

Raising the Floor on Nets

Introduction to the ITN Quality Framework

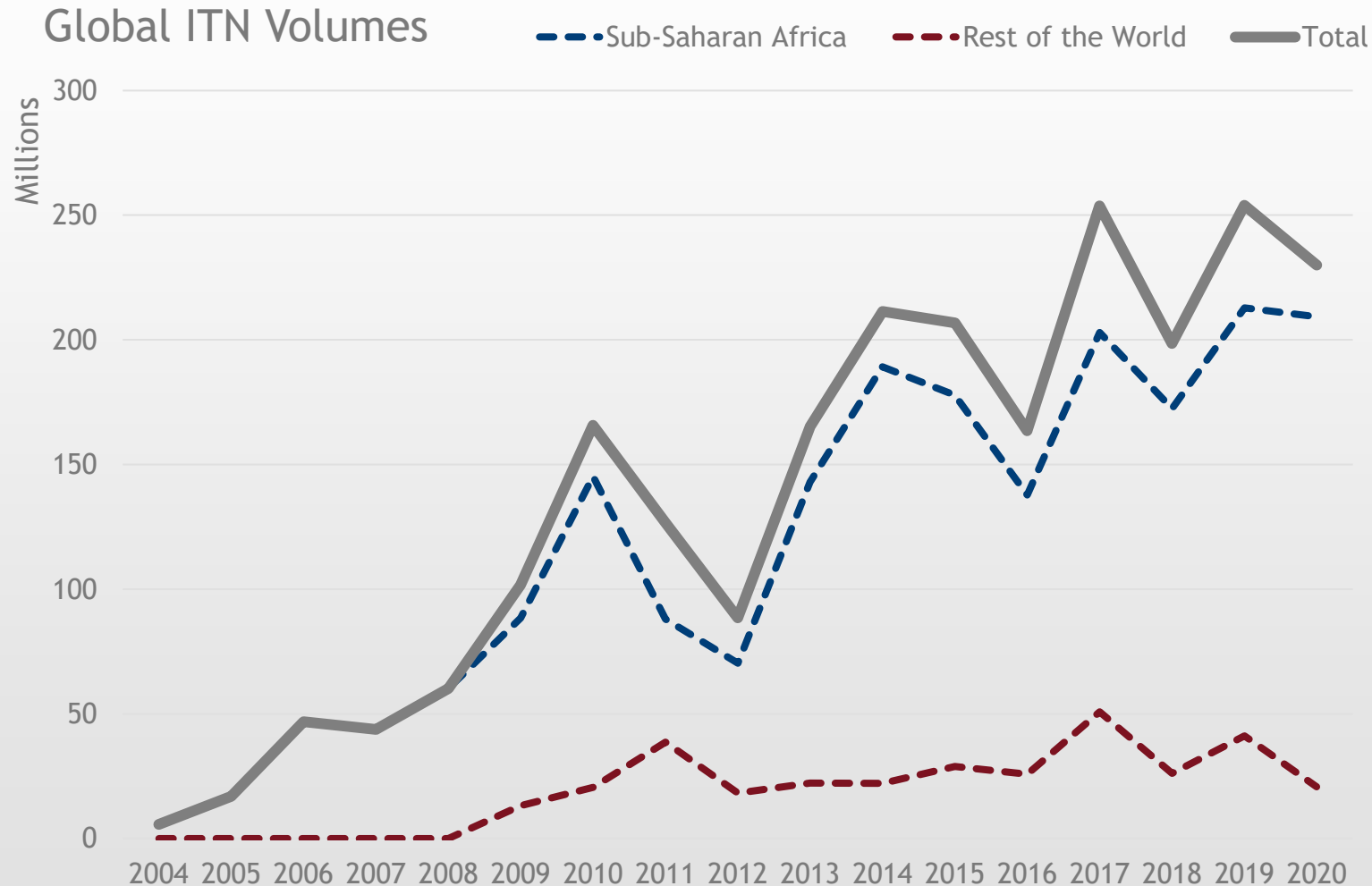
December 14, 2021

Angus Spiers, Tara Seethaler



BILL & MELINDA
GATES *foundation*

Enormous global investment in ITNs confer an ethical obligation to ensure high net quality



- ▶ Average annual net volume 2018-2020: **~218 million**
- ▶ Estimated annual spend on net commodities 2018-2020: **~\$460 million**
- ▶ Estimated number of people receiving nets in 2020: **338 million**

These volumes are made possible by:

- Commitment from donors and governments to invest in nets
- Global policies emphasizing universal coverage
- A competitive market with multiple players and razor thin margins
- Economies of scale supported by streamlined product sizes, colors, shapes, and pooled procurement mechanisms.

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

Explore content ▾ About the journal ▾ Publish with us ▾

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 this article](#)

3818 Accesses | 7 Citations | 82 Altmetric | [Metrics](#)

The New Times RWANDA

News Opinions Sports Lifestyle TimesTV Jobs & Tenders Citiz

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

KIPRESS

Home News ▾ Business & Tech ▾ Special Reports Voices Sports Society

BUSINESS & TECH

Rwanda To Halt Importing Mosquito Nets

By [Daniel Sabiti](#) March 04, 2019 at 5:44 pm

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

- South Sudan
- Nigeria
- Pakistan

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 only 17% (n = 167) of LLINs tested that were manufactured after 2013 fulfilled the required WHO bioefficacy standards of $\geq 80\%$ 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)

INDIA

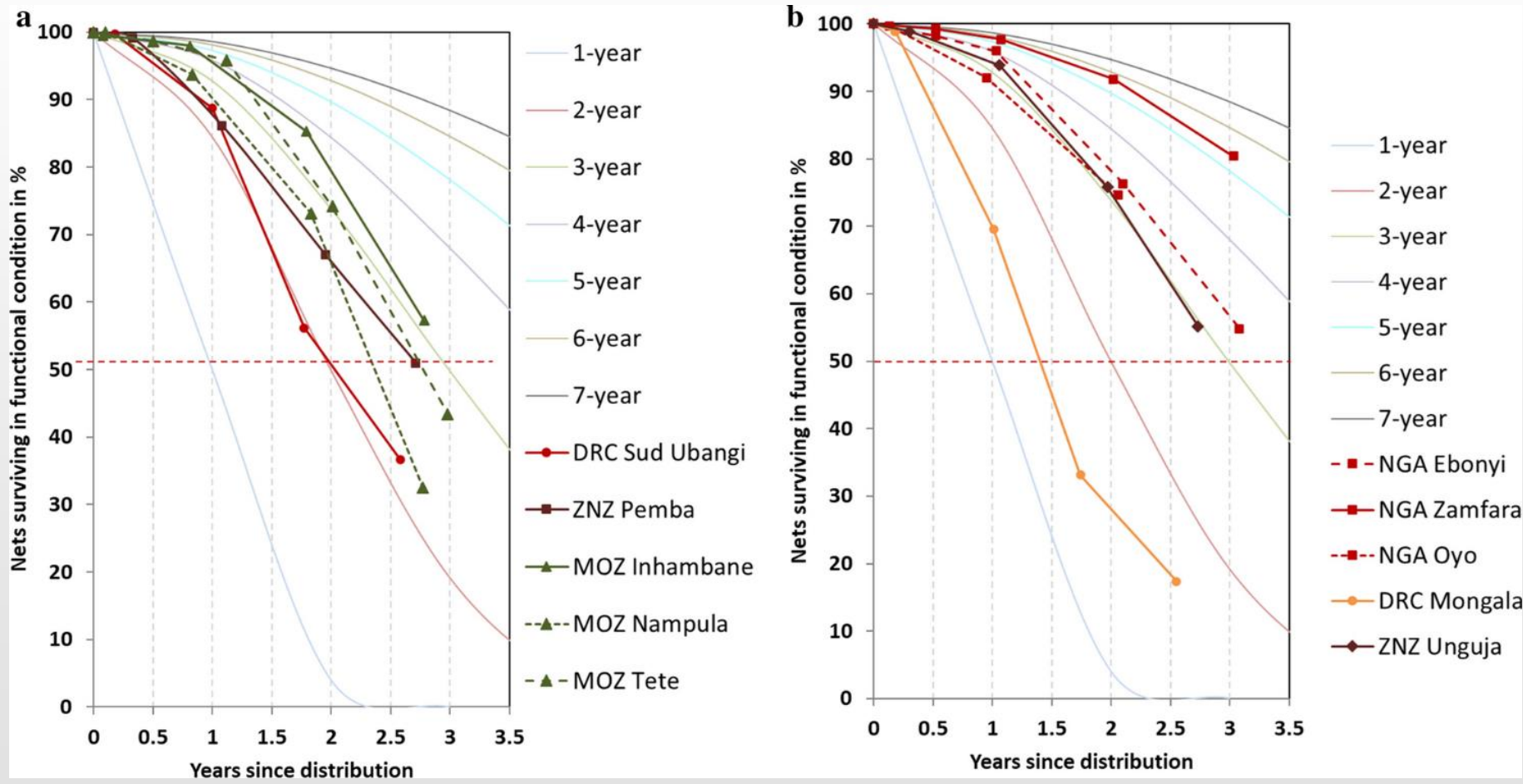
In 2013, the Indian national laboratory tested a part of an ITN and found that the nets "were impregnated with suboptimum concentrations of insecticide and thereby failed to meet WHO-required bioefficacy standards." (Binagwaho & Karema, 2015)

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

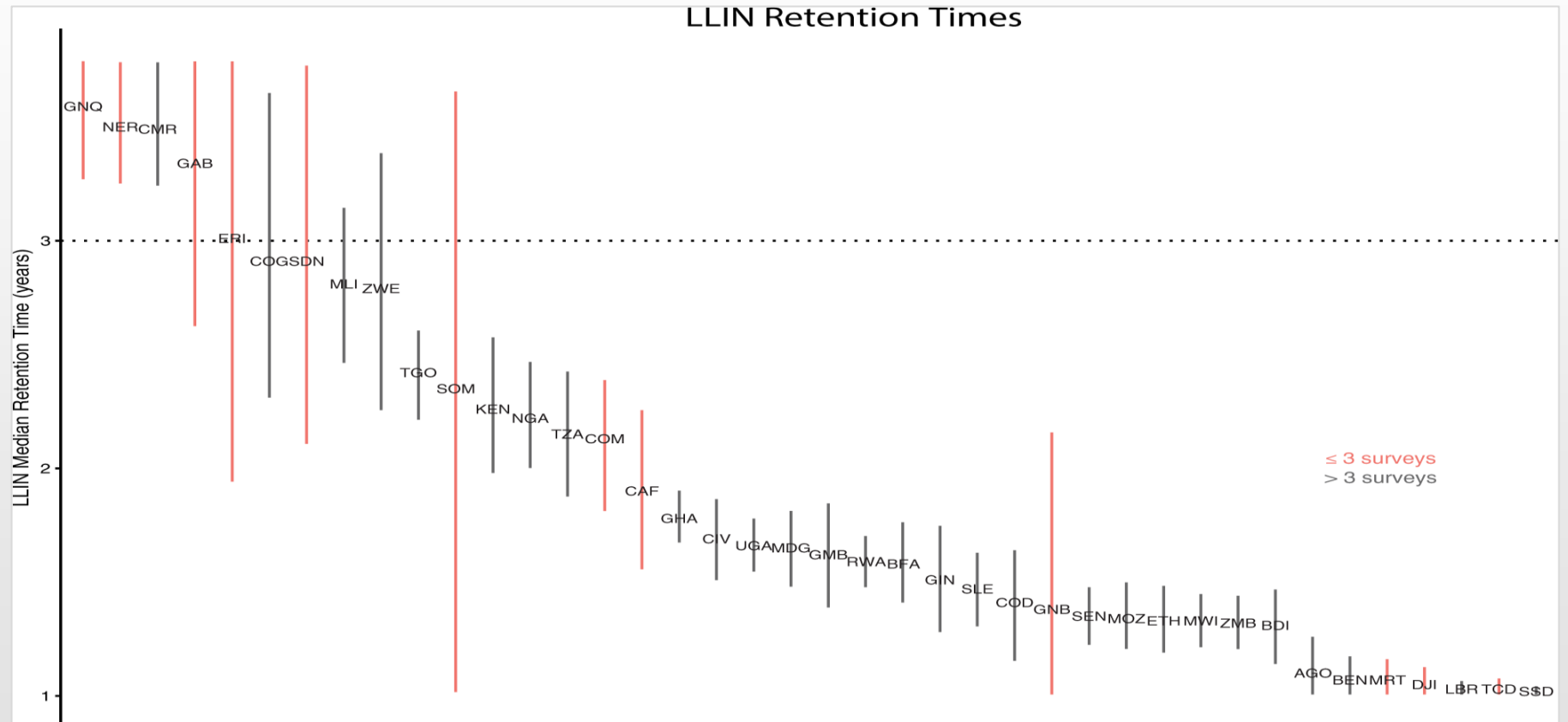


Kilian, A., Obi, E., Mansiangi, P. et al. Variation of physical durability between LLIN products and net use environments: summary of findings from four African countries. Malar J 20, 26 (2021). <https://doi.org/10.1186/s12936-020-03549-2>

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

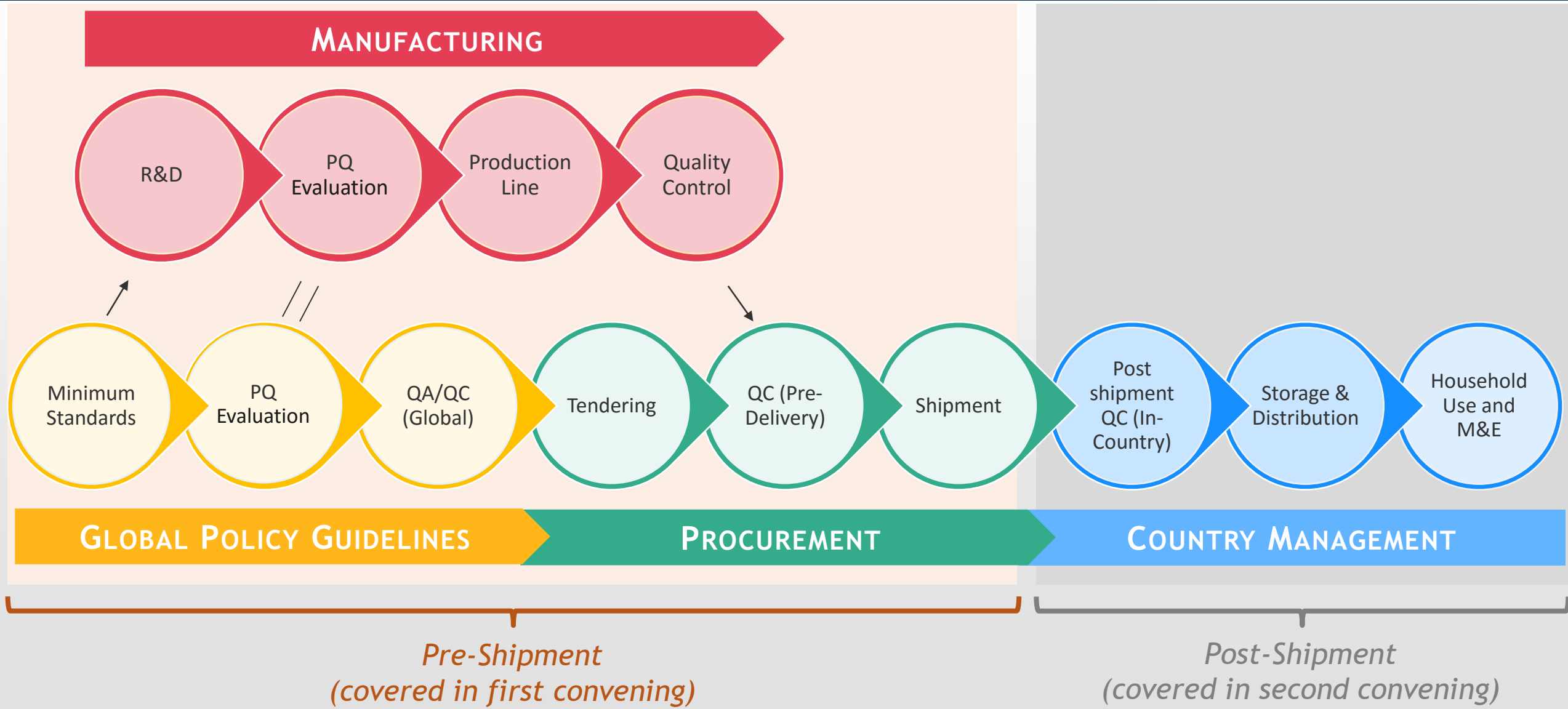
“the bulk of existing evidence supports the notion that median net retention is commonly lower than 3 years.”

“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.”

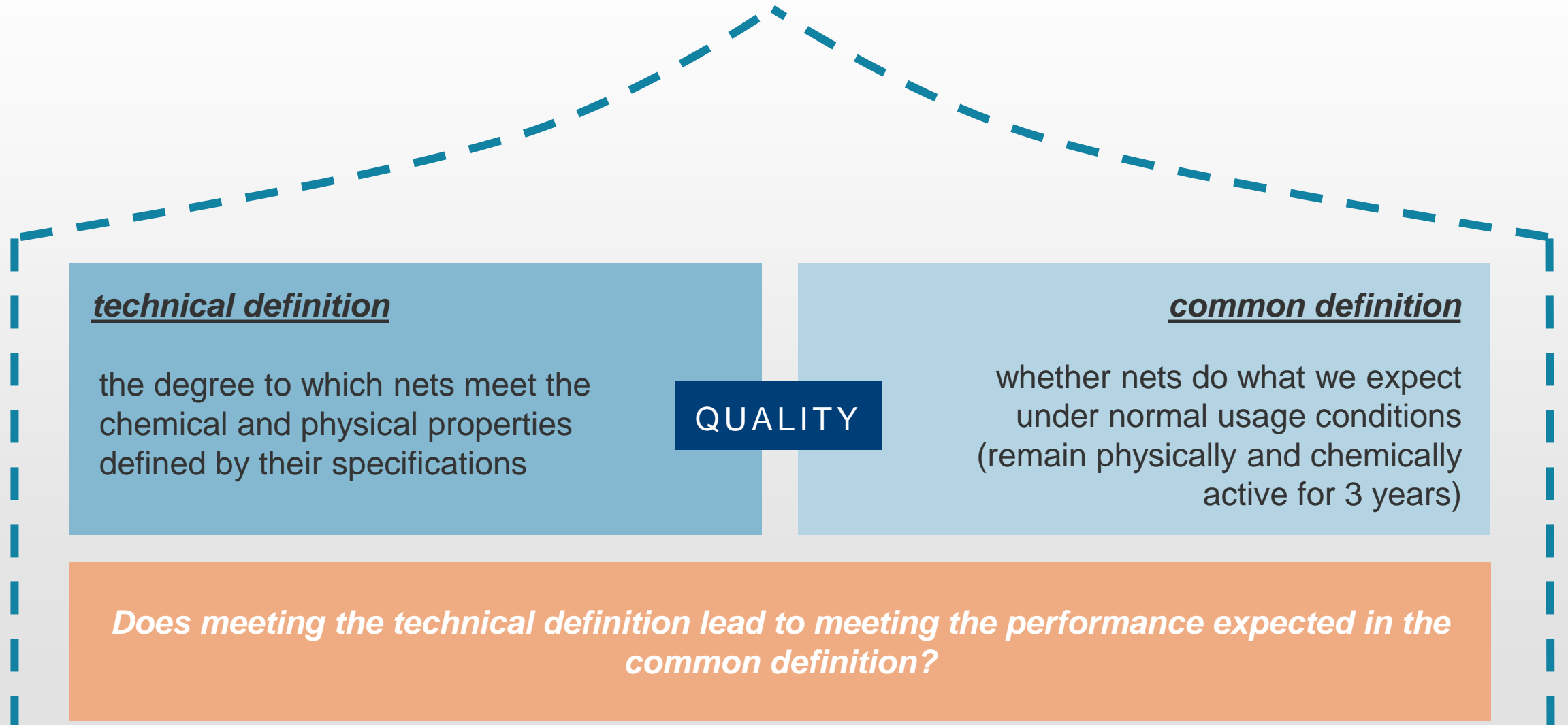


*Nets are not consistently performing as expected for the full three years in the field --
Why?*

Many aspects across the net lifecycle affect net field performance



Are we talking about the same thing?



Whether a net meets specifications is the primary technical measure of ITN quality

Vector Control Products

VCP

- About Vector Control Products Prequalification
- What We Do
 - Documents A-Z
 - List of Prequalified Vector Control Products
 - Prequalification Pipeline
 - Prequalification Procedures & Fees**
 - Determination of pathway
 - Pre-submission
 - Dossier preparation**
 - Submitting applications
 - Screening & assessment
 - Post-prequalification Procedures & Fees
 - Prequalification Reports
 - WHO Specifications for Pesticides
 - Guidance Documents

Dossier Preparation

A modular approach

The VCP Dossier Requirements follow a modular approach which is:

- Informed by eCTD and OECD standard dossier formats;
- easier to submit electronically;
- more efficient to screen for completeness;
- easier to provide the data to the appropriate experts; and
- contributing to collaboration and standardization.

NOTE: The modular approach is not a new requirement, it is simply the format in which the requirement information is communicated to WHO.

All information must be submitted in English.

It comprises six modules:

- MODULE 1: ADMINISTRATIVE INFORMATION AND LABELLING
- MODULE 2: DISCIPLINE SUMMARIES
- MODULE 3: QUALITY**
- MODULE 4: SAFETY
- MODULE 5: EFFICACY
- MODULE 6: INSPECTIONS

Information for

- Manufacturers
- Regulatory agencies
- Quality control laboratories
- Procurement agencies

MODULE 3: QUALITY

- Physical/Chemical Data
 - Ensure all supporting data is submitted
 - Ensure studies are finalized and include signatures, including for attestation of GLP compliance
 - The JMPS Manual is a guide for physical/chemical data requirements based on the formulation type of the product
 - JMPS Manual
 - Proposed draft specification
- WHO LN Specification template
- Declaration of Product Formulation
 - The complete formula must be provided
 - Sources of AIs must match those identified on the declaration of manufacturing sites or LOAs provided to verify intermediary distributors
 - All sources of AI (and synergists) must be supported by a current evaluation report confirming compliance with the established specifications
 - WHO PQT-VC Declaration of Product Formulation
- Description of Manufacturing Process
 - This is not a standardized form
 - Include a detailed description of the complete production process
- Declaration of Manufacturing Sites
 - All relevant sites must be identified
 - The information provided on this form will be used to publish the manufacturing sites for the product (upon prequalification)
 - WHO PQT/VCP Declaration of Manufacturing Sites

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?

MANUFACTURING

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

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?

These issues suggest the need to reorient around a new vision that puts equal emphasis on quantity *and* quality

- ▶ Refit the current one-size-fits-all model to one that incentivizes **quality and performance** to create a true value-based market
- ▶ Rethink value for money, moving to *# cases averted / \$* or *# deaths averted / \$* instead of *# people protected / \$*

Outline for the next three days

CONVENING DAILY OBJECTIVES:

Day 1

- **Describe** the components of the ITN quality framework
- **Develop a mutual understanding** of quality and how different factors and stakeholders influence it

Day 2

- Engage in collaborative discussion to **agree on issues, identify data gaps and develop a vision of success** across the ITN quality lifecycle

Day 3

- **Summarize** the most salient ideas presented in Day 2
- **Put together a roadmap with key activities** to support identified objectives

And Beyond

- Come together for a **second convening** to replicate this process for the post-shipment and country management quality component
- Continue to **foster collaboration** through working against a shared roadmap

Guiding questions throughout the three days

Defining the Problem

- What is(are) the problems?
- Do we understand the cause(s)?
- What decisions are affected?

Understanding the Problem

- 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 Problem

- 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?