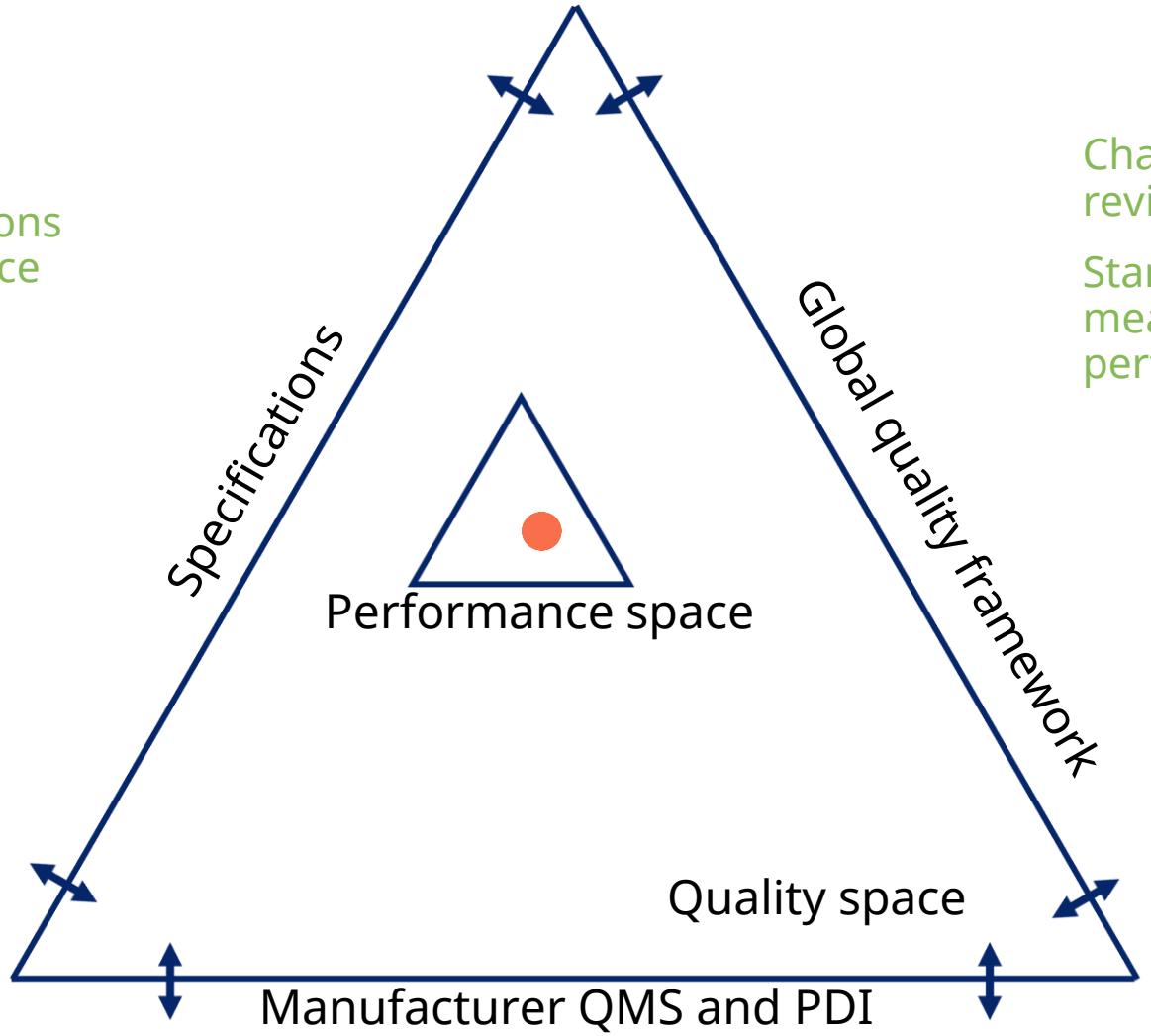
Recommendations

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



Change management process review

Standardise methods used to measure quality and performance

PDI process review

QC best practice guidelines

Testing to performance vs quality

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

The Higg FEM assesses:

- Environmental Management Systems
- Energy Use and Greenhouse Gas Emissions
- Water Use
- Wastewater
- Emissions to Air (If Applicable)
- Waste Management
- Chemical Management

The Higg FSLM assesses:

- Recruitment and Hiring
- Working Hours
- Wages and Benefits
- Employee Treatment
- Employee Involvement
- Health and Safety
- Termination
- Management Systems
- Empowering People and Communities

Thank you

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Day 1: Updates from first convening and discussion of post shipment issues

Time	Duration	Topic	Presenters
9.00	30 min	Registration of delegates and welcome	
9.30	30 min	Introduction and follow up on progress towards Roadmap goals	Angus Spiers
10.00	45 min	Key updates: • Manufacturer QA • Case Studies	Eddie Thomsen
10.45	**30 min**	**Coffee break**	
11.15	1hour 15 min	Panel discussion – progress since first convening • Marion Law • Dominic Schuler • Mattu Bockarie-Davis • Grit Thierfelder	Angus Spiers (chair)
12.30	1 hour	Lunch	
1.30	1 hour 15 min	Setting the scene for country management issues: • Session Objectives • The in-country life of an ITN • Discussion	Hannah Koenker (chair)
2:45	30 min	Coffee Break	
3.15	1 hour	• Findings from country interviews • Data availability and gaps • Data use • Discussion	Hannah Koenker (chair) Nandita Jaitly
4.45	15 min	Wrap up and next steps	
5.00	Close of day and cocktail reception		

Coffee break

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Panel discussion – progress since first convening

What are you most looking forward to discuss during the convening?

Mentimeter

What do you hope you'll get out of the convening?

Mentimeter

18

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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

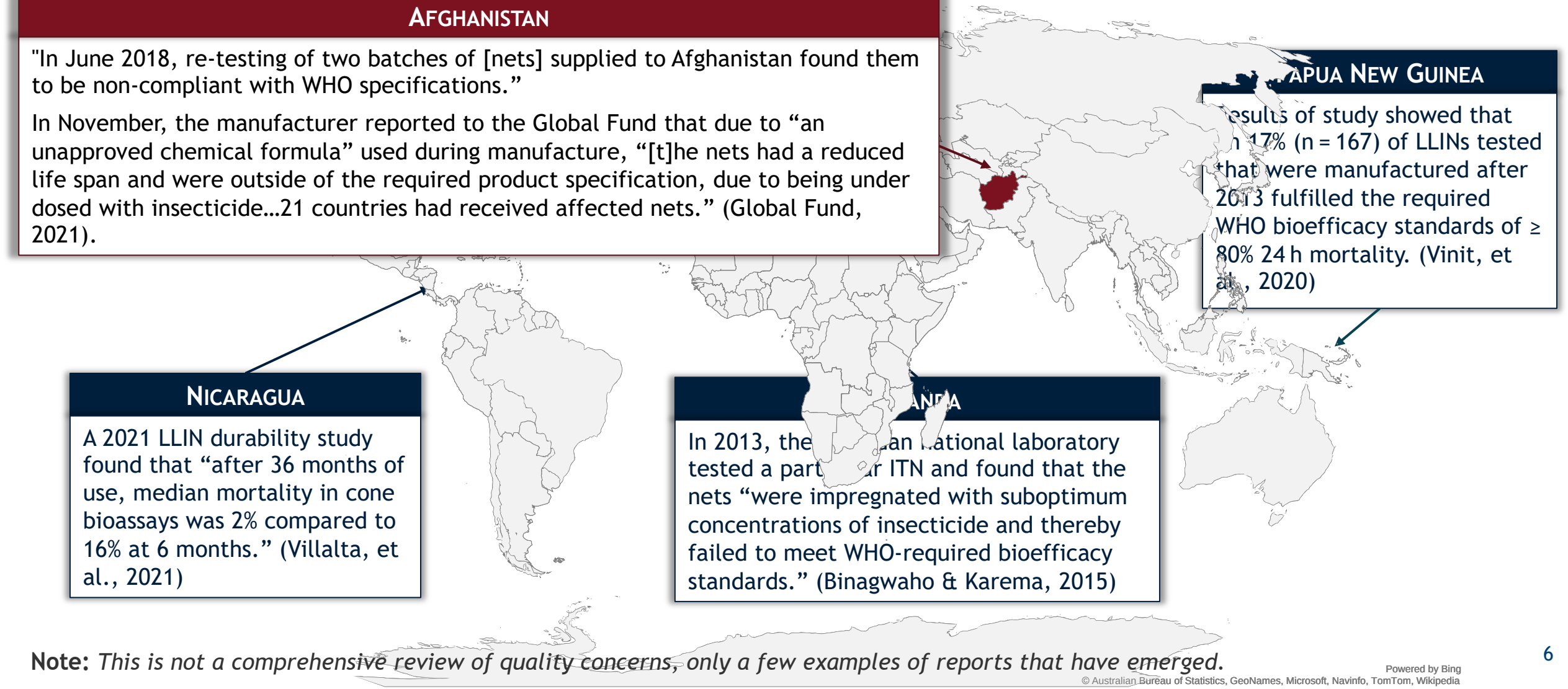
Review of key information from previous meetings and presentations

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 under dosed with insecticide…21 countries had received affected nets." (Global Fund, 2021).



Papua 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)

Nicaragua

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)

[illegible]anda

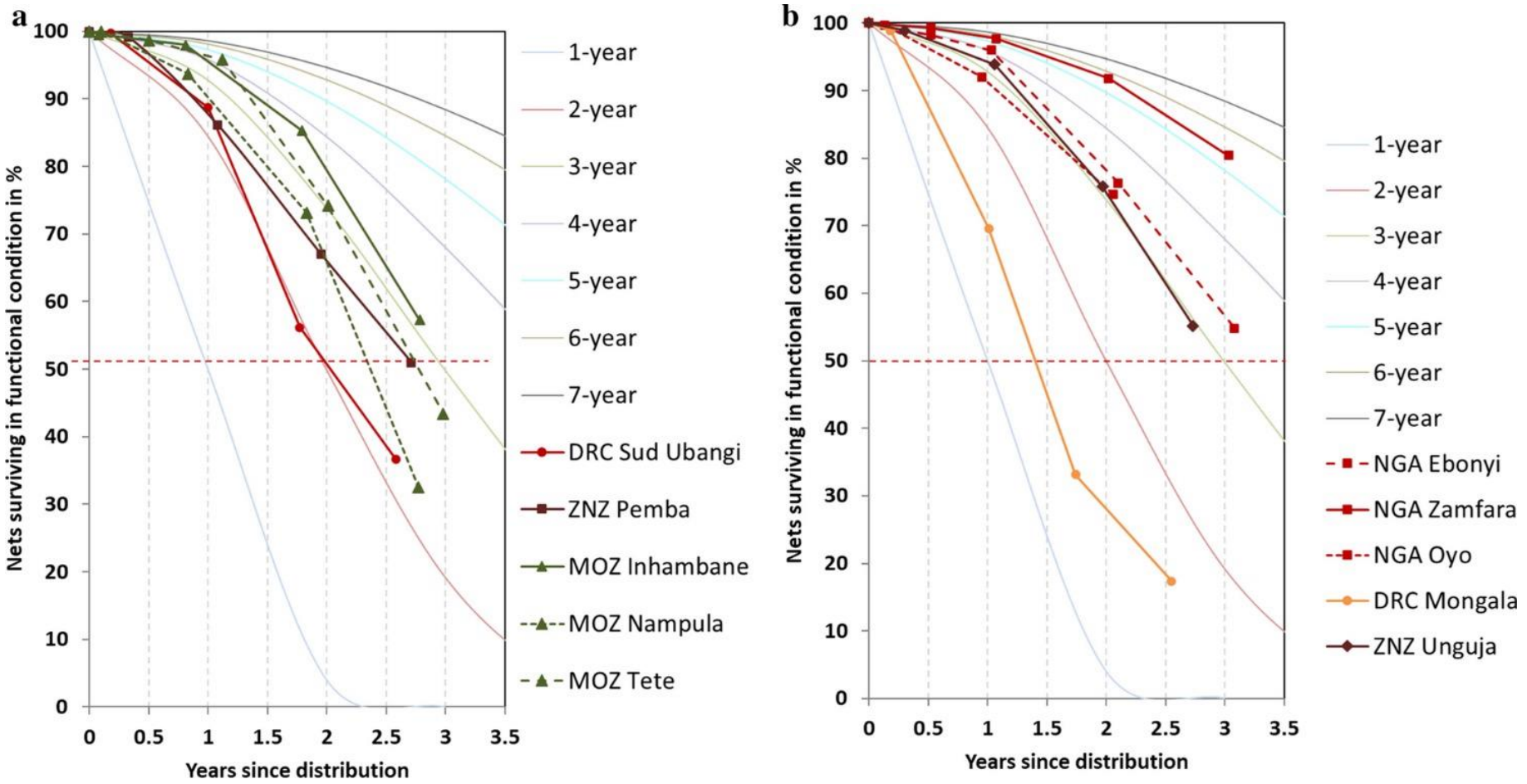
In 2013, the [illegible]an national laboratory tested a particular ITN and found that the nets "were impregnated with suboptimum concentrations of insecticide and thereby failed to meet WHO-required bioefficacy standards." (Binagwaho & Karema, 2015)

Note: *This is not a comprehensive review of quality concerns, only a few examples of reports that have emerged.*

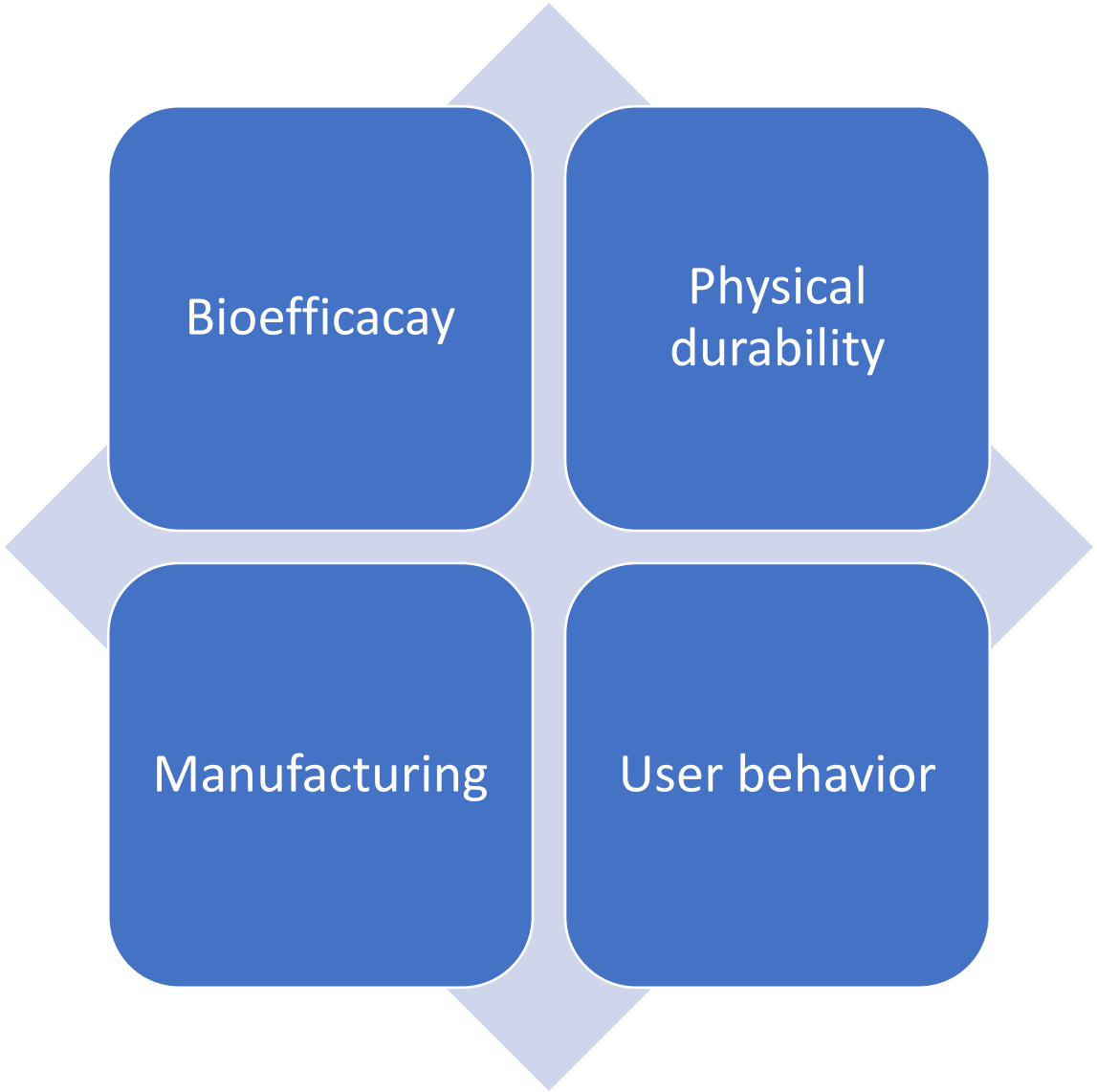
…while durability data has shown that nets are not lasting the expected three years in the field

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%.

Variation in Net Survival for Polyethylene & Polyester Nets



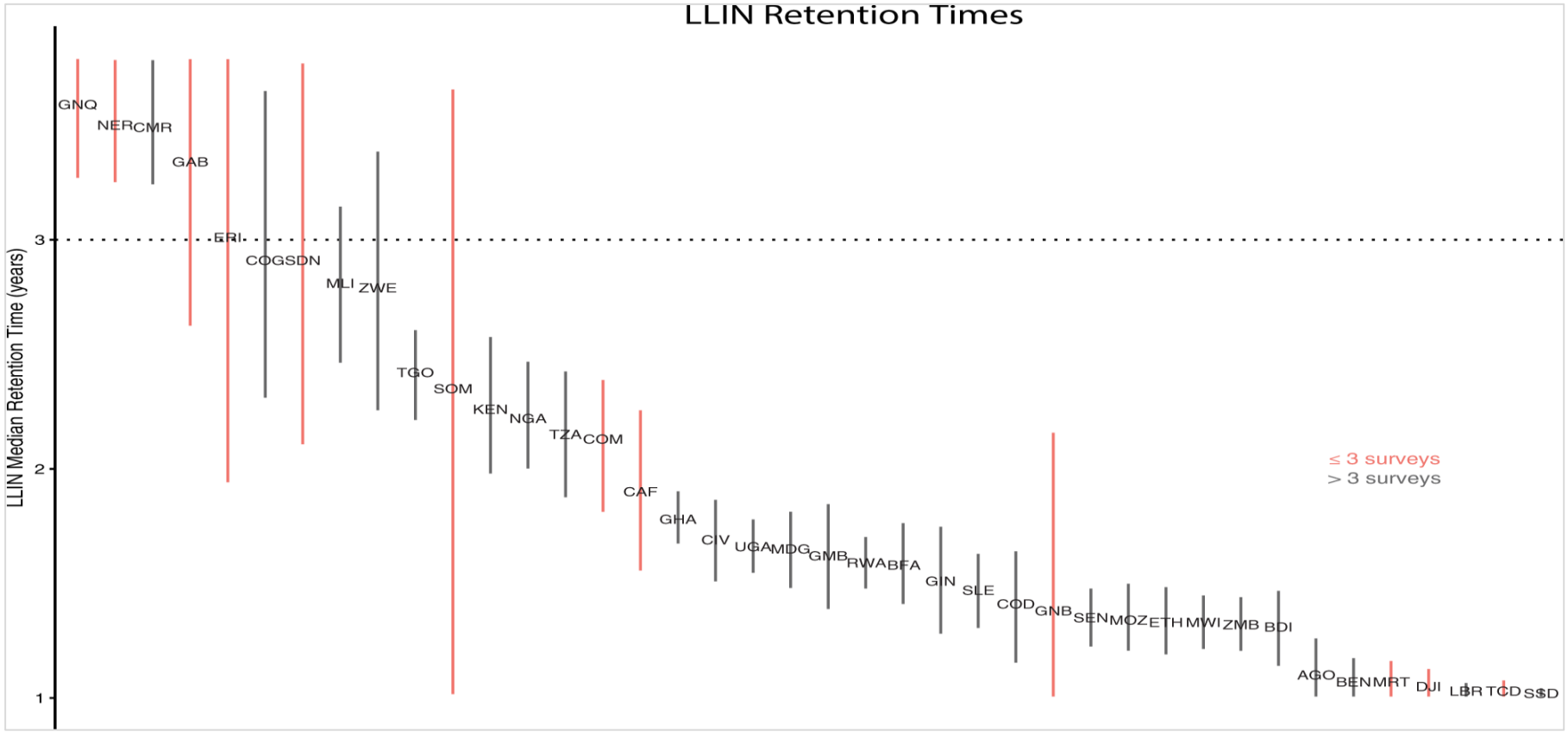
Kilian, A., Obi, E., Mansiangi, P. et al. Variation of physical durability between LLIN products and net use environments: summary of findings from four African countries. Malar J 20, 26 (2021). https://doi.org/10.1186/s12936-020-03549-2


Bioefficacay
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."



Bertozzi-Villa, A., Bever, C.A., Koenker, H. *et al*. Maps and metrics of insecticide-treated net access, use, and nets-per-capita in Africa from 2000-2020. *Nat Commun* **12**, 3589 (2021).

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?

Procurement

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

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?

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

Design/data generation	Pre-market evaluation	Production	Storage and distribution	End user
Manufacturer • R&D • Optimization • Pilot production • Data generation	**NRA/WHO** • Evaluation of dossier to support quality, safety and efficacy, and/or other parameters	**Manufacturer** • Scale up to commercial production • QA/QC procedures • Packaging	**Manufacturer, Procurer, Transport Service, Storage Authority, Distributors** • QC • Storage and transport in variable conditions	**User** • Proper and consistent use of the product

Maximising Impact: Effectiveness of ITNs

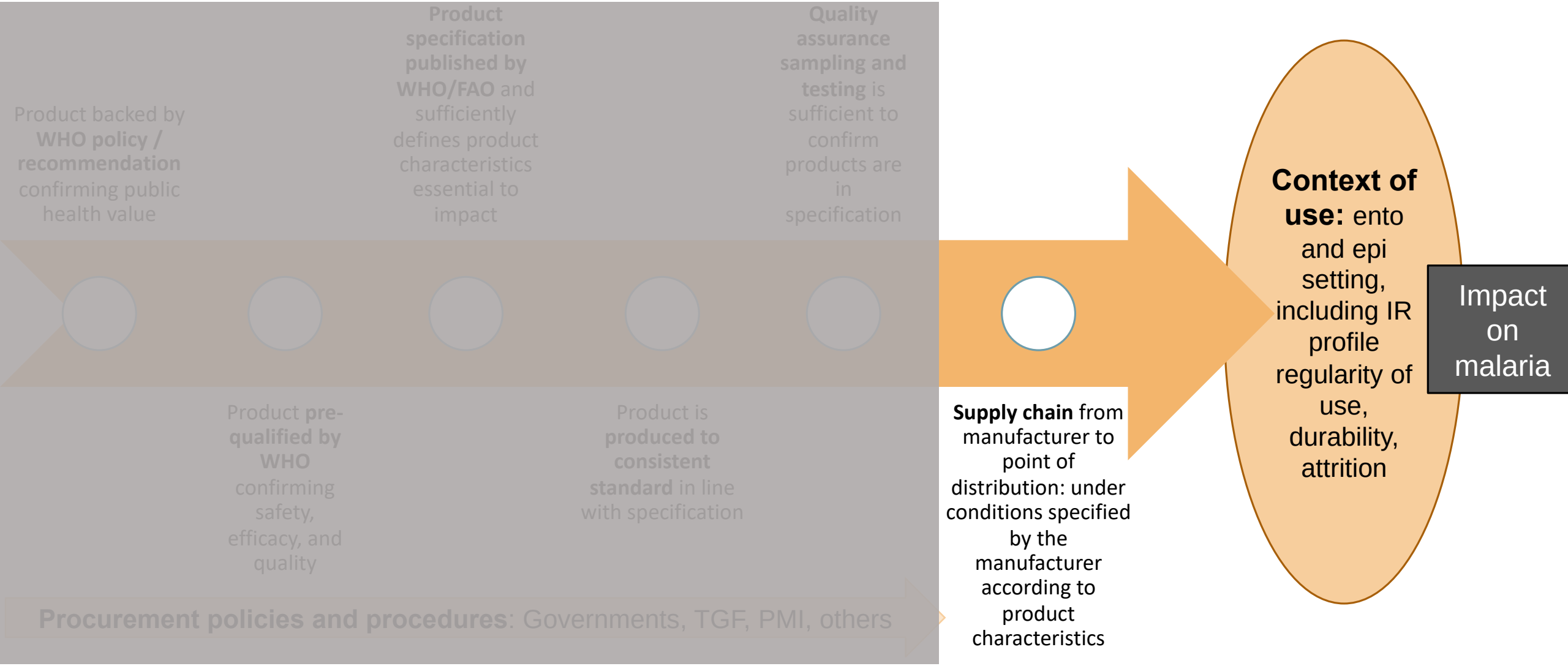
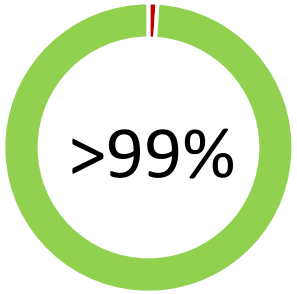


Figure: End-to-end analysis of factors influencing potential for impact from an ITN

Over 2 billion ITNs have been delivered to malaria-endemic countries since 2004

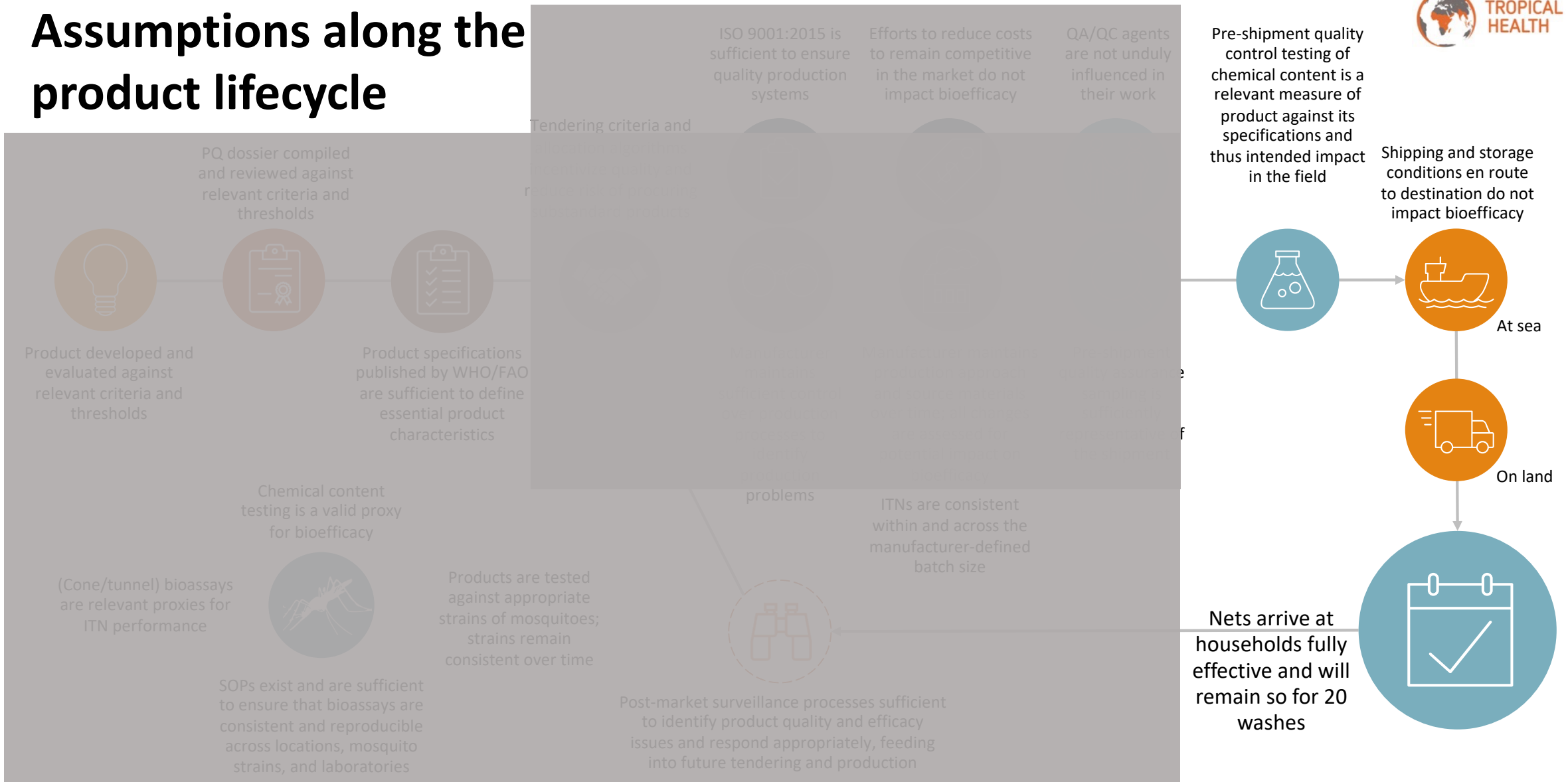


PMI

Percent of shipments for which products meet pre-shipment testing specifications for chemical content (2016-present)

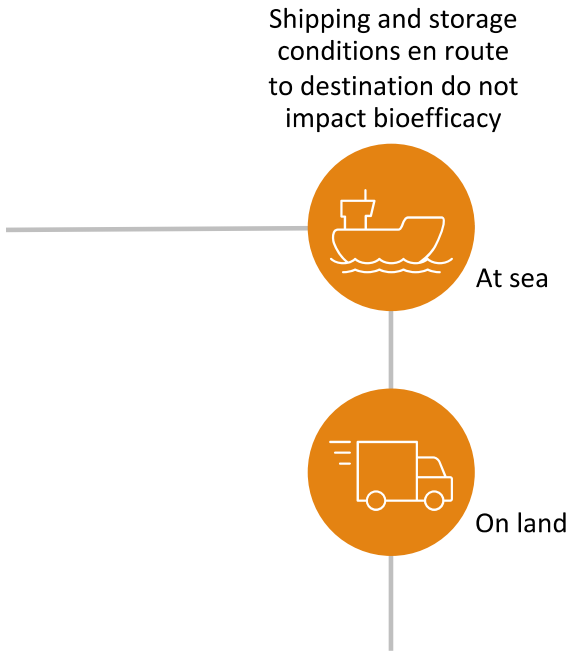
AFR total since 2004; other regions' totals since 2009. AMP Net Mapping Project

Assumptions along the product lifecycle



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

Post-market surveillance processes sufficient to identify product quality and efficacy issues and respond appropriately, feeding into future tendering and production

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

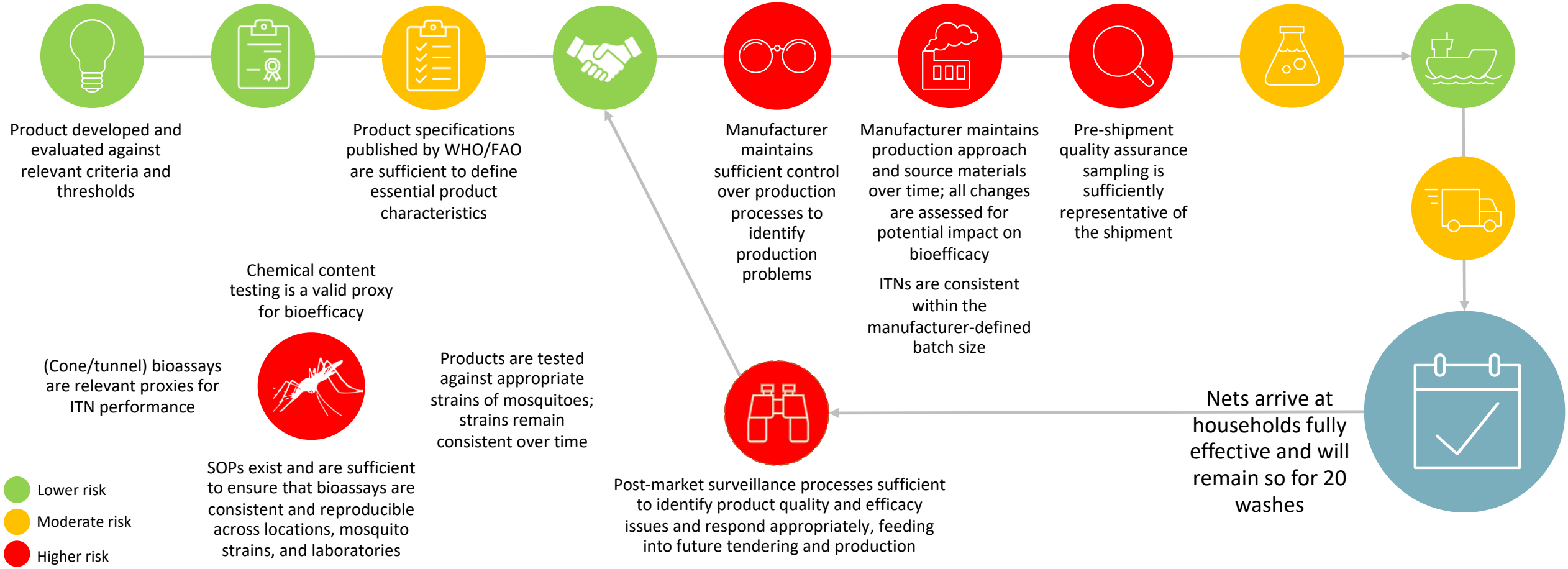
A. Develop consensus approach for post-shipment testing at country level.

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



Priority risk areas

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**
- **Why?:** A review of product specifications will ensure they are relevant and specific enough to ensure quality and bioefficacy.
- **Proposed lead**: WHO PQT/VCP ; WHO-GMP
- **Proposed stakeholders**: Suppliers, research institutions
- **Wider impact (i.e. beyond ITN bioefficacy prior to distribution):** potential for positive impact on other ITN characteristics, including durability, safety, and ecological impact

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

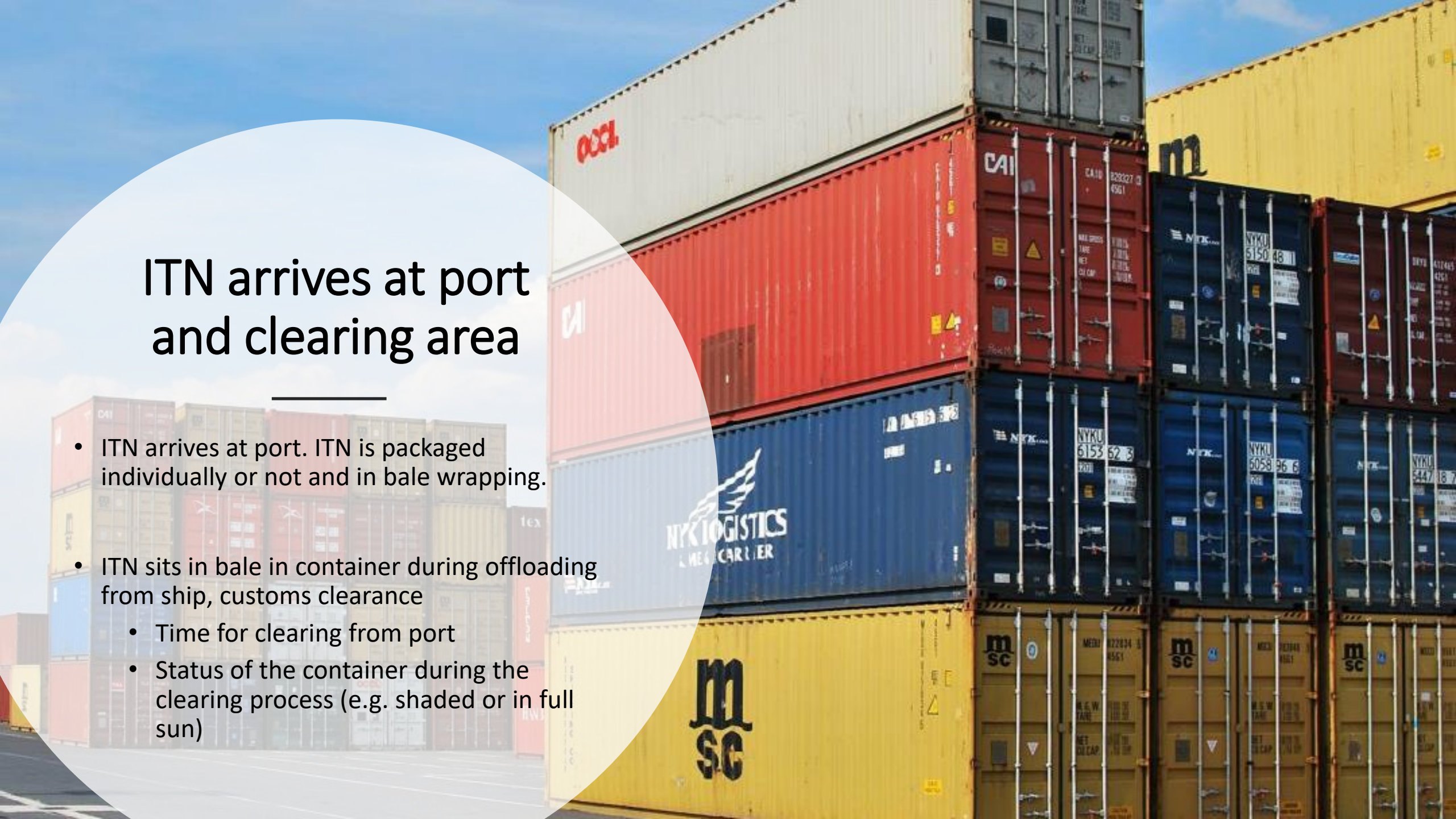
- **Develop guidelines on effective use of resources for post-shipment testing.**
- **Why? :** Approaches to post-shipment testing vary considerably across countries and cost and time pressure are a significant barrier. Recommendations on effective approaches for post-shipment testing as well as the 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

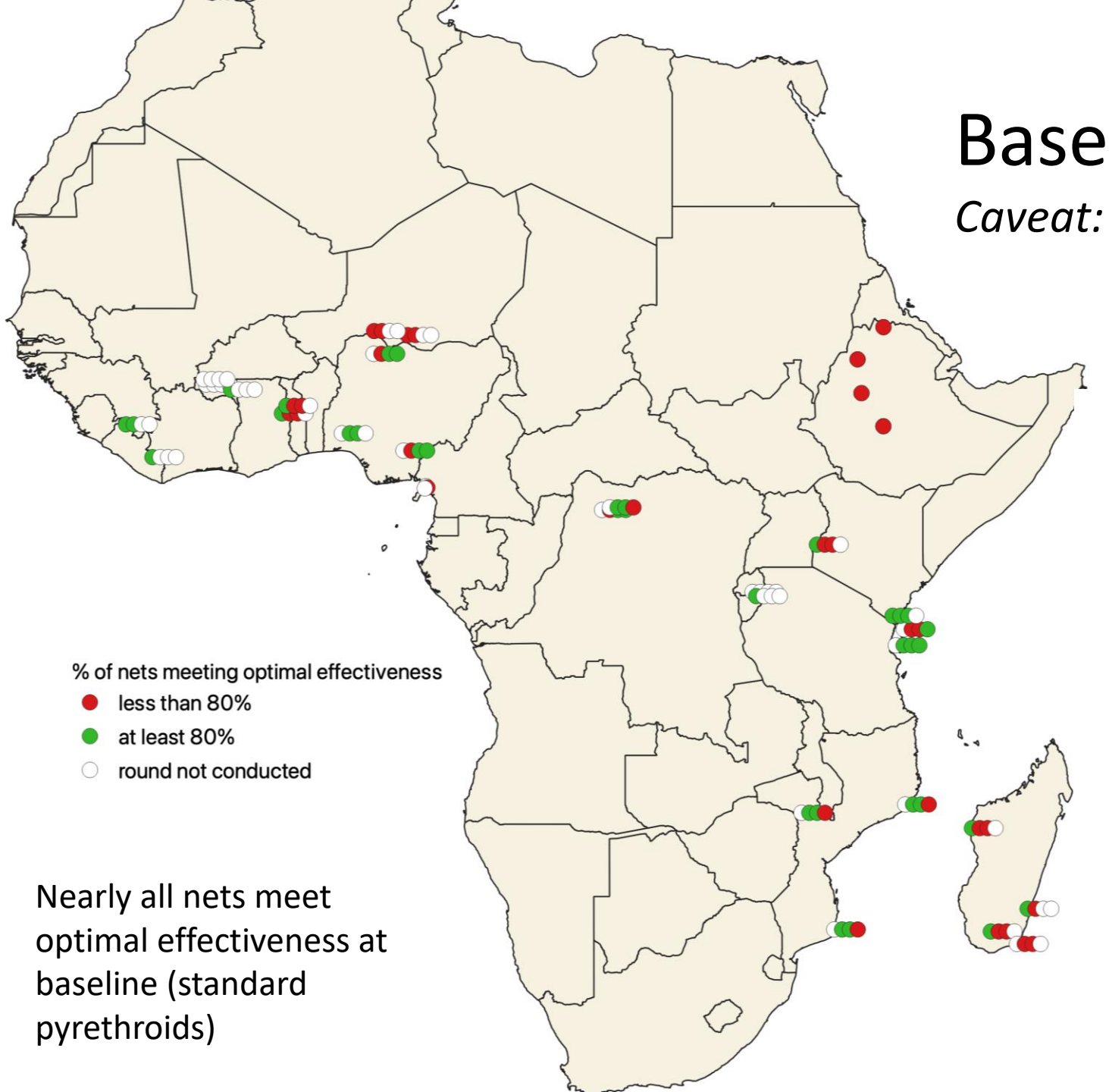
ITN stored at various levels and distribution location

- 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

Baseline results largely fine!

Caveat: limited data



Nearly all nets meet optimal effectiveness at baseline (standard pyrethroids)

Percent of nets surviving in serviceable condition

country	baseline	12m	24m	36m
drc	99.5	85.6	65.2	56.5
gha	98.2	92.9	75.5	73.0
ken	97.9	87.4	78.7	67.4
lib	99.7	98.7	94.6	89.4
moz	99.5	97.5	89.1	71.1
moz2	95.6	80.7		
nig1	99.9	97.3	90.8	85.9
nig2	100.0	97.9		
znz	99.2	93.3	80.9	65.6

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

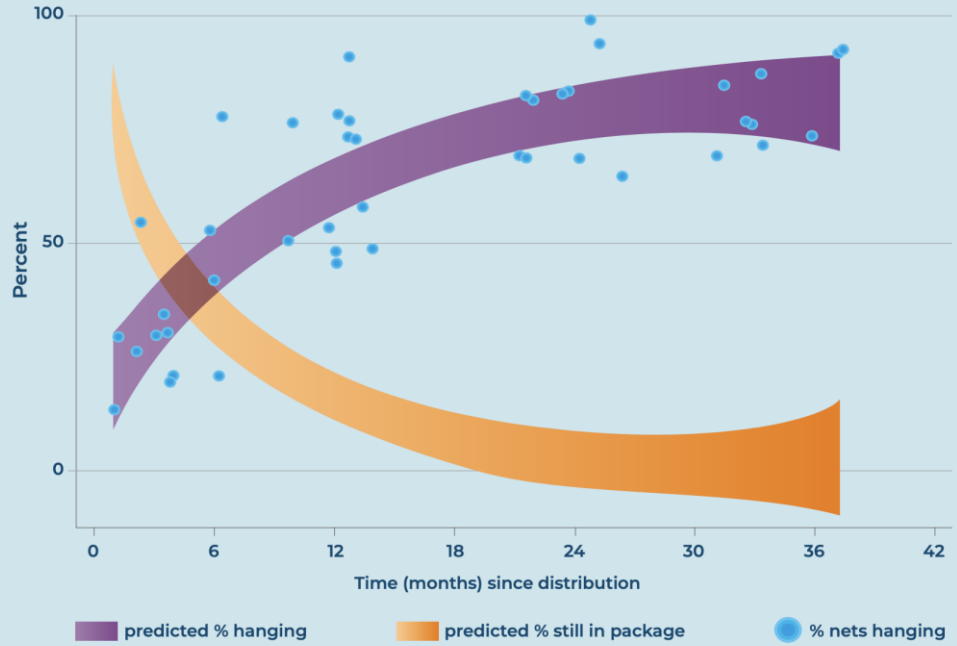
ITN transported to its forever home!

- 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[7,8,9,10]



ITN airing

ITN is aired in the shade for 24 hours before use (or more or less or sun or other) before hanging

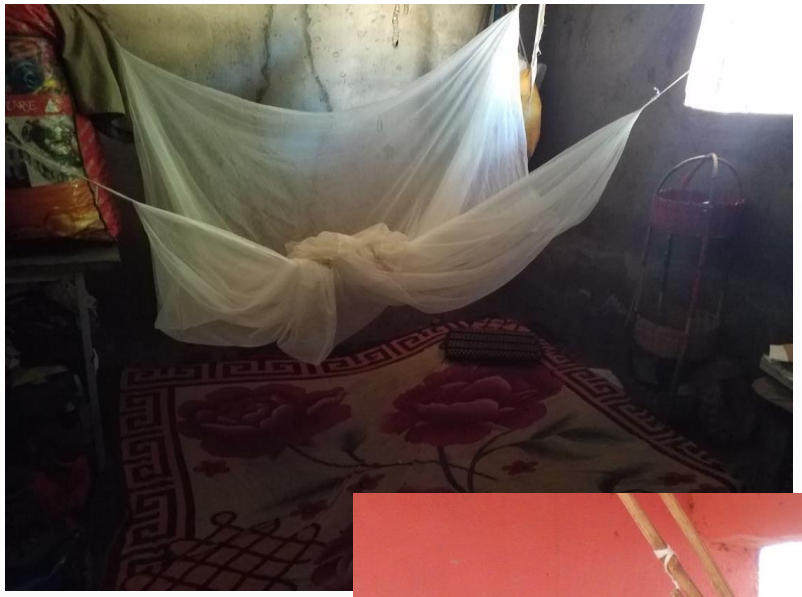
Management of leftover campaign ITNs

- 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)

Gets washed (frequency, materials, drying)

ITN lives in house…



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?

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1.30	1 hour 15 min	Setting the scene for country management issues: • Session Objectives • The in-country life of an ITN • Discussion	Hannah Koenker (chair)
2:45	30 min	Coffee Break	
3.15	**1 hour**	**• Findings from country interviews** **• Data availability and gaps** **• Data use** **• Discussion**	**Hannah Koenker (chair)** **Nandita Jaitly**
4.45	15 min	Wrap up and next steps	
5.00	Close of day and cocktail reception		

Findings from country interviews

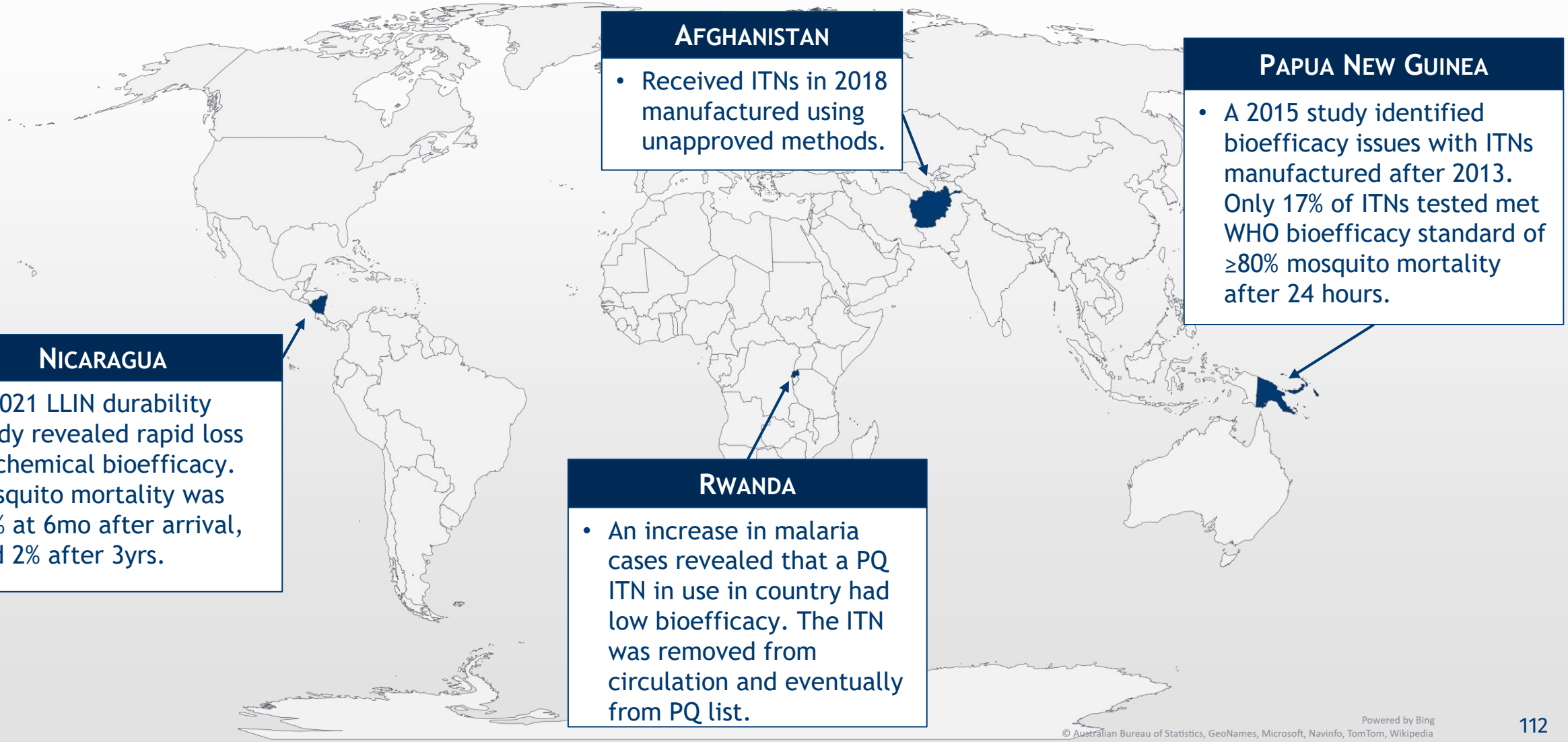
Raising the Floor on Nets

Findings from Country Interviews

May 2022

BILL & MELINDA GATES *foundation*

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.

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.

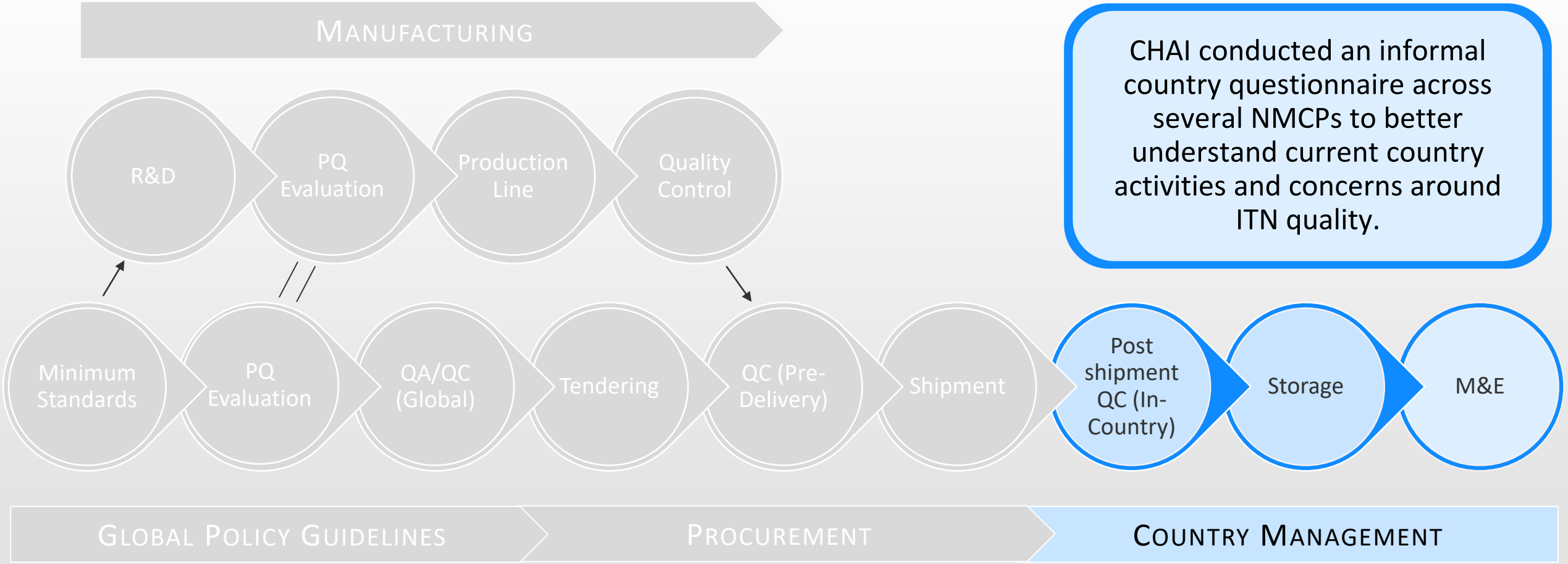
NICARAGUA

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

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*

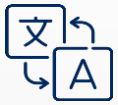
- Whether guidelines and SOPs exist to support ITN Quality Assurance/ Quality Control (QA/QC) in country
- Whether country has access to ITN QC test results conducted by procurers
- Information on ITN QC testing conducted in country
- Satisfaction with ITNs distributed during last campaign
- Information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

Country Interviews: Findings

ITN QA/QC Policies

3 of 10 programmes reported that they have guidelines to support in-country ITN QA/QC

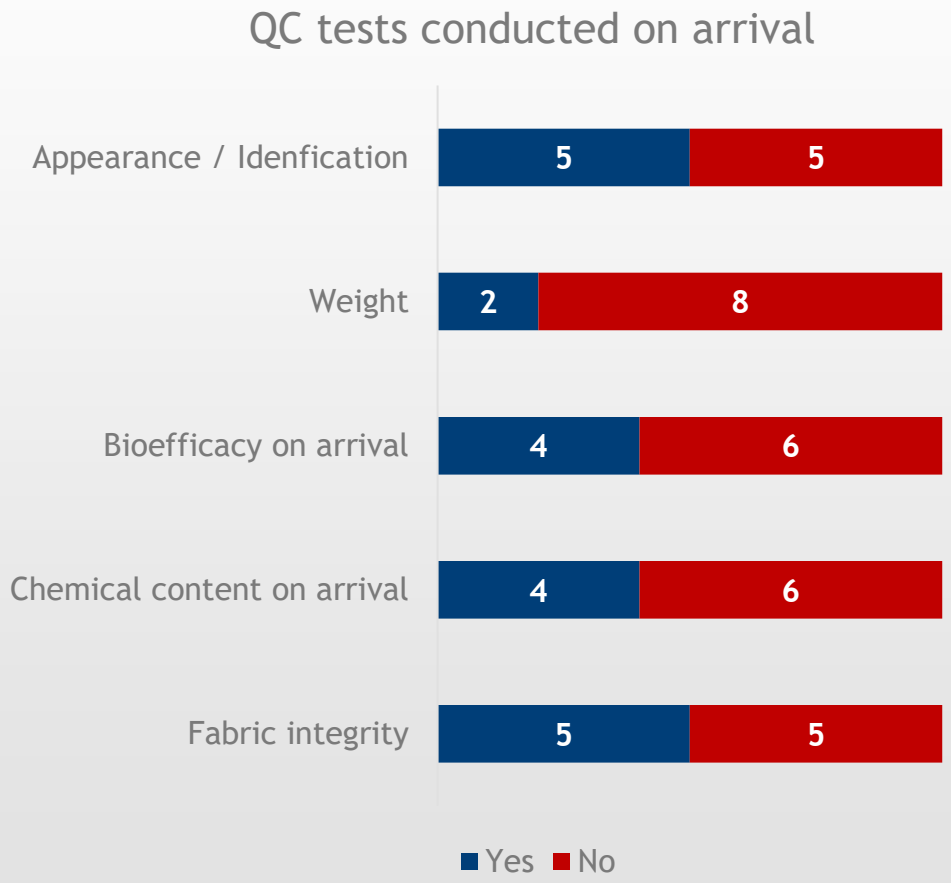
5 of 10 programmes reported that they have SOPs detailing how to perform QC procedures on ITNs

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

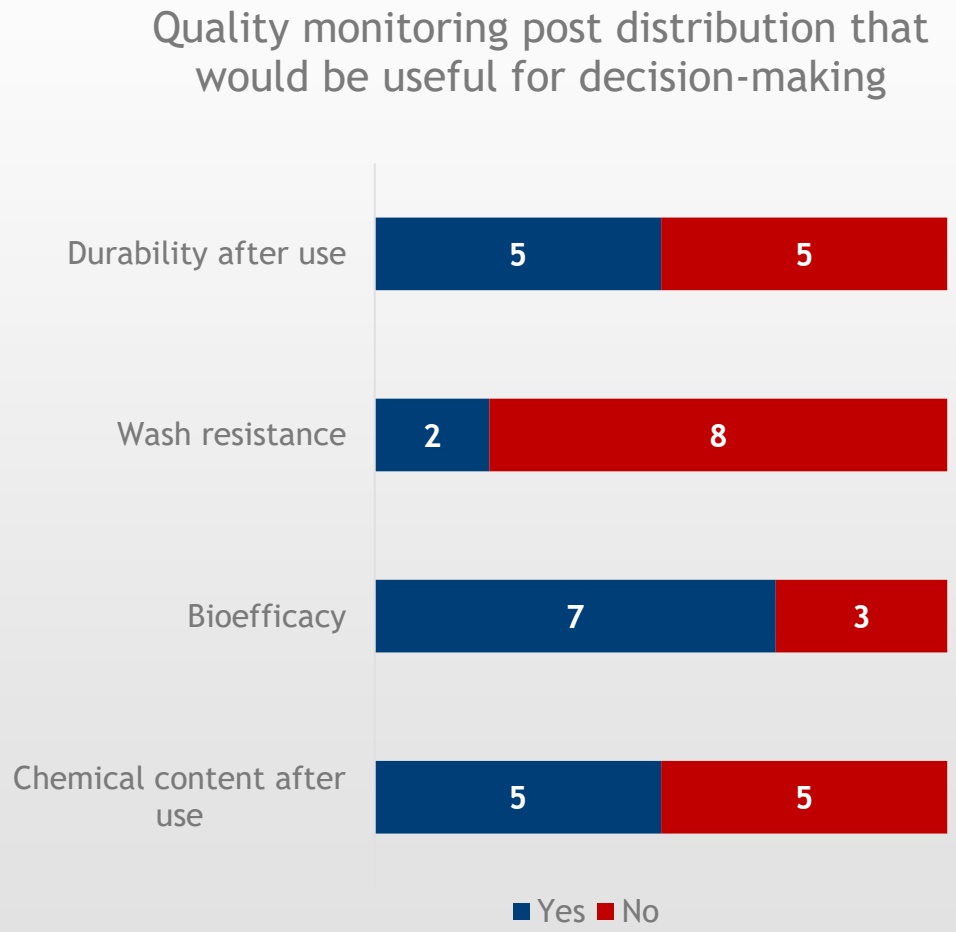
QC being conducted on arrival

- 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.*



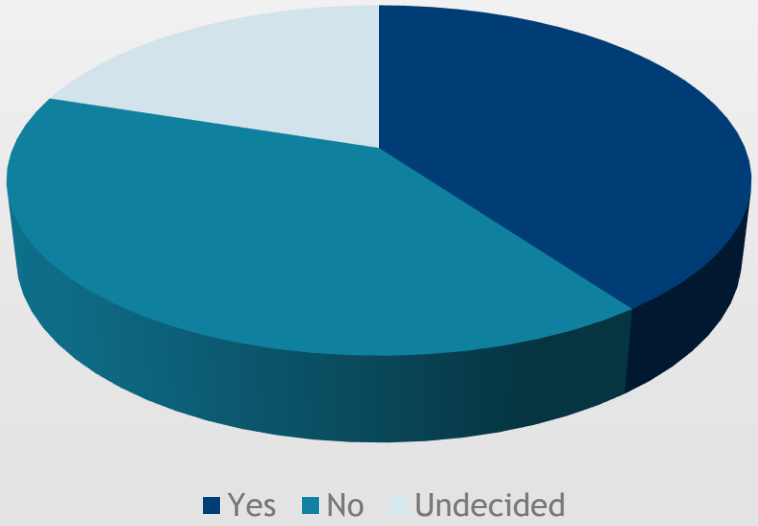
Quality monitoring being conducted post distribution

- 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.*

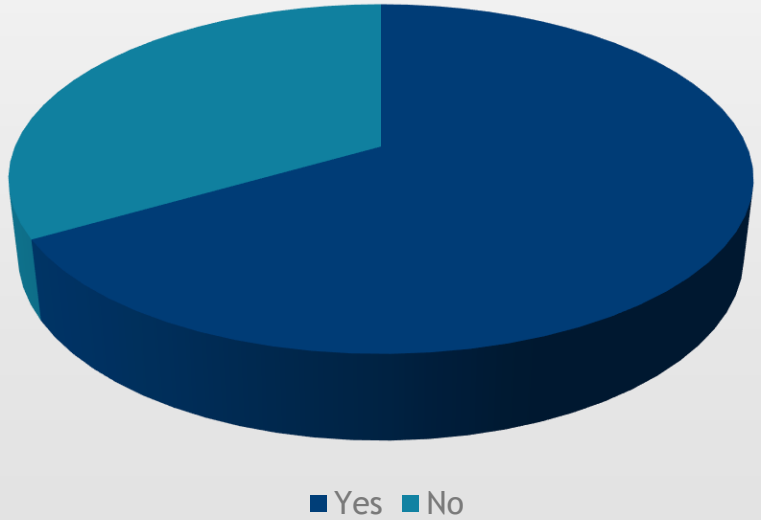


Countries cited capacity issues in conducting pre and post shipment QC

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.

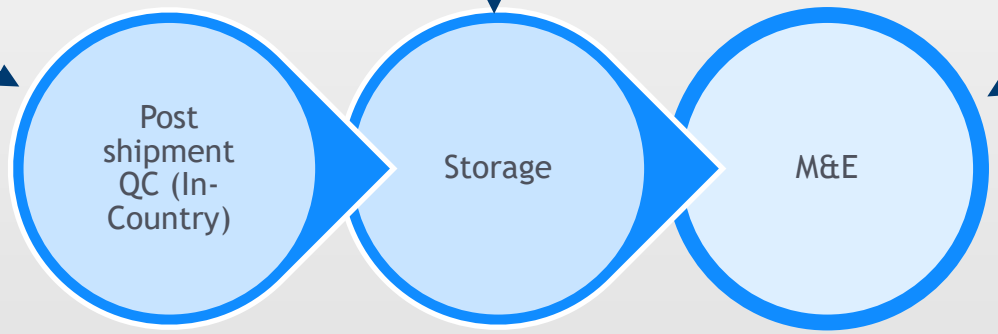
Representatives from 6 programmes suggested that establishing and adhering to policies and protocols, infrastructure and capacity to drive locally-owned QC efforts would help improve the quality of ITNs in-country

Discussion Points

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/ de-selection 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:

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Nandita Jaitly - njaitly@clintonhealthaccess.org

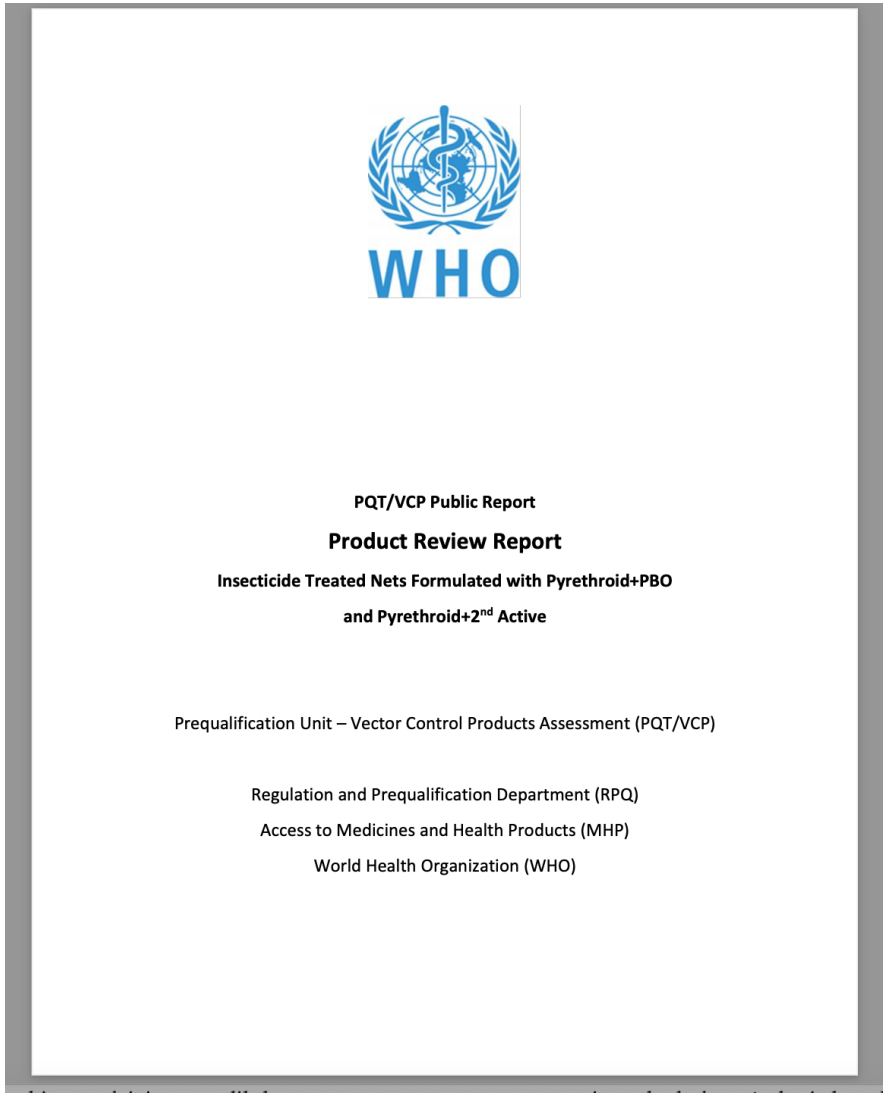
Discussion on data

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*



WHO

PQT/VCP Public Report

Product Review Report

Insecticide Treated Nets Formulated with Pyrethroid+PBO and Pyrethroid+2nd Active

Prequalification Unit – Vector Control Products Assessment (PQT/VCP)

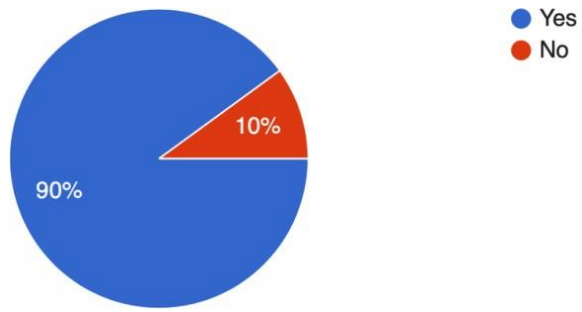
Regulation and Prequalification Department (RPQ)

Access to Medicines and Health Products (MHP)

World Health Organization (WHO)

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]



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?**

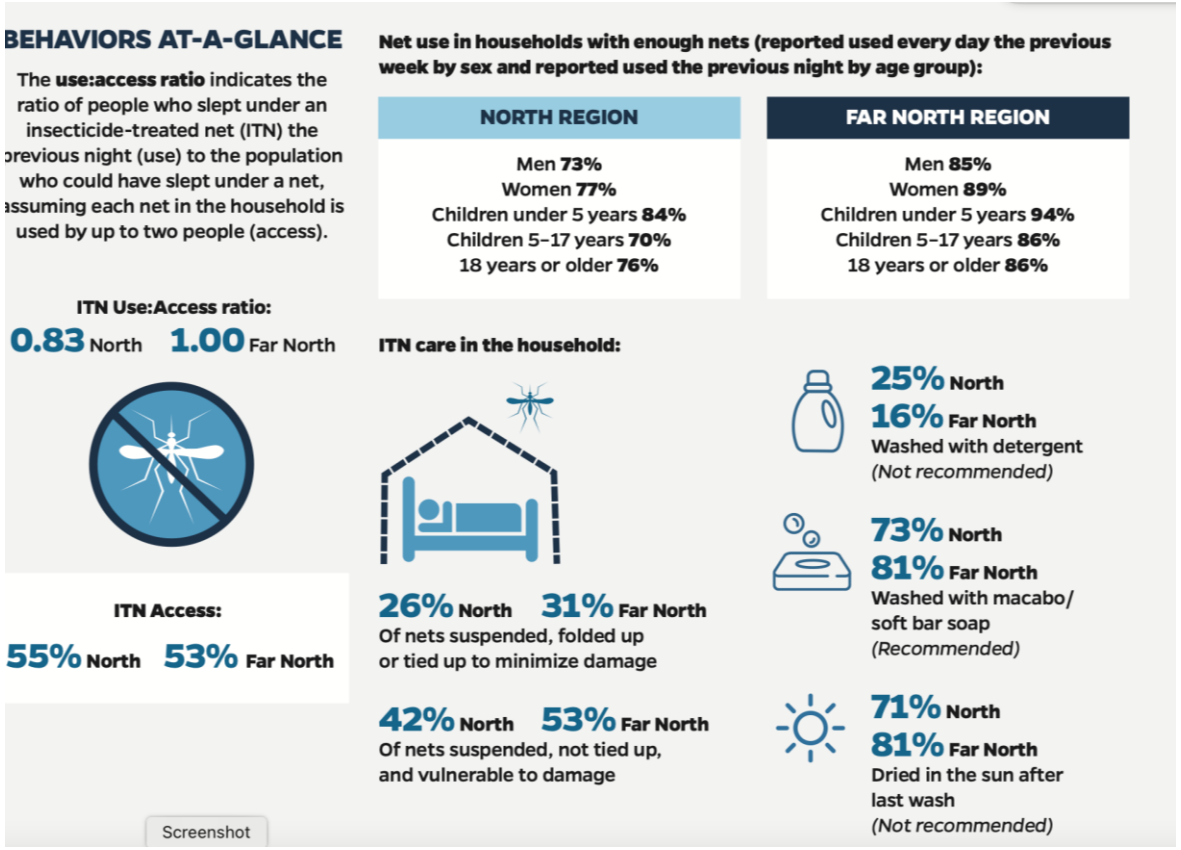
Facilitated discussion – 1

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?

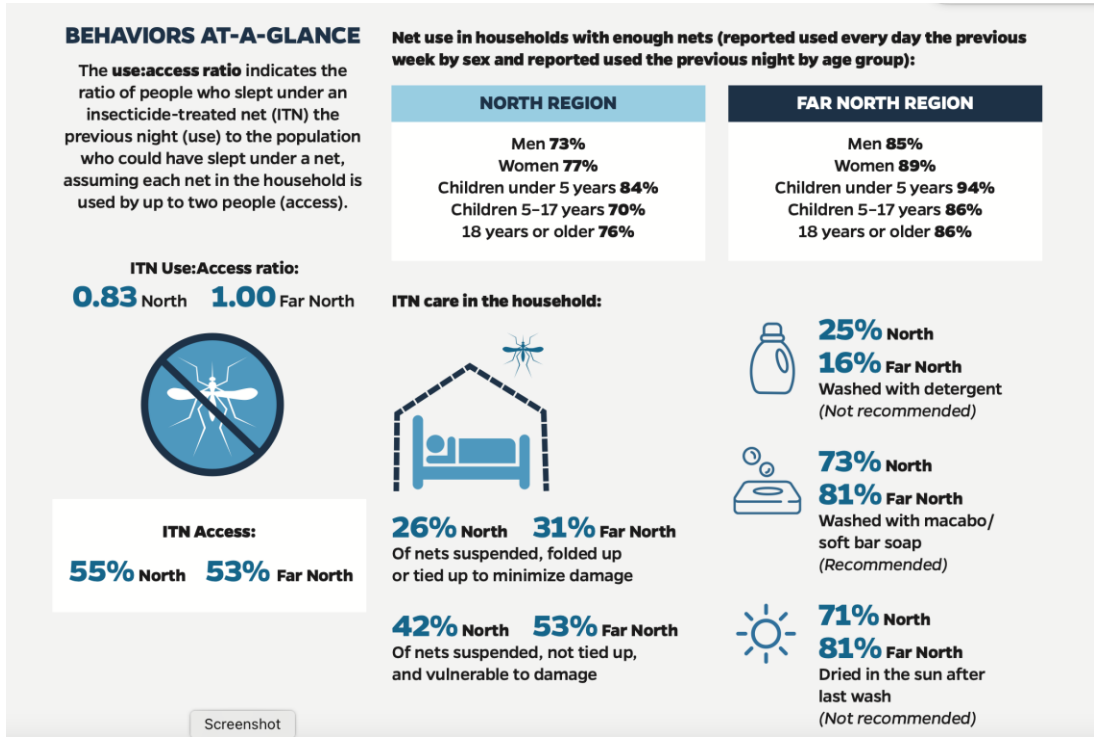
NOTE: for the purposes of discussion, it is assumed that funding is needed across areas



Facilitated discussion – 2

Questions:

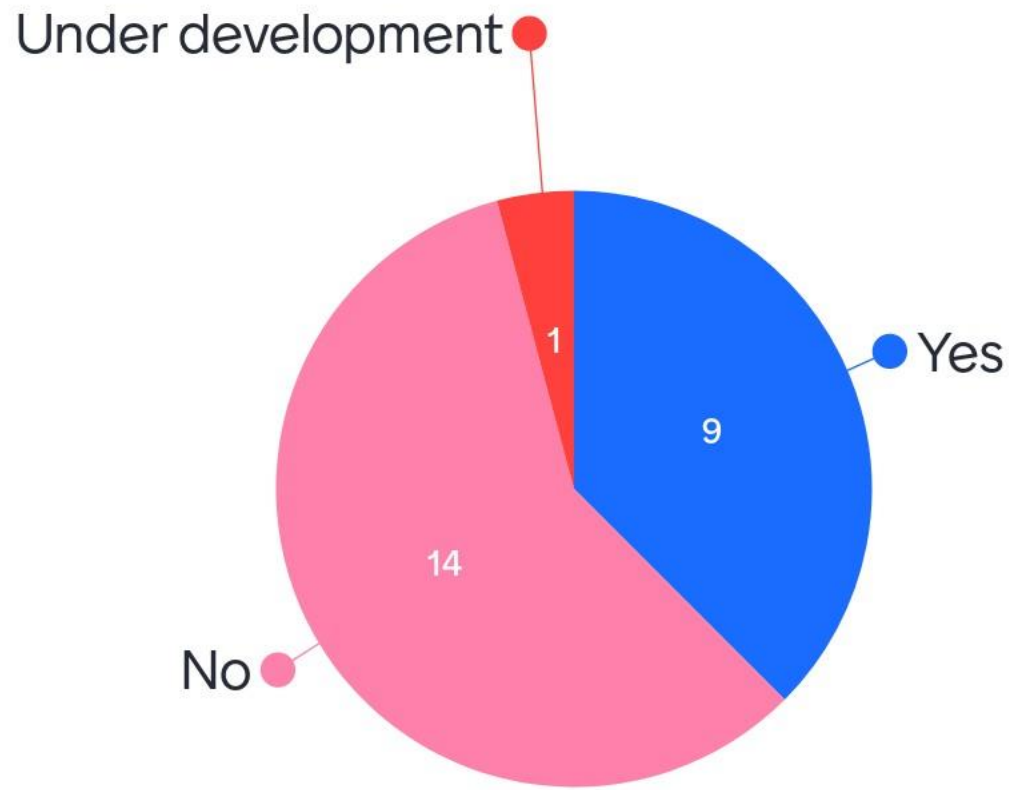
1. What data are missing for improvements to ITN in-country stewardship?
2. Is it possible to set indicators and standards for different points of ITN in-country stewardship?
3. Is data collected timely for decision-making?



Point in in-country life	Types of data	Standard data collection method exists	Data available	Policies available	Structures in place to collect data / assess adherence to policies
Arrival and clearing from customs	Post arrival inspection, temperature, humidity, delay tracking				
Storage	Warehouse condition, temperature, humidity				
Transport	Transport condition, temperature, humidity, delay tracking				
Handling after distribution - MOH	Unpackaged nets from campaigns, storage and issuing conditions, damage tracking				
Handling after distribution – HH	Bioefficacy, durability, acceptance, Malaria Behavior Surveys				
End of life	Durability, qualitative				

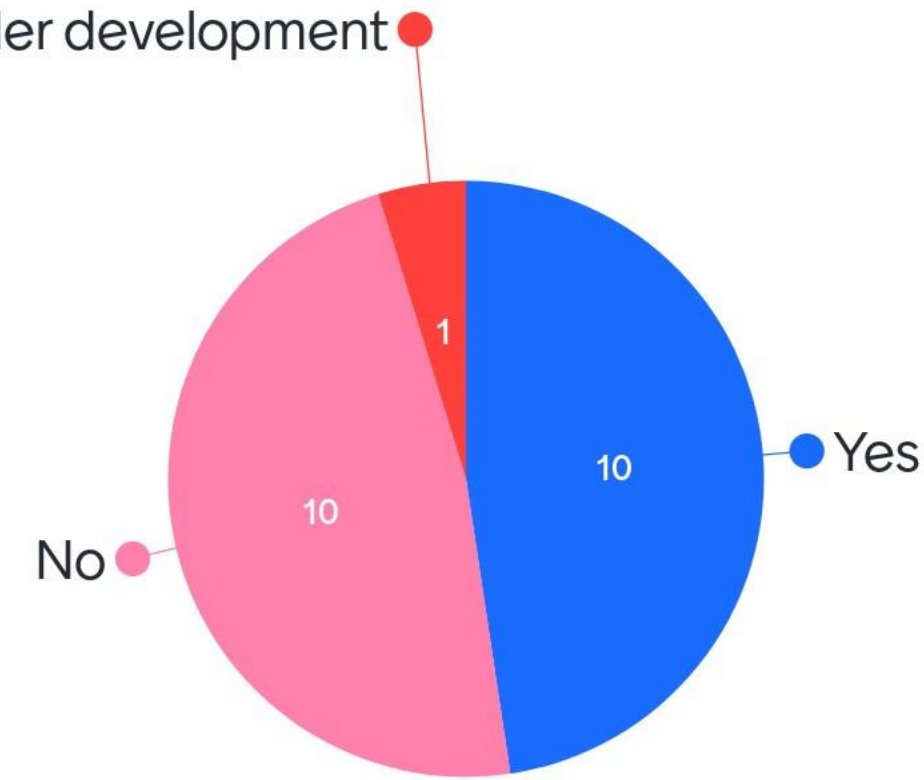
What is the biggest challenge in country management related to ITN quality/performance that we need to address?

Are there policies in place that set standards for warehousing and transport of ITNs?



Are there policies in place that set standards for distributor ITN handling up to recipient?

Mentimeter



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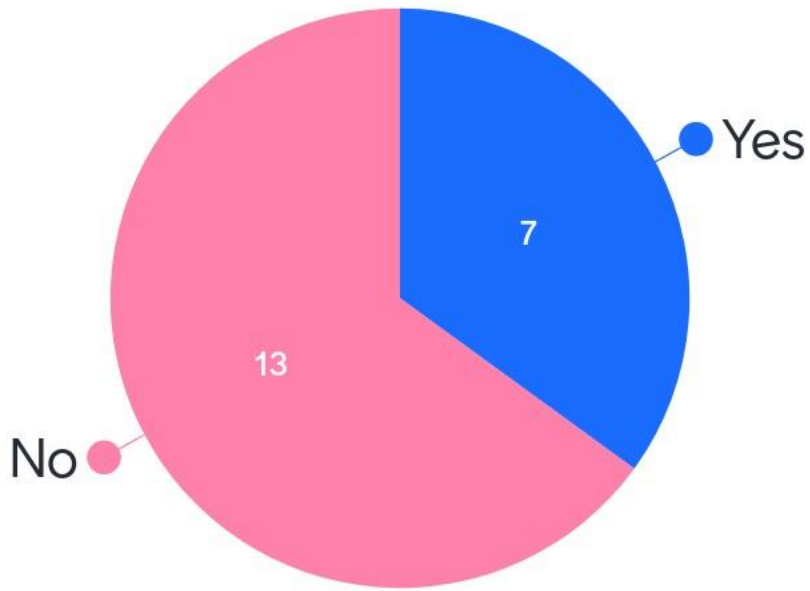
Are there policies in place that set standards for recipient ITN handling?

Mentimeter



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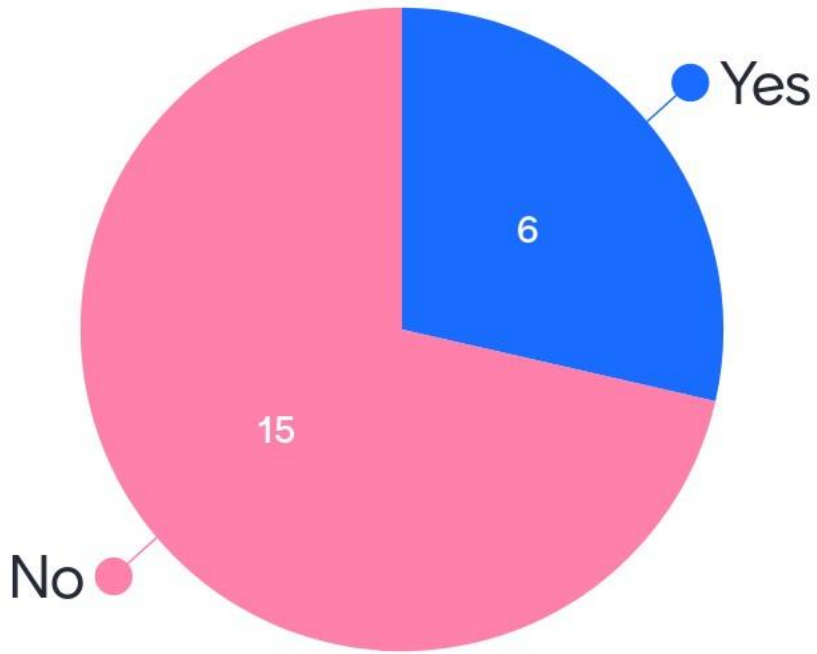
Are there policies in place for end of life nets?

Mentimeter



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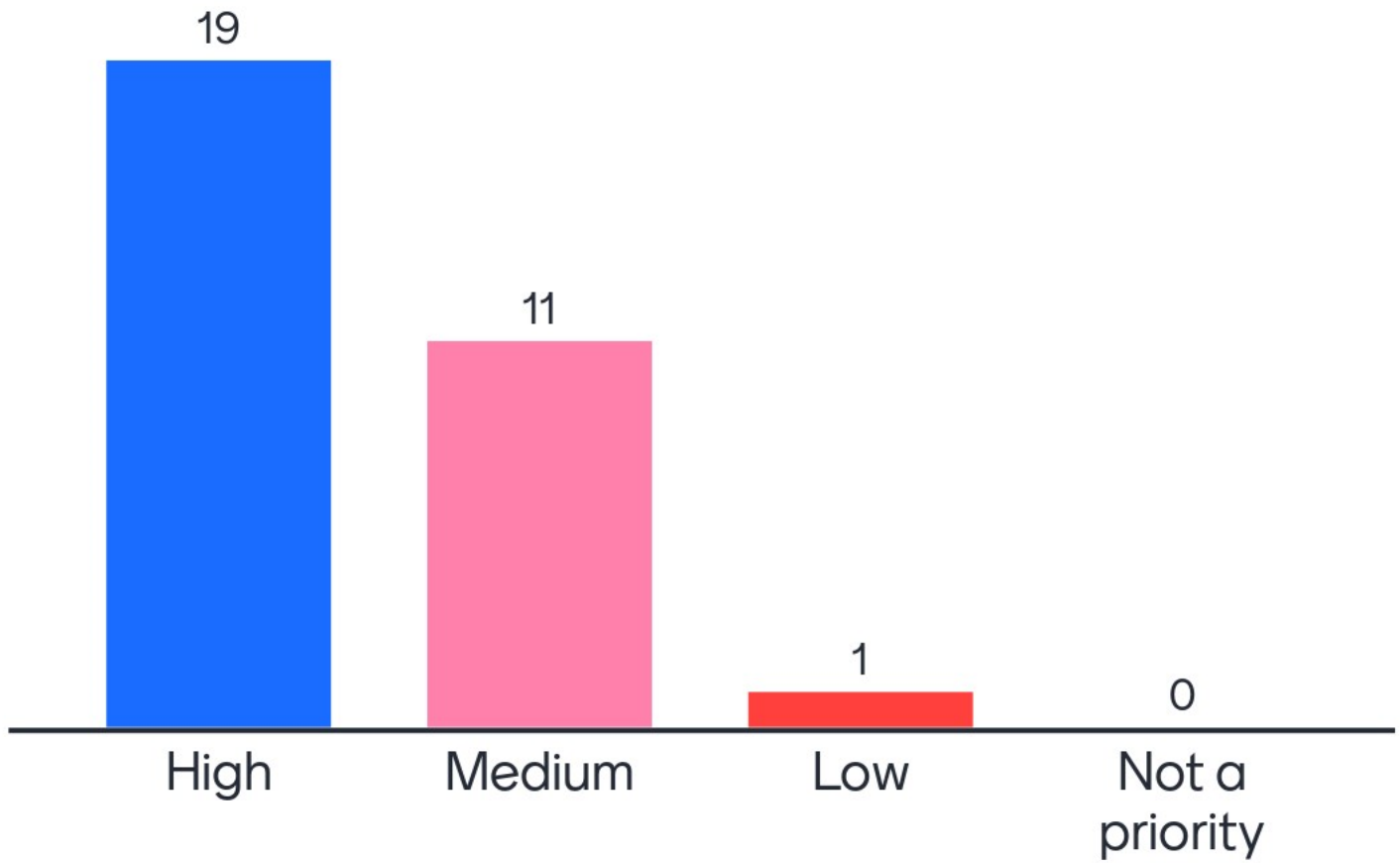
How important is it that we have the policies mentioned in the previous slides?



What are the priorities for in-country stewardship of ITNs moving forward?

Final discussion points, wrap up and closing

Wrap up and next steps