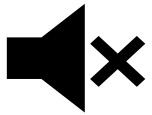
ITN Buyer Seller Summit

Co-hosted by The Global Fund & PMI

9 December 2024
Geneva – Hilton Hotel

Housekeeping Rules

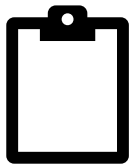


Kindly switch your mobile phones to silent mode during the sessions and refrain from using laptops for taking notes. Please use the notebooks and pens provided.

Restroom facilities are located on the left side of the main entrance.

Please return promptly from break times to ensure sessions start on time.

Questions should be reserved for Q&A sessions and directed through the microphone.



We value your feedback. Please complete the survey at the end of the event. [Wi-Fi Access: Hilton Honors]

Morning Agenda

TIME	TOPIC	SPEAKERS/MODERATORS
8:30 – 9:00	Registration/Welcome Coffee & Pastries	
9:05 – 9:20	Welcome Remarks	Hui Yang, Head of Supply Operations, the Global Fund Lisa Hare, Chief, Malaria Supply Chain Branch, President's Malaria Initiative
9:20 – 9:50	WHO/PQ and GMP updates	Dominic Schuler, Team Leader, WHO PQ Seth Irish, Technical Officer, WHO GMP - recorded
09:50 – 10:00	Q&A	
10:00 – 10:20	Innovating for Impact	Ioana Ursu, Senior Manager, Global Market Insights and Access, IVCC
10:20 – 10:30	Q&A	
Networking and Breakfast: 10:30 - 10:50		
10:50 – 11:10	Correlating RD Scores with ITN Durability	Julie-Anne Tangena, Technical Program Manager, Innovation 2 Impact Frank Mechan, Post Doctoral Research Associate, Innovation 2 Impact
11:10 – 11:20	Q&A	
11:20 – 11:50	Procurement Highlights from AMF and UNICEF	Ruth Hattersley, Senior Operations Manager, Against Malaria Foundation Valeria Markova, Contracts Specialist, Supply Division, UNICEF
11:50 – 12:10	Scanning Barcodes on ITNs and Bales – "Lessons Learned"	Sidharth Rupani, Senior Advisor Supply Chain, The Global Fund Chris Warren, Senior Supply Chain Technical Advisor - President's Malaria Initiative
12:10 – 12:25	Q&A	
Networking and Lunch: 12:25 – 13:30		

Afternoon Agenda

TIME	TOPIC	SPEAKERS/MODERATORS
13:30 – 14:30	Procurement Highlights from PMI	Lisa Hare, Chief, Malaria Supply Chain Branch, President's Malaria Initiative Chris Warren, Senior Supply Chain Technical Advisor, President's Malaria Initiative Grace ADEYA, Task Order Director, GHSC-PSM Alexis MOORE, Procurement Specialist, GHSC-PSM Mattu Bockarie-Davis, TO2 QA/QC Team Manager, GHSC-PSM
14:30 – 14:45	Q&A	
14:45 – 14:50	Video	Market Shaping: How the Global Fund is Saving Lives and Delivering on the Future of Health. Friends of the Global Fight U.S.
14:50 – 15:15	Transforming Malaria Prevention: Advancing Market Shaping for Insecticide - Treated Nets and Dual AI Transition	Kate Kolaczinski, Senior Specialist Malaria, the Global Fund Clarisse Morris, Manager, Market Shaping and Partnership, the Global Fund
15:15 – 15:30	Ensuring Excellence: Quality Assurance Policy for Vector Control Products & Related Equipment	Olivier Ducamp, Senior Manager, Quality Assurance & Compliance, the Global Fund
15:30 – 15:40	Q&A	
Networking and Coffee/Tea: 15:40 - 16:00		
16:00 – 16:45	Navigating the Future of ITNs: Addressing Challenges and Opportunities in Dual AI Transition and ITN Market Dynamics	Moses Muputisi, Manager, Demand and Planning, the Global Fund Eric Nyiligira, Manager, Health Product Management, the Global Fund Lin Li, Senior Manager, Direct Sourcing, the Global Fund Anne-Sophie Briand, Senior Specialist Vector Control, the Global Fund
16:45 – 17:00	Q&A	
17:00 – 17:25	Common Perspectives & Closing Remarks	Lisa Hare, Chief, Malaria Supply Chain Branch, President's Malaria Initiative Lin Li, Direct Sourcing Manager, the Global Fund
17:25 – 17:30	Live Feedback	
End of Meeting		

Objective of the Summit

In light of the WHO recommendation and updated WHO PQ QA requirement and swift transition to the dual active ingredient (a.i.) insecticide-treated nets (ITNs), the meeting aims to bring together key partners and industry stakeholders to build a resilient supply chain and accelerate the scale-up of new intervention tools to address ITN bio efficacy resistance

WHO/PQ and GMP Updates

Dominic Schuler, Team Leader, WHO PQ
Seth Irish, Technical Officer, WHO GMP - recorded

Partnerships

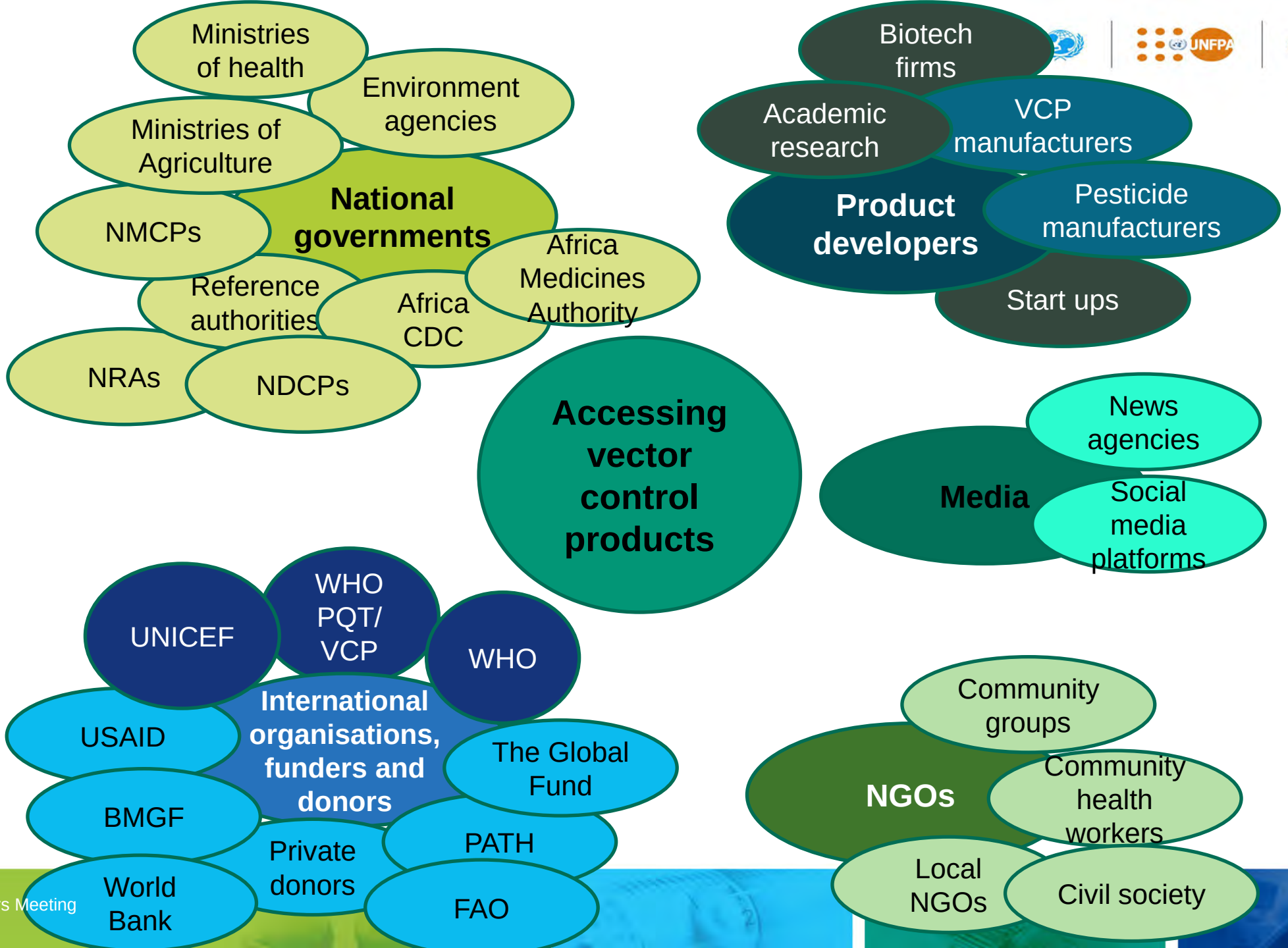
Ensuring Health Equity: Partnerships For Accessible Quality Products

Vector Control Product Assessment Team

World Health Organization

Dominic Schuler
Team Leader, WHO PQ





Ministries of health
Environment agencies
Ministries of Agriculture
National governments
NMCPs
Reference authorities
Africa CDC
Africa Medicines Authority
NRAs
NDCPs
Biotech firms
Academic research
VCP manufacturers
Product developers
Pesticide manufacturers
Start ups
Accessing vector control products
News agencies
Media
Social media platforms
UNICEF
WHO PQT/ VCP
WHO
USAID
International organisations, funders and donors
The Global Fund
BMGF
PATH
Private donors
World Bank
FAO
Community groups
NGOs
Community health workers
Local NGOs
Civil society

Assessment session for vector control products (ASVCP)

- 2 assessment sessions held in 2024: March (Dar es Salaam, Tanzania), November (Brasilia, Brazil)
- New strategy for ASVCP meetings – rotation among WHO offices

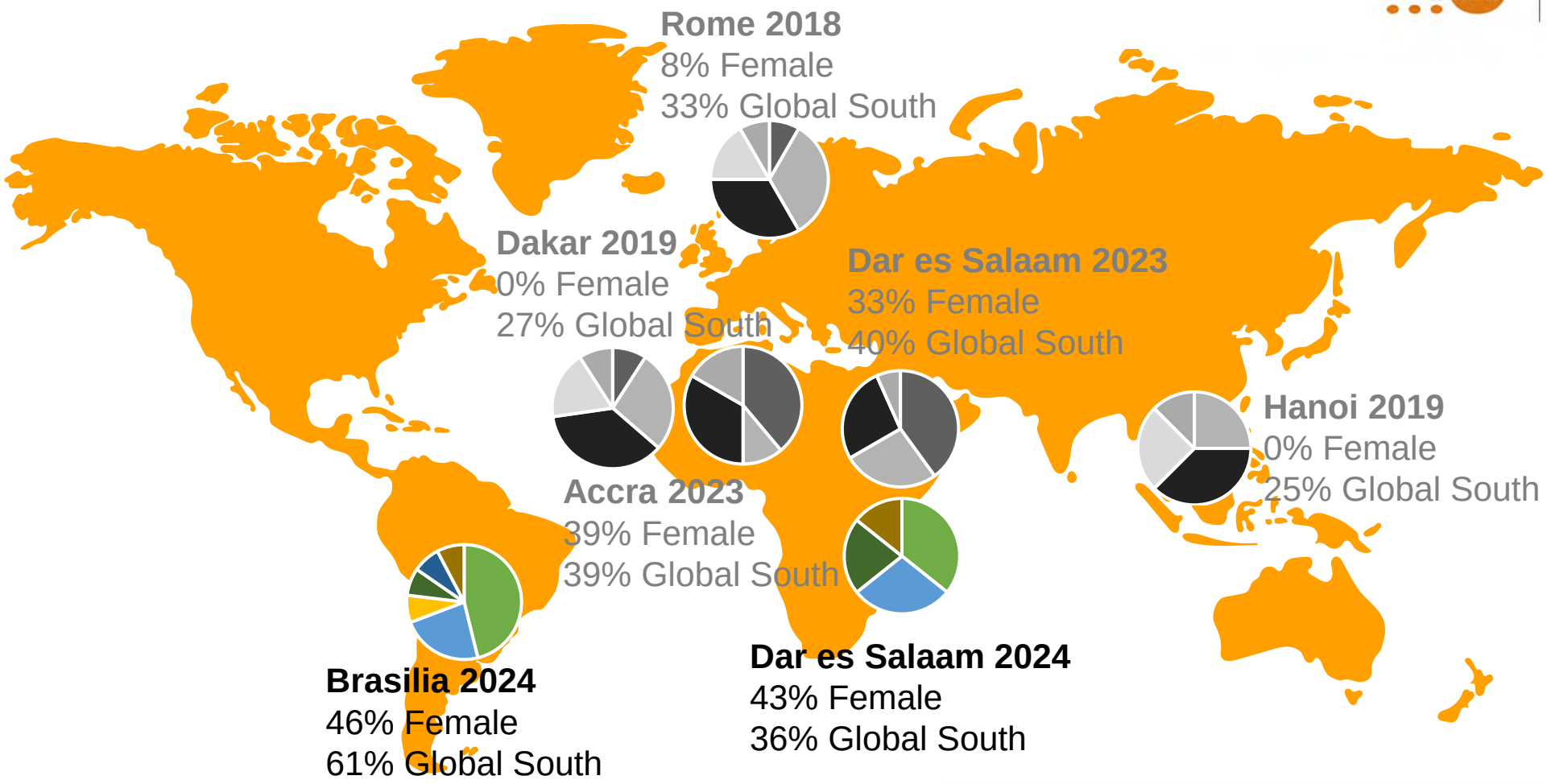
Assessments happen year-round and are not dependent on the timing of ASVCP meetings

Regional rotation of ASVCP meetings

- Engage with regional offices to plan ASVCP meetings
  - 2024 – AFRO, AMRO/PAHO
  - 2025 – WPRO, EMRO
  - 2026 – SEARO, EURO
- Generate opportunities for engagement with regional/country offices and local authorities

Regional rotation of ASVCP meetings

- 2024.2 ASVCP in Brasilia – Engagement day
  - Eighteen participants - Representation from PAHO Washington DC, OPAS Brazil country office, ANVISA, PQT/VCP, Brazilian Ministry of Health
  - Increased awareness of -
    - PQT/VCP purpose, processes, and requirements
    - ANVISA supporting legislation, processes, and requirements
    - MoH VC programs, implementation strategies/challenges, pursuit to deploy novel strategies (e.g. modified mosquitoes) all within the social/environmental contexts and disease pressures/burden in Brazil
    - PAHO/OPAS role in procurement and support to MoH in supply of VCPs and QA mechanisms



WHO regional representation 2019 - 2023

AFRO AMRO
EMRO EURO
SEARO WPRO

WHO regional representation 2024

AFRO AMRO
EMRO EURO
SEARO WPRO

Image by Freeimages.com

Assessor statistics (%)			
Female assessors	43	Global South	48

Image by Freeimages.com

Key Performance Indicators – New product assessments

- New Products
  - Submission cohort based on date accepted for assessment:
    - 2023/2024 – 3 products prequalified (avg 209 days)
  - Decision cohort:
    - 2023 – 4 products prequalified (avg 443 days)
    - 2024 – 6 products prequalified (avg 359 days)

- Proportion of **Study Protocol submissions** completed ≤ WHO target time (90 days)
  - Decision cohort 2024 – 93% (Avg time 43 days)
  - 2023 – 6 applications received/closed
  - 2024 – 74 applications received to date, 56 closed
    - 1,133% increase in applications due to ITN guideline implementation plan

Increasing decisions and decreasing timelines

Time to PQ considerations – PQT/VCP inputs

- Active preparation for increased applications (including responses to implementation plan for ITNs)
- Expansion of consultant roster along with advanced training of new assessors
- Expansion of expertise in roster to prepare for novel product types and designs
- Rolling submissions
- Protocol reviews
- Pre-submission meetings

PQT/VCP is not a technical adviser nor consultant for manufacturers

Time to PQ considerations – Mfr inputs

- Clear commercial strategy – potential place for the product in the marketplace
- Clear understanding of the product and its intended use
- Well prepared and good quality dossiers improve efficiency and timelines for assessment
- Responsiveness to RFIs – timeliness and quality of responses
  - Addressing the scientific questions as compared to telling PQ why the product can be prequalified
- Recognizing accountability as owner of the product and of the application – reducing overreliance on CROs to answer questions

Guideline(s) plan(s) – WHO Guideline for the prequalification assessment of insecticide treated nets

- Community studies protocol:
  - Designed to provide the necessary information for applicants to conduct studies previously conducted by WHOPES (Phase III)
  - Changes/additions from WHOPES protocol
    - Sample size calculations based on attrition as primary endpoint
    - Semi-field study for estimation of entomological efficacy
    - Reduced sampling timepoints
    - WRI/Surface AI estimation as part of quality testing
  - Circulated on PleaseReview platform

<u>Comments due 23 December 2024</u>

2025 – Focus of workplan

- Prequalification applications
- TAG-VCPR
- Guidelines
- Vector Control Active Ingredients (VCAIs)
  - VCAI Overview document – Procedures for WHO
- JMPS
  - Submissions
  - Joint Terms of Reference
  - Open call for experts
  - Operations Manual
- Supporting expansion of CRP
- ePQS – full implementation
- Continued communication and advocacy

WHO ITN guidelines

World Health Organization

Seth
Irish

- ITN guidelines
- Other updates

World Health Organization

ITN Recommendations

- Recommendations in the *WHO guidelines for malaria*
  - Most recent update October 2023

- Pyrethroid only
- Pyrethroid PBO
- Pyrethroid-chlorfenapyr
- Pyrethroid-pyriproxyfen

Strong recommendation for, High certainty evidence

Pyrethroid-only nets (2019)

Conditional recommendation for, Moderate certainty evidence

Pyrethroid-PBO ITNs (2022)

Strong recommendation for, Moderate certainty evidence

Pyrethroid-chlorfenapyr ITNs vs pyrethroid-only LLINs (2023)

Conditional recommendation for, Moderate certainty evidence

Pyrethroid-chlorfenapyr ITNs vs pyrethroid-PBO ITNs (2023)

Conditional recommendation for, Moderate certainty evidence

Pyrethroid-pyriproxyfen ITNs vs pyrethroid-only LLINs (2023)

Conditional recommendation against, Moderate certainty evidence

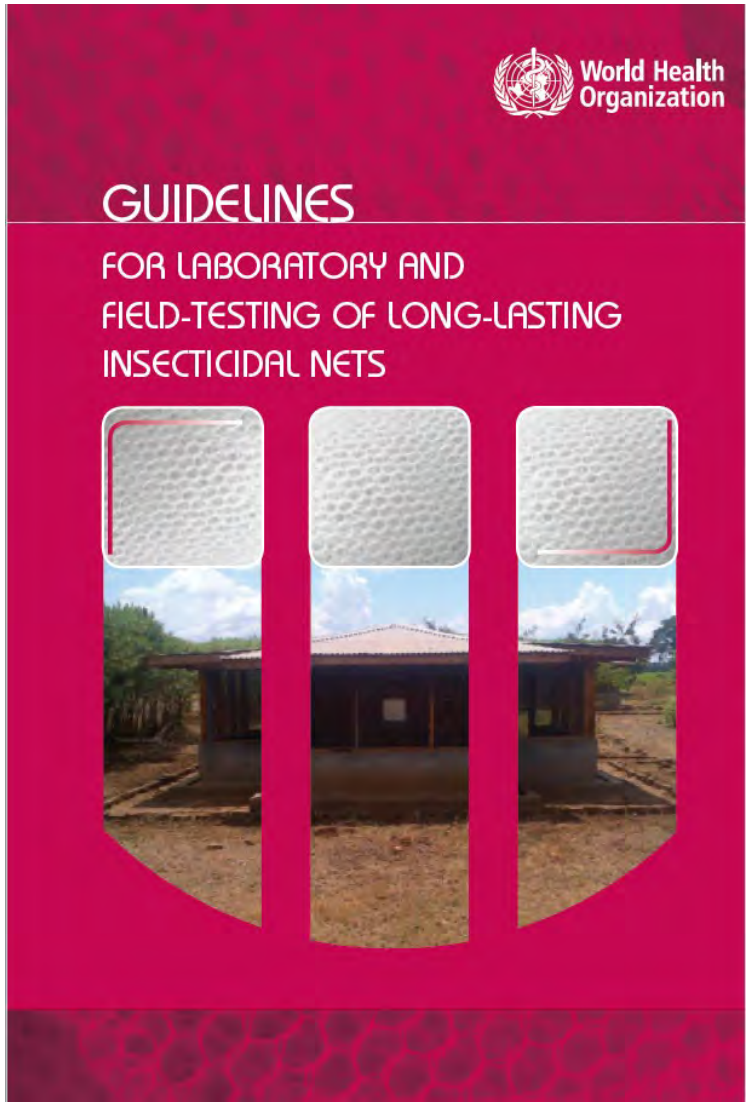
Pyrethroid-pyriproxyfen ITNs vs pyrethroid-PBO ITNs (2023)

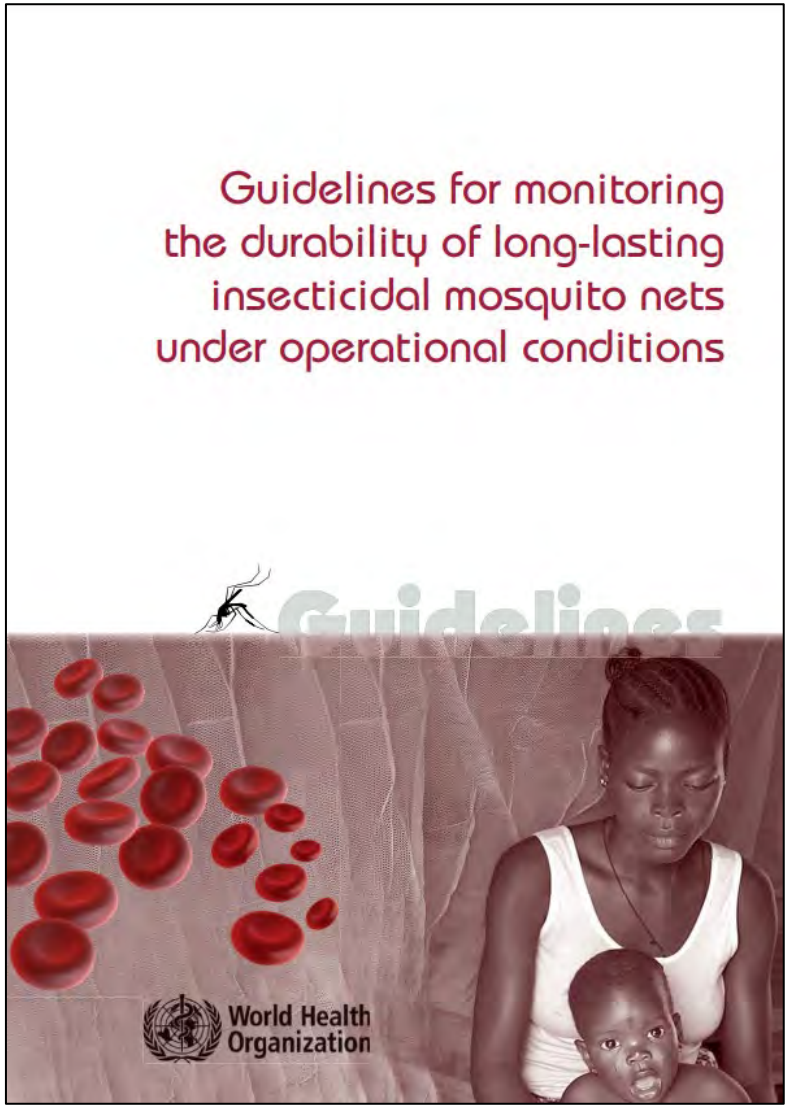
Strong recommendation for, High certainty evidence

Insecticide-treated nets: Humanitarian emergency setting (2022)

ITN guidance

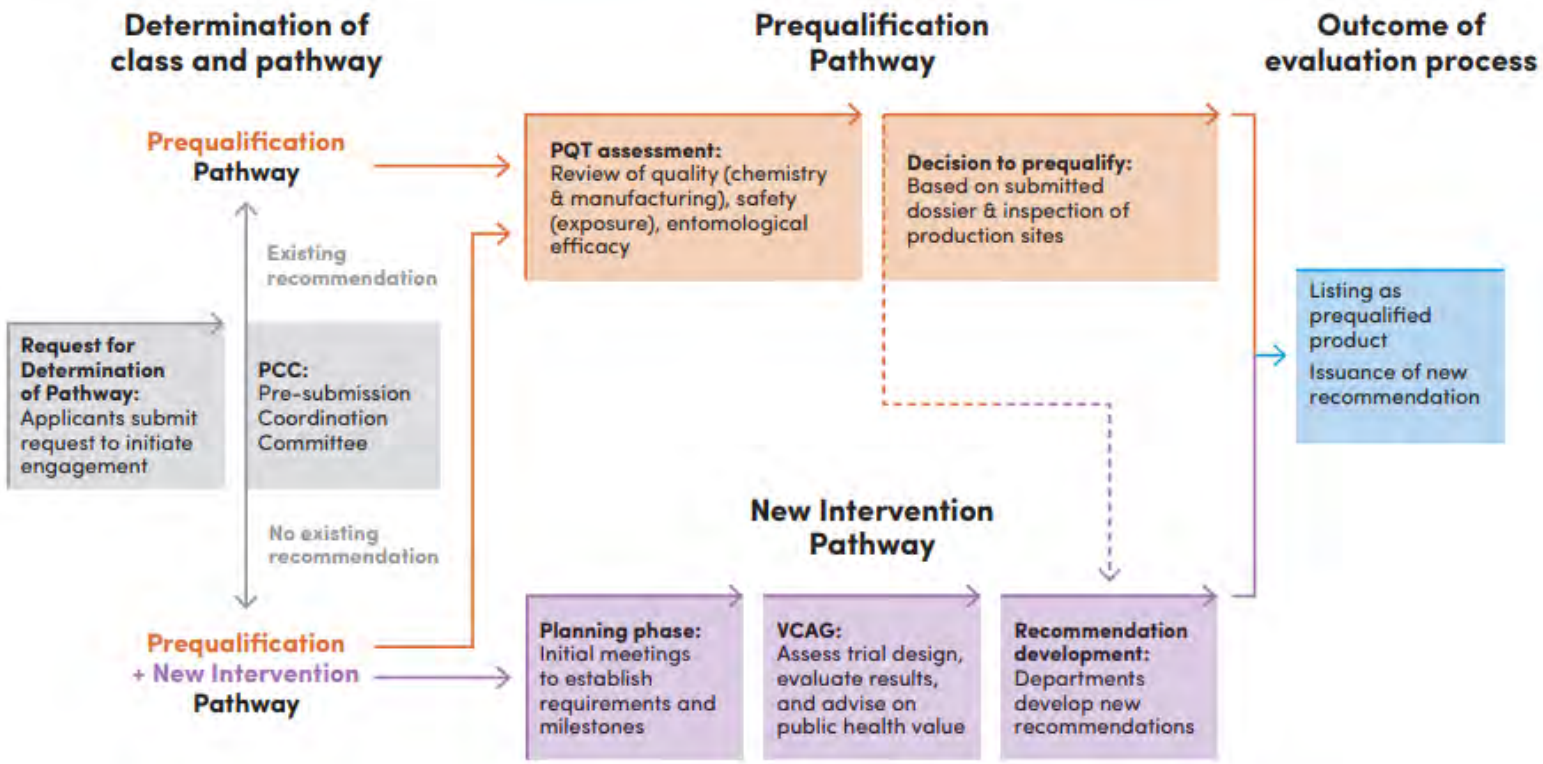
- In addition to the recommendations, there is other guidance produced by WHO
- Guidelines for laboratory and field testing of LLINs (2013)
- Guidelines for monitoring the durability of LLINs under operational conditions (2011)





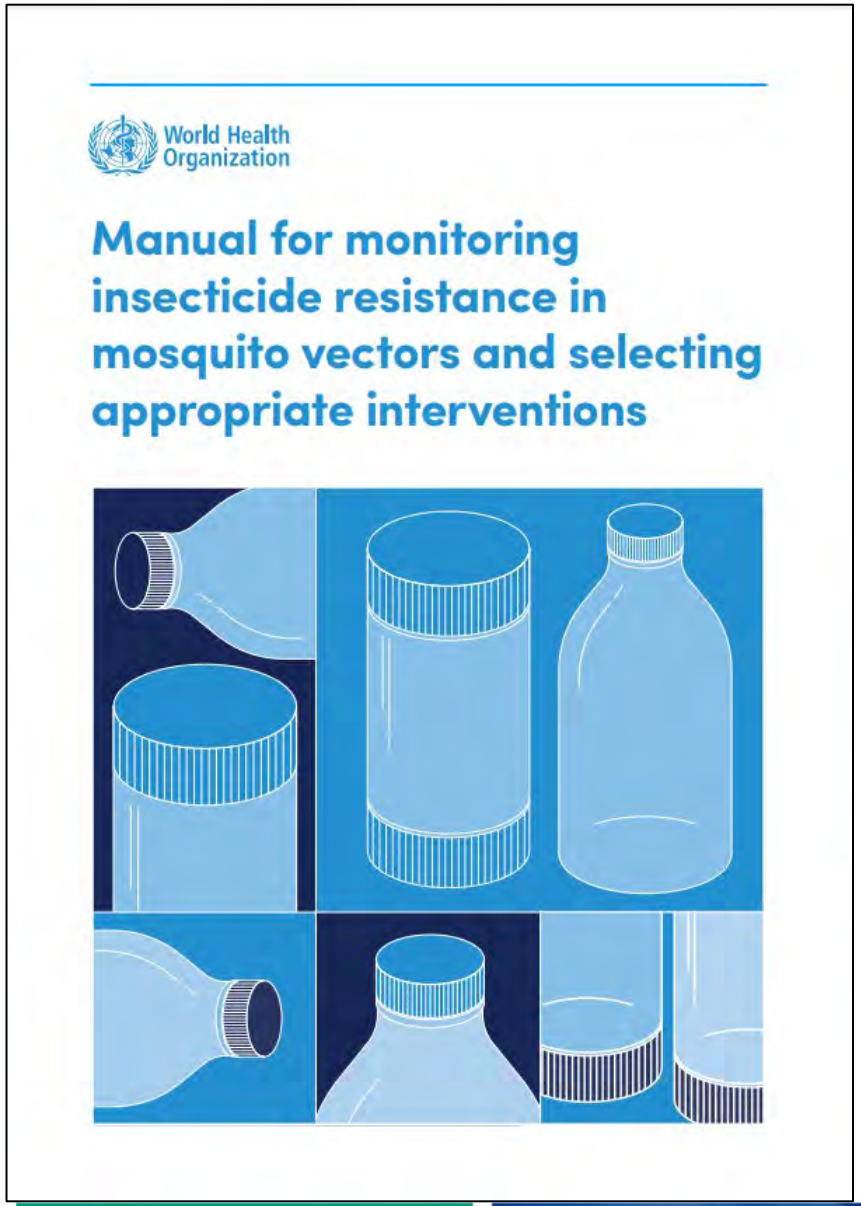
Comparative efficacy

- Comparative efficacy was used by GMP to guide determination of the applicability of recommendations for second-in-class products.



Insecticide resistance monitoring

- Important to monitor resistance to insecticides used for ITNs
- Manual for monitoring insecticide resistance published in 2022
  - Pyrethroids (with and without PBO)
  - Pyriproxyfen
  - Chlorfenapyr
- In September 2024, a technical consultation was convened to define chlorfenapyr susceptibility
  - Demonstration of resistance requires:
    - Testing of susceptible strain
    - Maintaining temperature and humidity conditions
    - Three bioassays demonstrating greater than 90% mortality at 72h post exposure



Future work

- Most effective deployment
  - Tradeoffs with coverage vs. type of net
  - Frequency of distribution / durability of ITNs
  - Distribution channels
  - Post-distribution monitoring of ITNs
  - New ITNs

Thank you

For more information, please contact:
Seth Irish
Technical Officer
irishs@who.int

World Health Organization

PUBLIC

IVCC









Innovating for Impact - the ITN market from a pipeline perspective

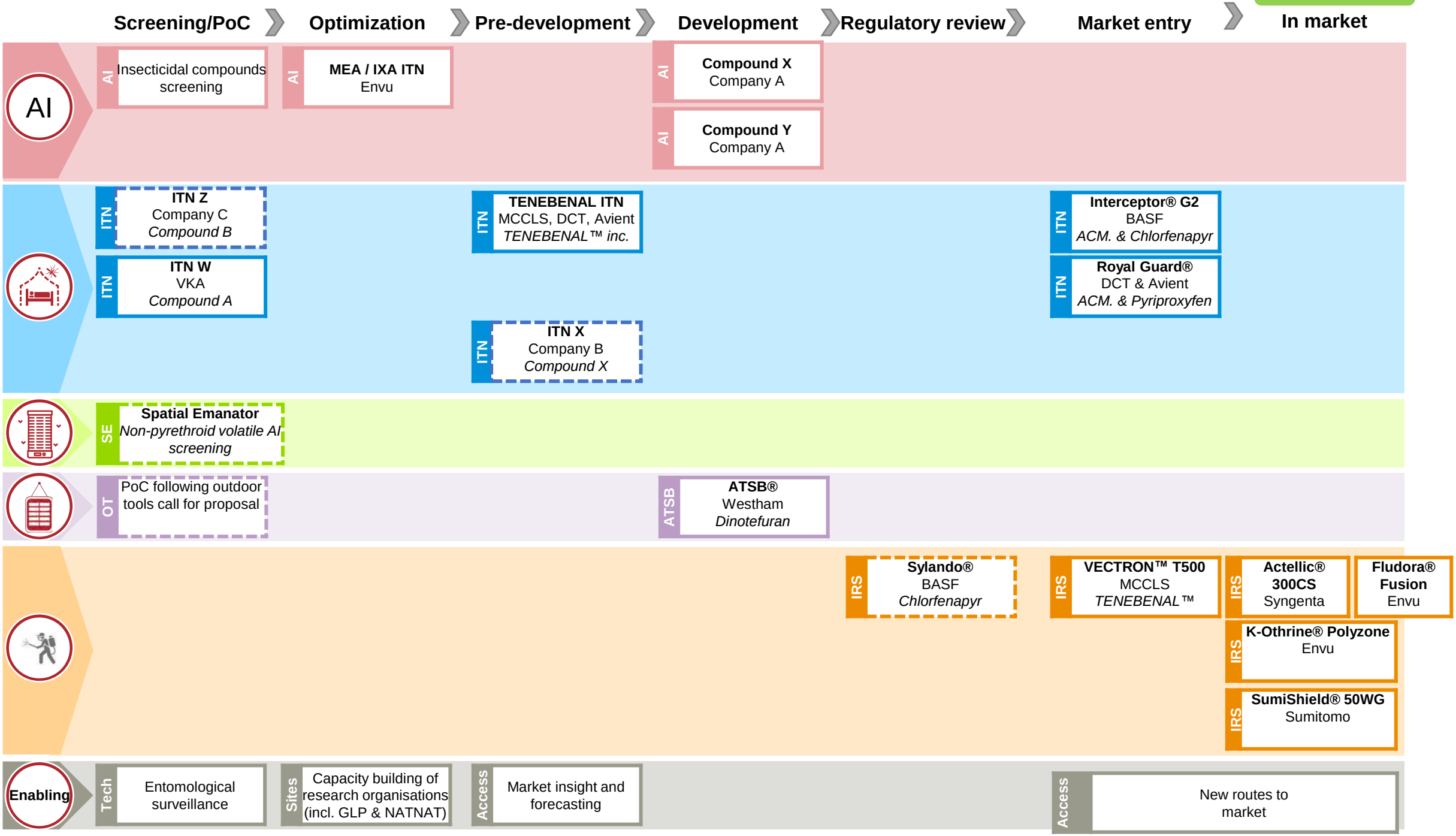
ITN Global Summit

Geneva

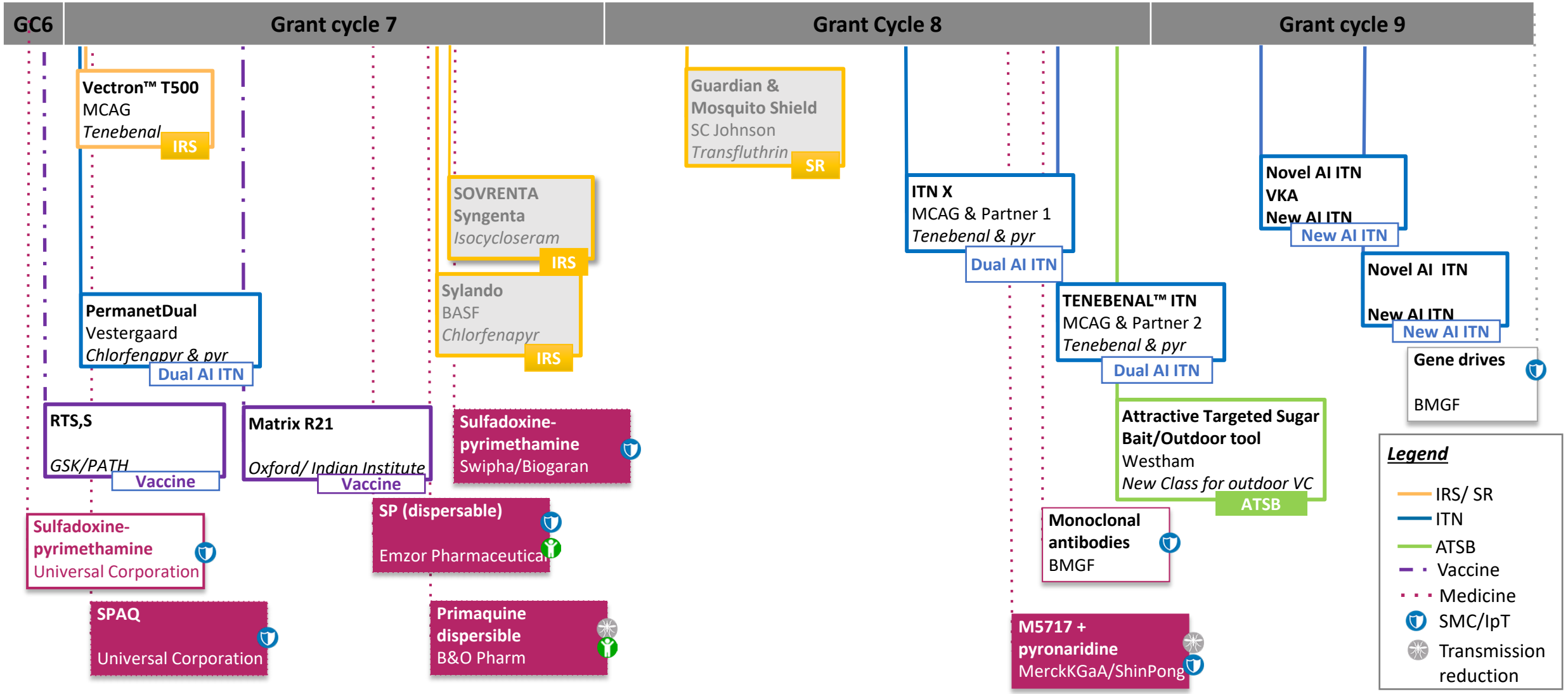
Presentation by: Ioana Ursu, IVCC

Date: December 9-10, 2024

PUBLIC

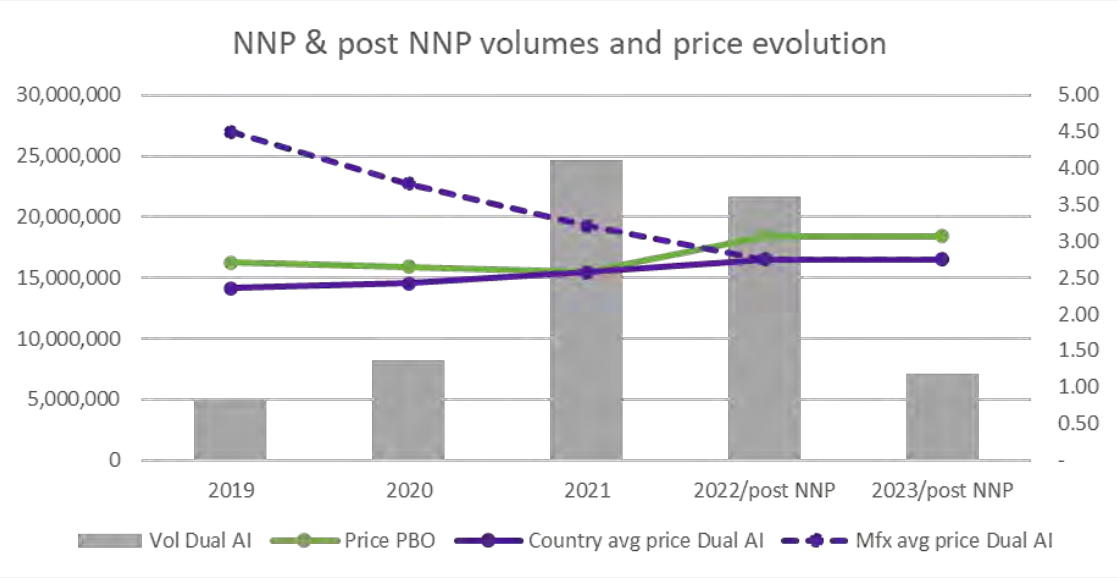

Screening/PoC
Optimization
Pre-development
Development
Regulatory review
Market entry
In market
AI
AI
Insecticidal compounds screening
AI
MEA / IXA ITN
Envu
AI
Compound X
Company A
AI
Compound Y
Company A
ITN
ITN Z
Company C
Compound B
ITN
ITN W
VKA
Compound A
ITN
TENEBENAL ITN
MCCLS, DCT, Avient
TENEBENAL™ inc.
ITN
ITN X
Company B
Compound X
ITN
Interceptor® G2
BASF
ACM. & Chlorfenapyr
ITN
Royal Guard®
DCT & Avient
ACM. & Pyriproxyfen
SE
Spatial Emanator
Non-pyrethroid volatile AI screening
OT
PoC following outdoor tools call for proposal
ATSB
ATSB®
Westham
Dinotefuran
IRS
Sylando®
BASF
Chlorfenapyr
IRS
VECTRON™ T500
MCCLS
TENEBENAL™
IRS
Actellic® 300CS
Syngenta
Fludora® Fusion
Envu
IRS
K-Othrine® Polyzone
Envu
IRS
SumiShield® 50WG
Sumitomo
Enabling
Tech
Entomological surveillance
Sites
Capacity building of research organisations (incl. GLP & NATNAT)
Access
Market insight and forecasting
Access
New routes to market

Malaria prevention pipeline in relation to funding cycles



Launch dates assuming 12 months from PQ submission to listing.

Introduction of innovative products requires a well-orchestrated approach involving public and private sector partners

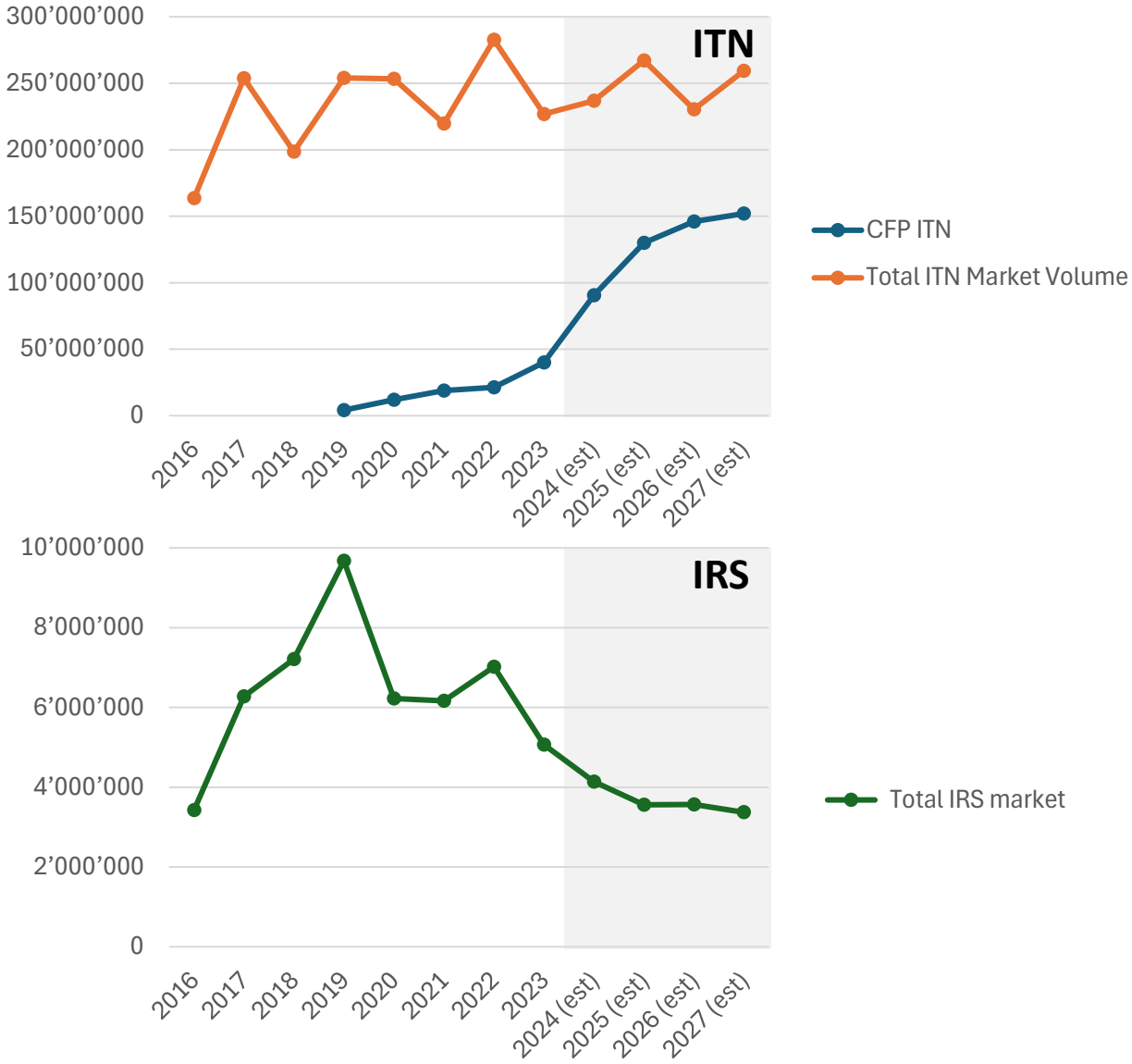


- New Nets Project (NNP), a market shaping intervention, sought to catalyse increased country uptake of CFP-PYR nets and scale up manufacturing capacity to meet growing demand, as well as generate the evidence to inform country decision-making and support a WHO policy recommendation
  - Demand – Provide co-payment to accelerate reduction in price to countries, and help countries distribute new ITNs
  - Supply – A volume guarantee and accurate forecasting of annual demand provided manufacturers confidence to invest in scaling up production capacity
  - Price – Agreement on progressive price reductions as demand increased, with a target price similar to PBO nets could be sustained

- Manufacturing partners: BASF & DCT
- Funding partners: GFATM/Unitaid (co-payments); MedAccess/Gates Foundation (*volume guarantee– non-NNP*)
  - Additional funding to country programmatic country funds GFATM & PMI
- Evidence generation funding: GFATM/Unitaid; Gates Foundation (RCT top up funding - non-NNP); Wellcome Trust (TZ RCT non-NNP)
- Evidence generation partners: LSTM, LSHTM, PATH, Imperial College, Tulane
  - In-country evidence partners: CREC, CNFRP, RBC/University of Rwanda, PNCM/INS Mozambique/Tropical Health, NIMR/Tropical Health
- Implementation partners: PSI, AMP
- Coordinator: IVCC

We expect a similar level in engagement to happen only if the new intervention is expected to shift disease paradigm (e.g. considerable public health impact)

Funding remains a challenge when introducing innovative products: evolution of the ITN & IRS markets

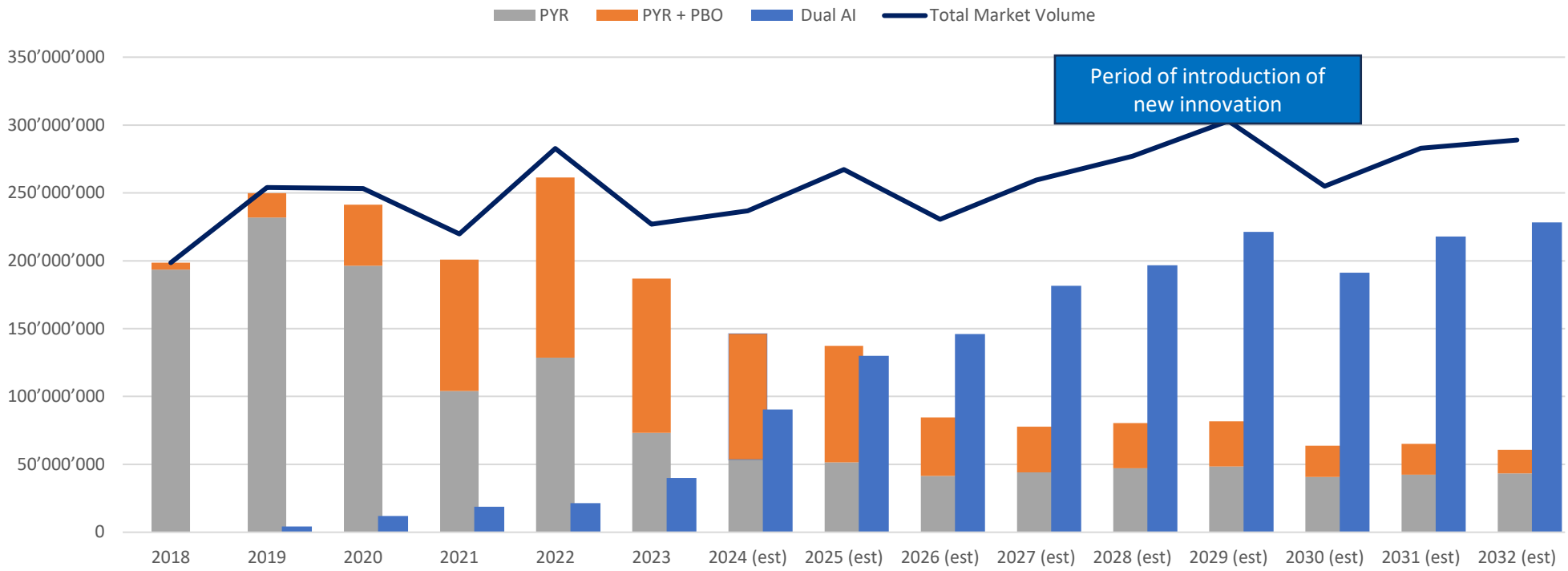


KEY MESSAGES

- Very successful uptake of chlorfenapyr Dual-AI nets
- However, donor agencies challenged to manage the introduction of multiple new tools within flat or decreasing budgets
- Additional investment in dual-AI ITNs meant there is less funding support for IRS.
- A number of countries are advocating for more targeting of multiple interventions within the context of SNT, and therefore allow for a mix of interventions

Source IVCC | Data expressed in volume (units)

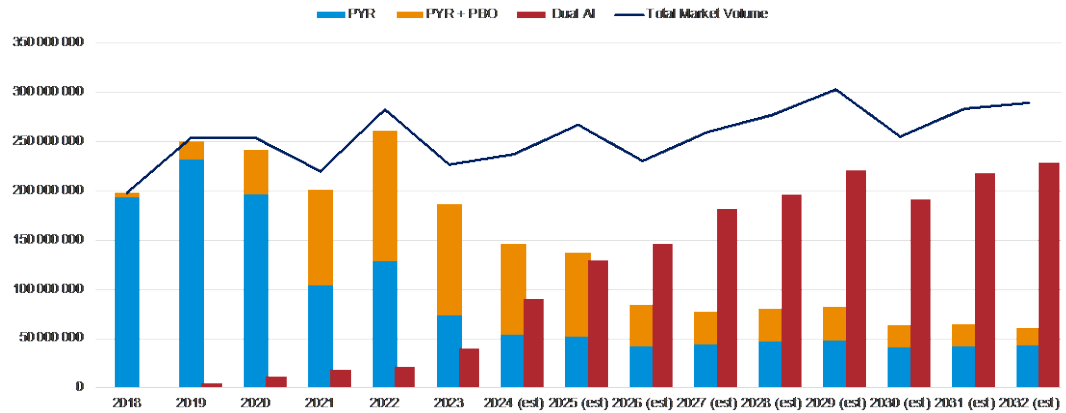
Projecting to the future:
The dramatic growth of demand for Dual AI ITNs through forecast period



Main assumptions/findings:

- ITN budget increase aligned with latest G7 GFATM cycle (still lower than population growth)
- Dual AI (CFP) ITN prices decline slightly and then stabilize from 2027 onwards
- By 2027, 70% of the market will be covered by Dual AI (CFP) nets, with slower market growth afterwards; by 2030, there will be >200M Dual (CFP) AI nets in the market yearly
- PYR resistance high in Africa, less intense in RoW: PYR nets continue to be bought outside of SSA (20-25M); elimination settings in Southern Africa continue to use PYR nets
- PBO nets relegated to a "stop-gap" approach (financial/ political/ CFP resistance reasons)

Learning from the recent past:



Lessons

- When a new solution to address resistance becomes available (at right price) the market shifts at speed (1-2 years) – see IRS and PBO market evolution
- Extremely challenging lag-time for "generic" entry (from PQ submission to procurement – at least 2 years)
- Risk for bottlenecks in supply
- Price parity with existing reference points (e.g. CFP to PBO nets (+10-15% margin) helps the switch/ rotation

Implications

- Risk of CFP resistance build-up: by 2027, there is expected to be over 180M CFP nets distributed per year
  - Significant proportion (e.g. 70-90M ITN) should be rotated per year; volume to be rotated could be as high as 150M ITN by 2032
  - Uptake (rotation) of new AI ITN more likely if manufacturers are able to offer new ITNs at price in range of the then-current CFP prices
- The rapid switch from PYR to PBO then to CFP ITNs, coupled with introduction of rotation, suggests:
  - Need to have at least two types of nets in the portfolio to cope with the peaks and throughs of the ITN demand curve
  - Early engagement needed in developing new AI ITNs (eg. even before the class is established)

OUR VALUES

PARTNERSHIP

We believe in the power of partnership, collaboration and teamwork.

INNOVATION

We embrace ideas that drive vector control innovation, deliver impact and save lives.

RESPECT

We value diversity and treat each other with respect.

Image credits: 1: PMI, Mali. 2: Goodbye Malaria. 3 Bayer, Monheim am Rhein, Germany. 4. Health Forefront Organization Phnom Pehn, Cambodia. 5: Goodbye Malaria.

Funding Partners

RESISTANCE TO DAMAGE (RD) SCORE

Analysis and utility of factors affecting ITN durability

Dr. Julie-Anne Akiko Tangena

Dr. Frank Mechan

Innovation To Impact

9/12/2024

Agenda

- Introduction
- History of RD score
- Refining RD score
- Avenues to innovation

Introduction

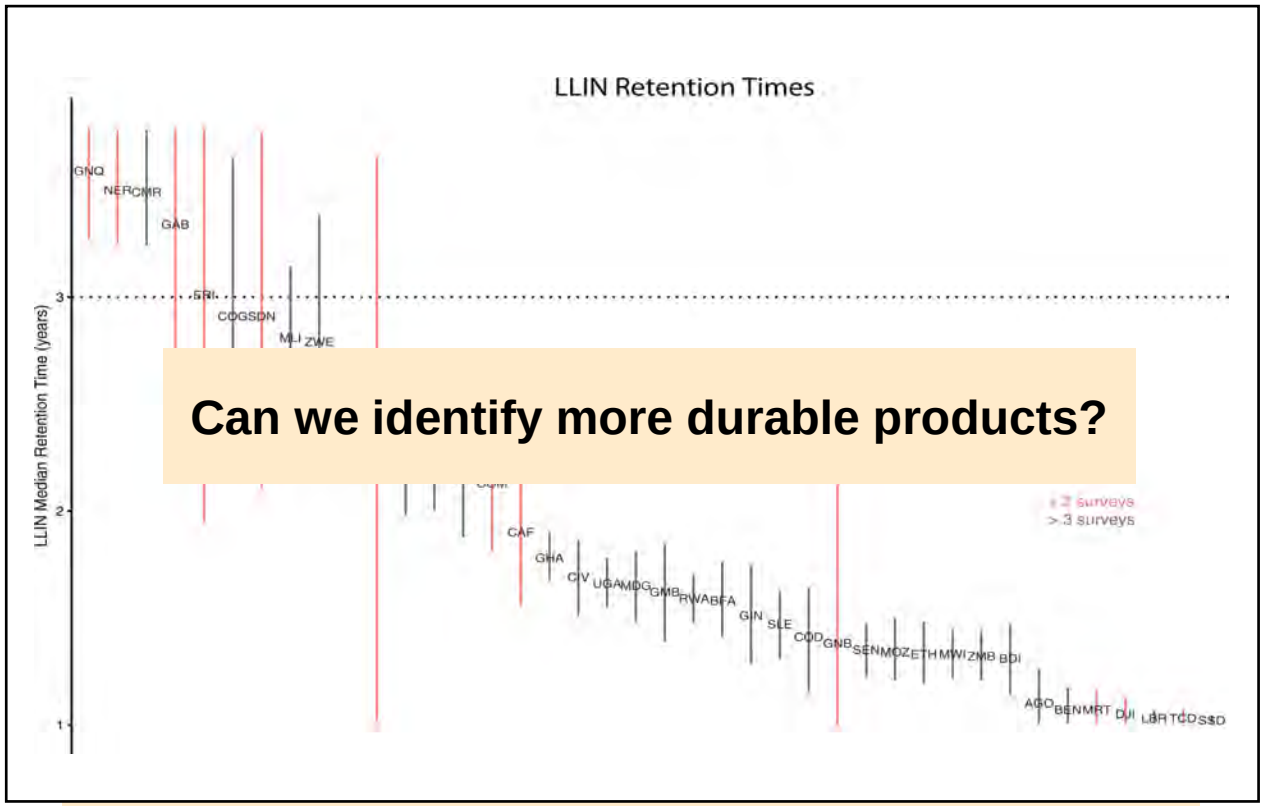
Bertozzi-Villa, A., et al.,. Nat Commun 12, 3589 (2021)

IMPOSSIBLE VC TRIANGLE

MAINTAIN COVERAGE

MORE, AND MORE EXPENSIVE, TOOLS

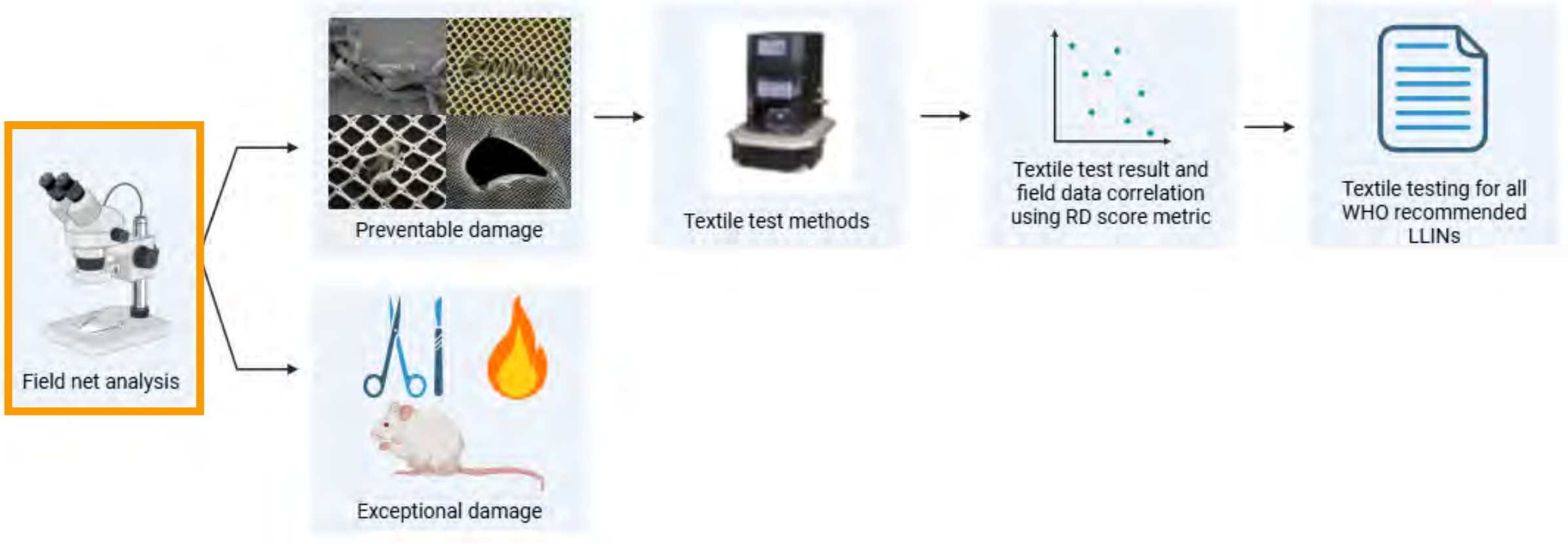
FLAT BUDGET



Can we identify more durable products?

Overall median value of 1.64 years LLIN retention

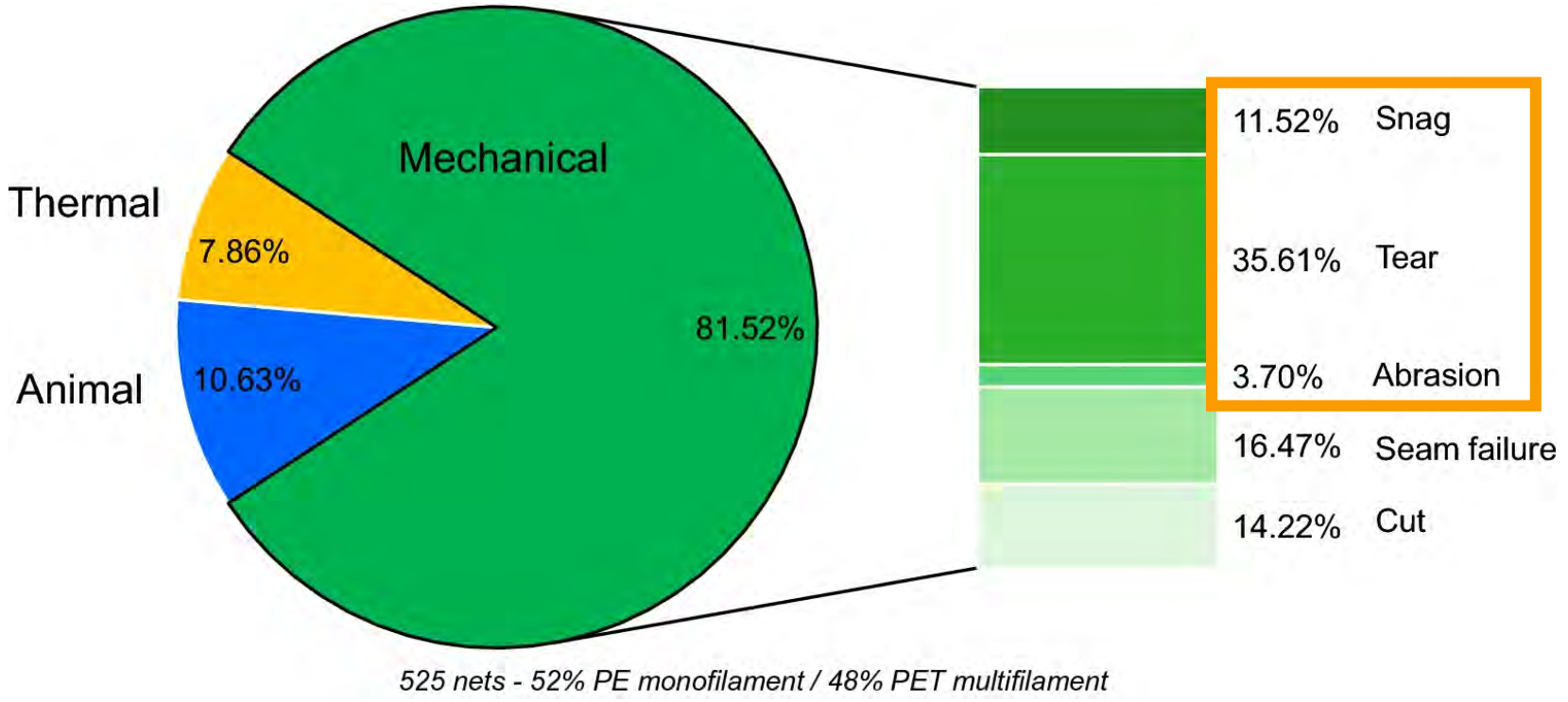
History of RD score - Overview



History of RD score – Field net analysis

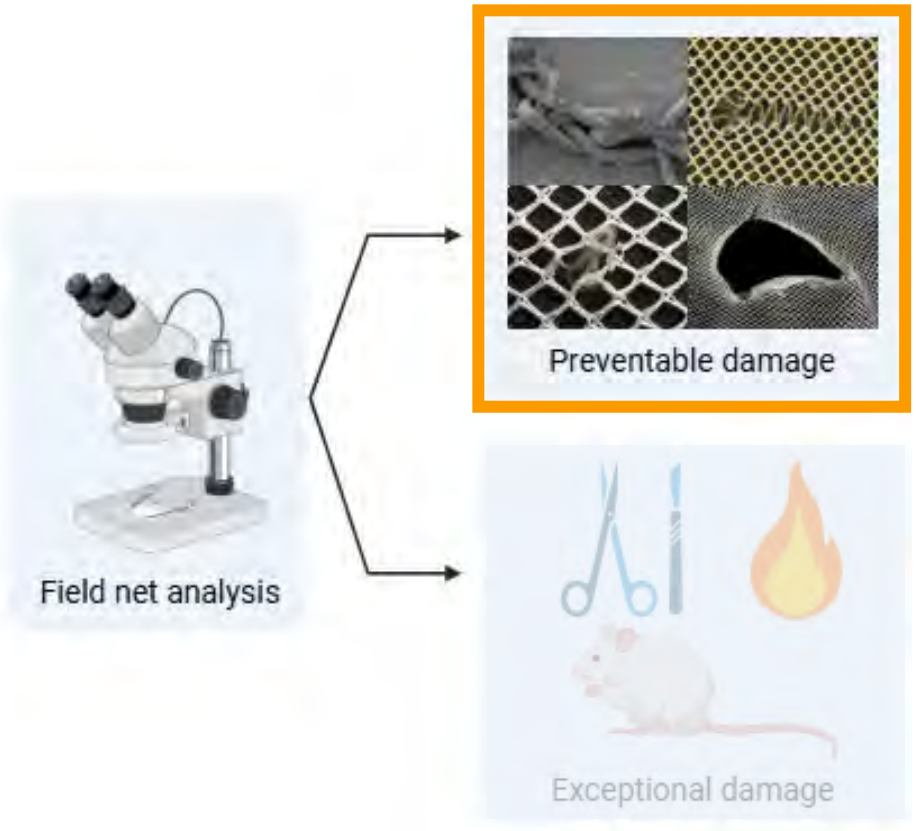
Wheldrake A, Malar J. Jan 19;20(1):45 (2021)

Forensically classified >40,000 damaged areas in 526 ITNs collected from 5 countries



Majority of damage is preventable

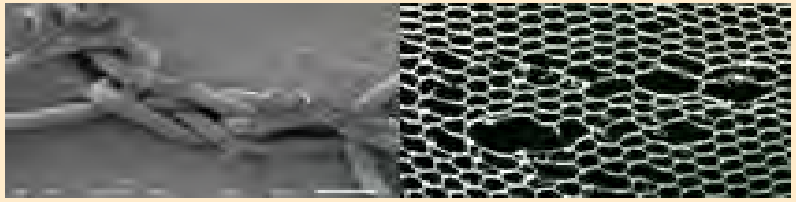
History of RD score – Division of hole types



Holes formed

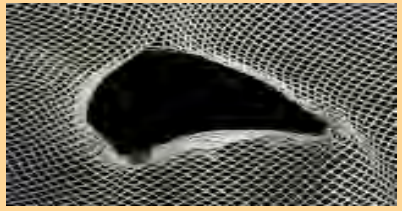
Snag/burst

Abrasion

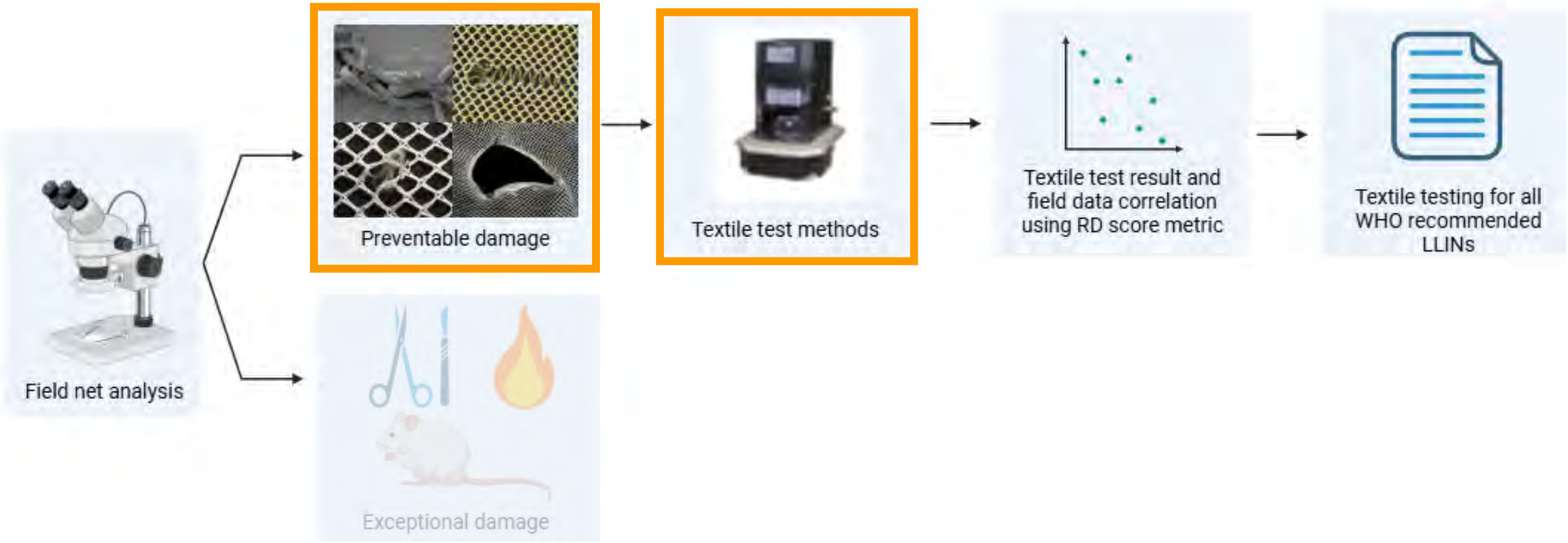


Holes enlarged

Ladder/Unravel



History of RD score – Textile test methods



History of RD score – Textile test methods

Wheldrake, A.,. *Malar J* **20**, 47 (2021)

Preventable damage

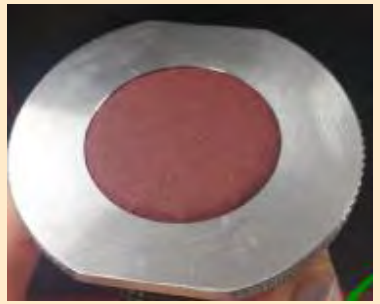
Textile test methods

Holes formed

Bursting strength
ISO 13938-2:1999

Snag strength
ISO 13934-2:2014

Abrasion resistance
ISO 12947:1998



Holes enlarged

Hole enlargement resistance
ISO 13938-2:1999

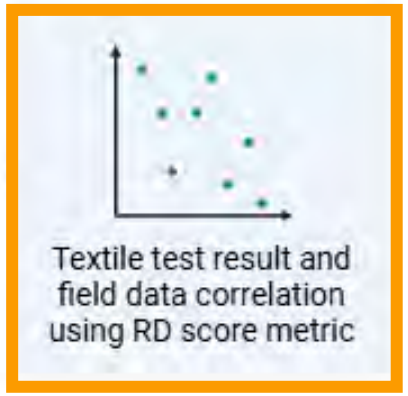
THE GLOBAL FUND

History of RD score – RD score development

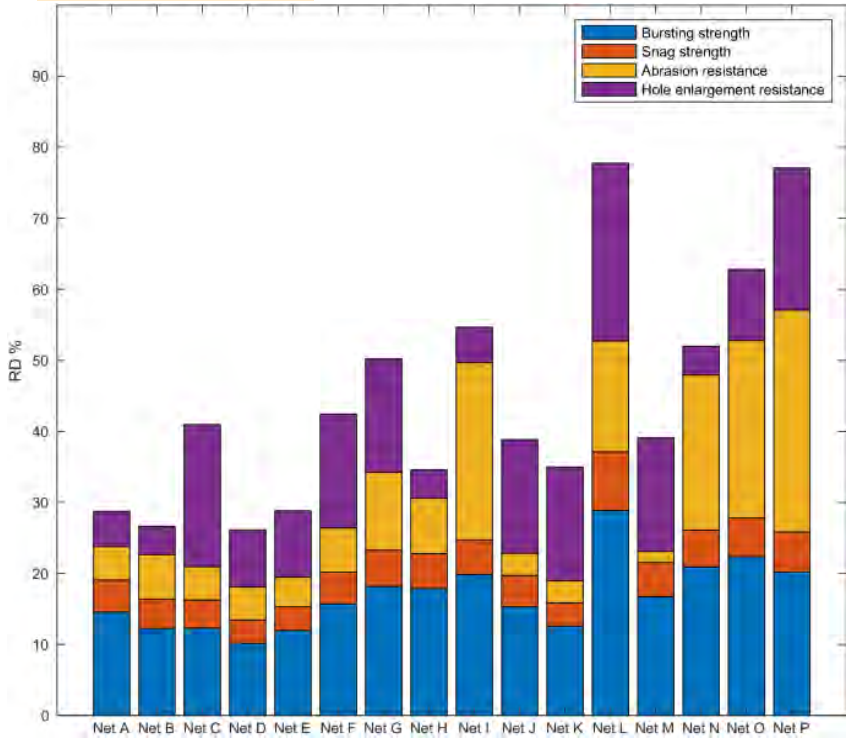
History of RD score – Existing results

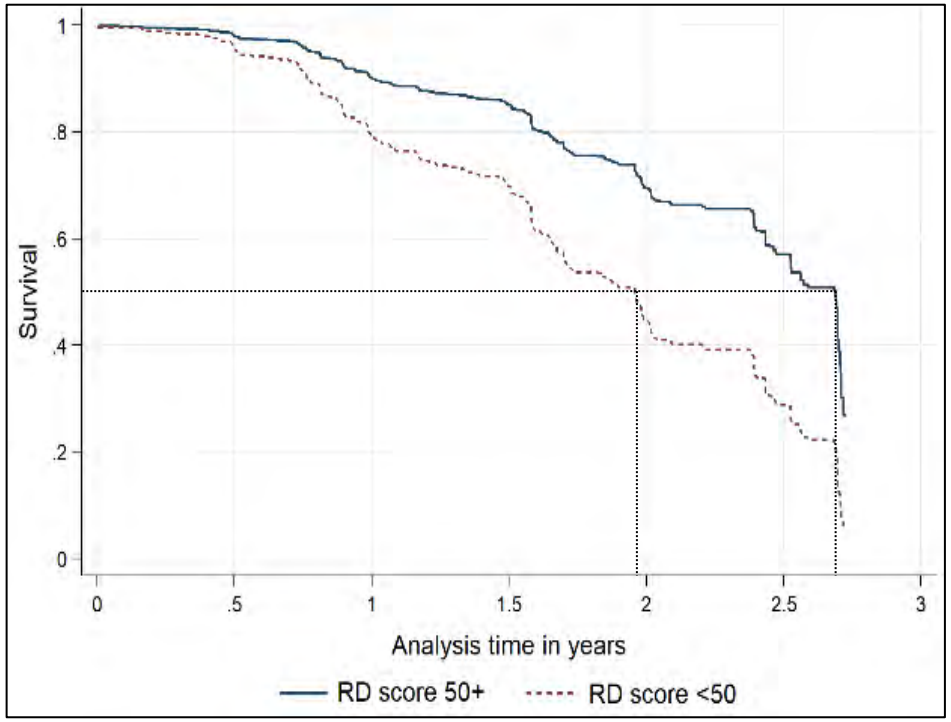
Wheldrake,. *Malar J* 20, 46 (2021)
Kilian, A.,. *Malaria journal*, *20*(1), 29 (2021)

25 %	Snag resistance	25 %	Bursting strength	25 %	Hole enlargement	25 %	Abrasion resistance

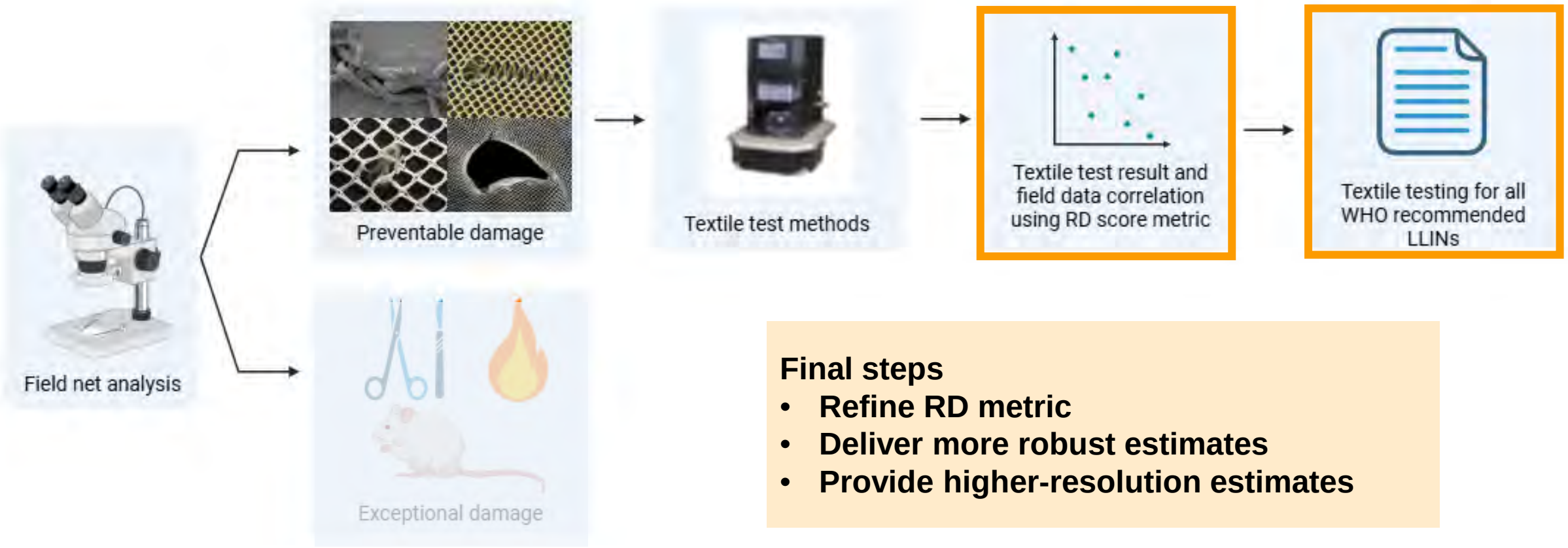


Pre-2021





History of RD score – Final steps



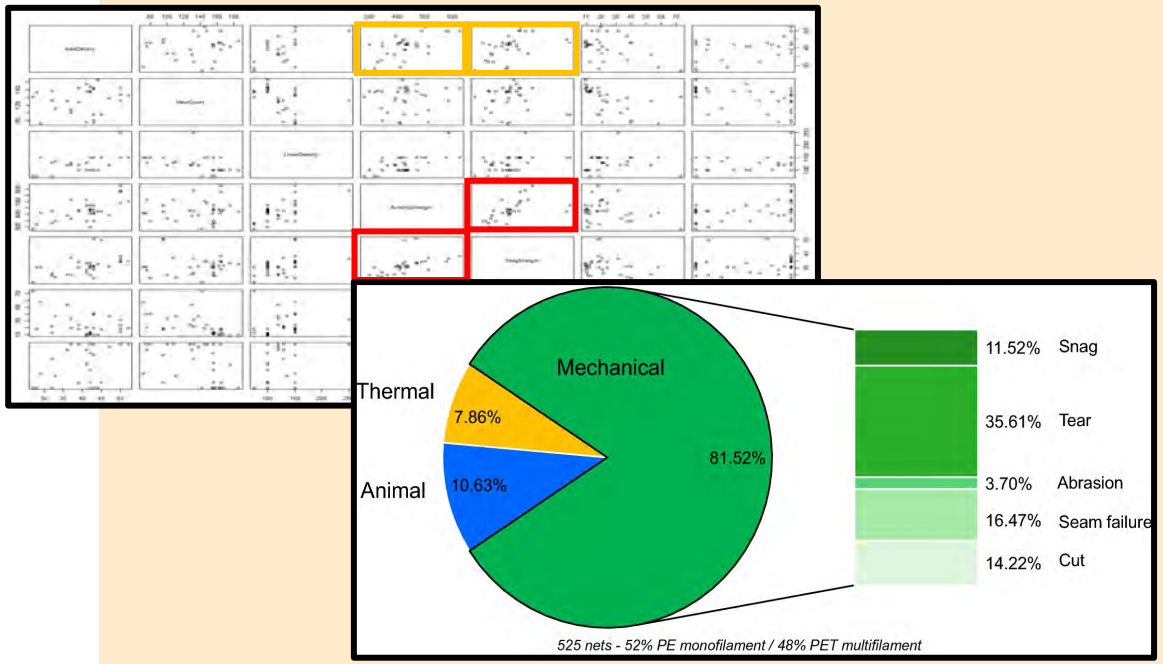
Final steps

- **Refine RD metric**
- **Deliver more robust estimates**
- **Provide higher-resolution estimates**

Refining the RD score – Combined approach

Empirical

What does a deep-dive into the data tell us?



Holistic

What are we trying to achieve?

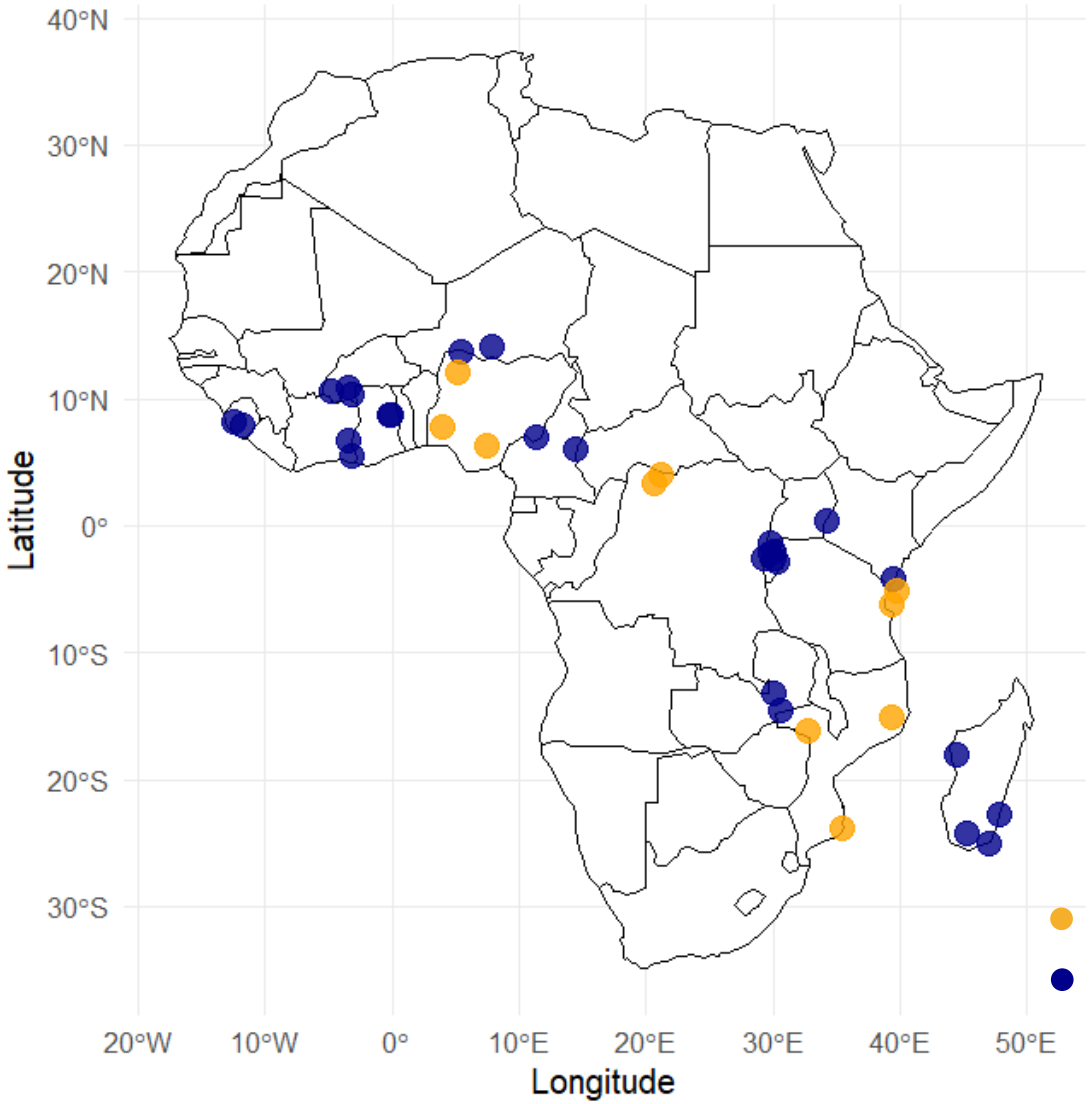
Purpose of durability is encourage retention and keep mosquitoes out

- Holes become major concern when they grow larger

Should we place greater **emphasis on ability to prevent hole enlargement**?

Refining the RD score - More durability data

Kilian, A.,. *Malaria journal*, *20*(1), 29 (2021)



	Kilian et al., 2021	2024
Countries	4	14
Durability mon. sites	10	37
LLIN brands	6	13
Campaign LLINs	4700	9500

Refining the RD score – Abrasion removed and hole enlargement increased

Field net analysis

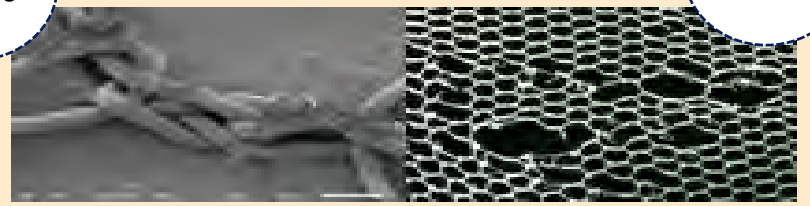
Preventable damage

Exceptional damage

Holes formed

Snag/burst **50%**

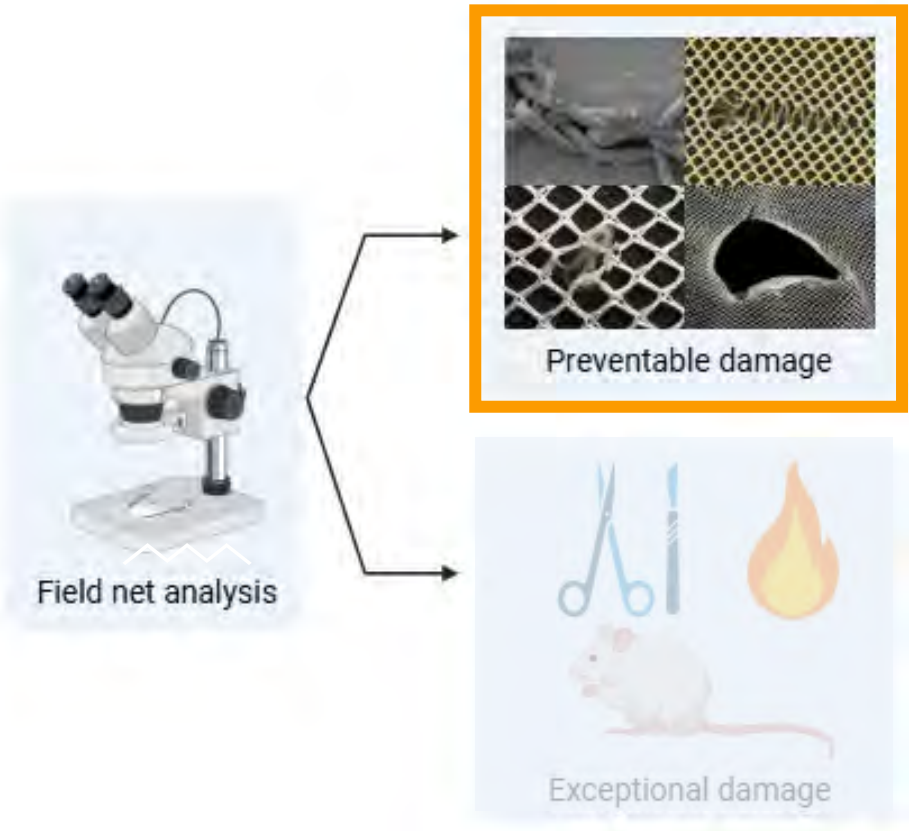
Abrasion **25%**

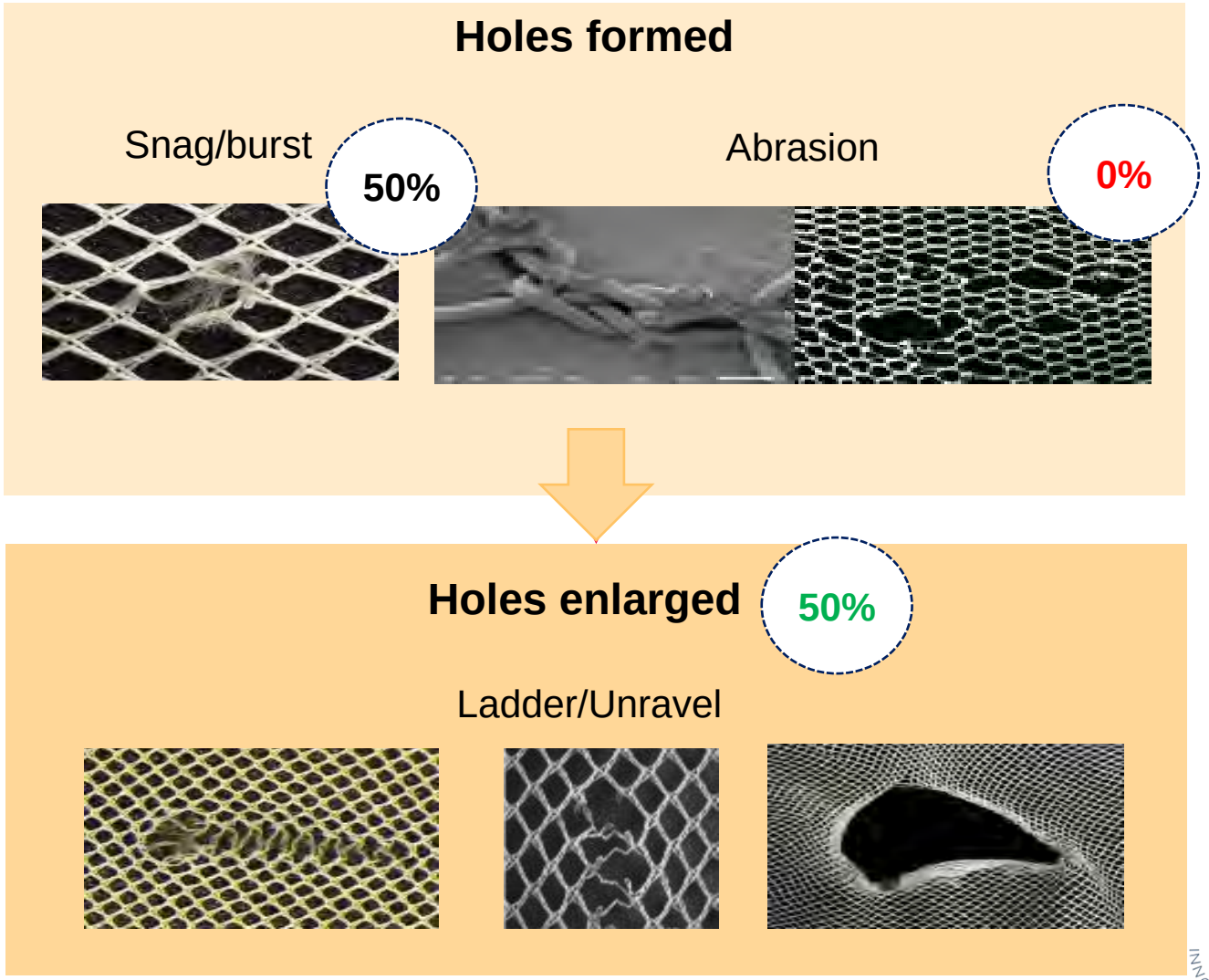


Holes enlarged **25%**

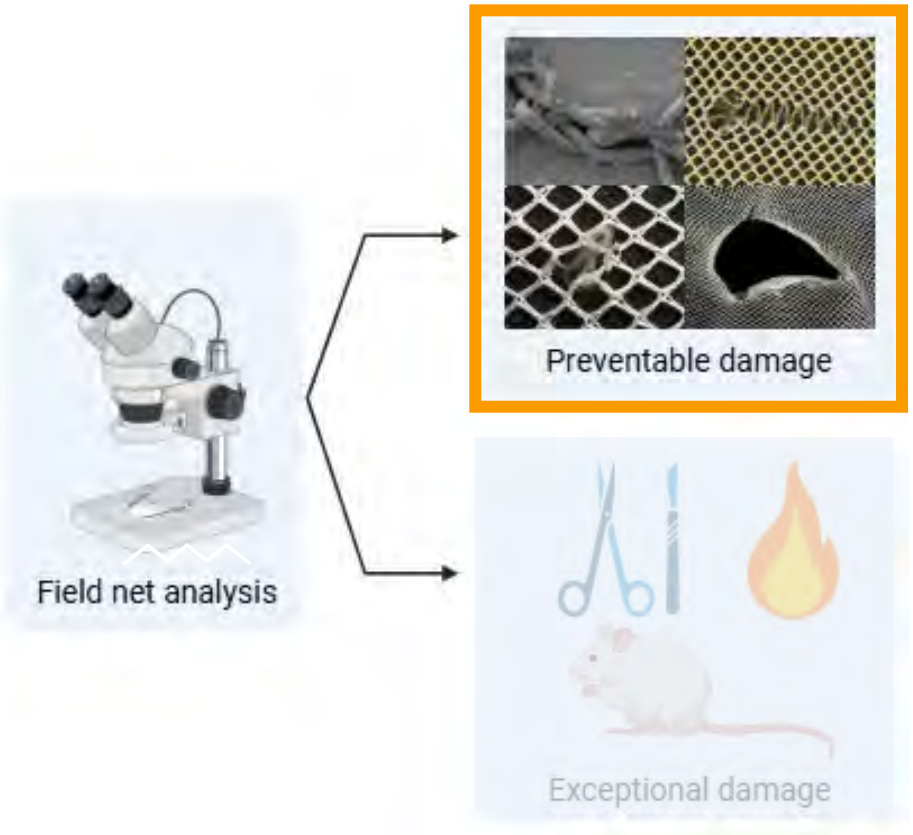
Ladder/Unravel

Refining the RD score – Abrasion removed and hole enlargement increased





Refining the RD score – Abrasion removed and hole enlargement increased



Holes formed

Snag/burst **50%**

Abrasion **0%**

Negligible detrimental effect when removed from RD

Holes enlarged **50%**

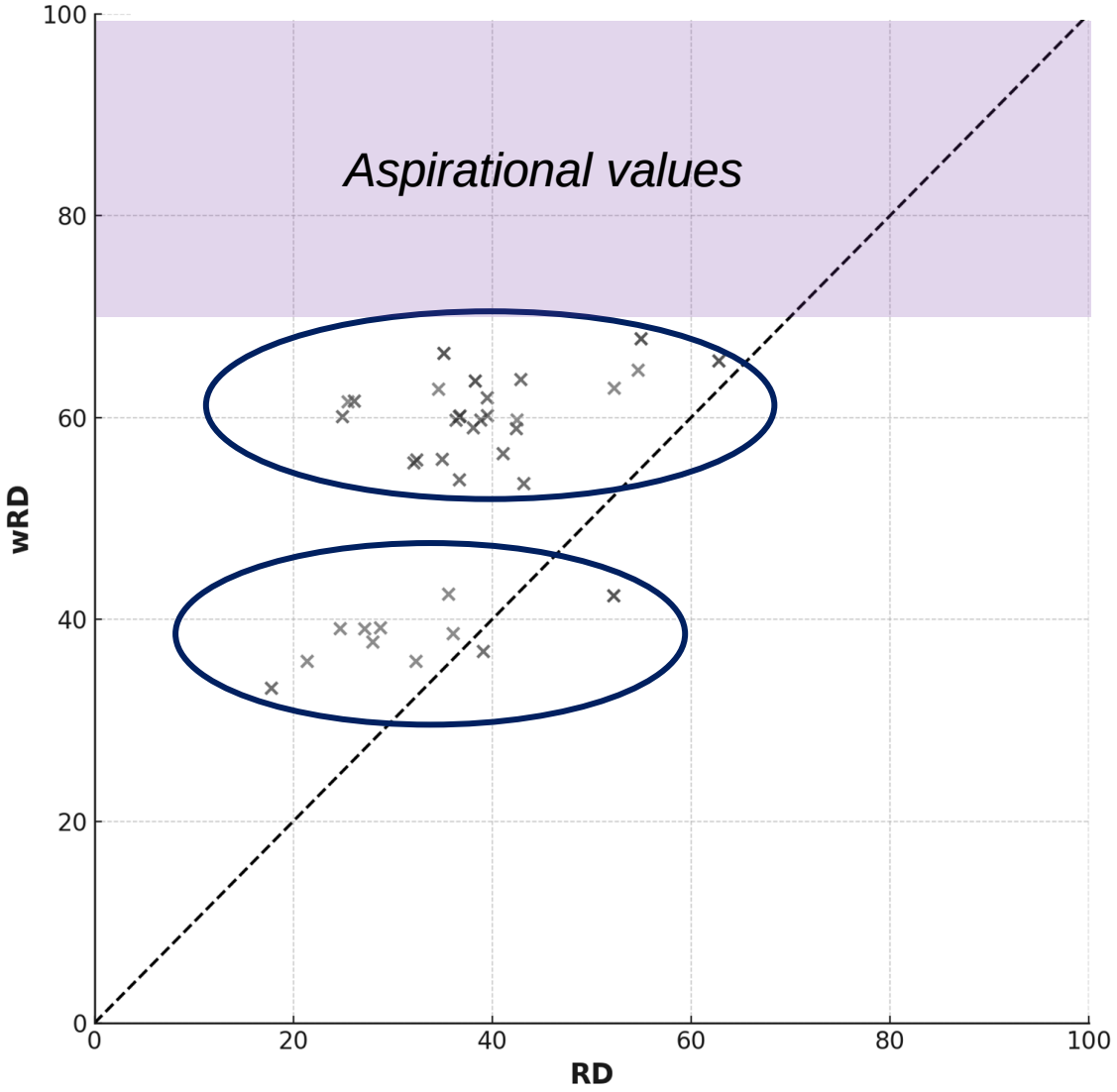
Increasing weighting of hole enlargement improves lifespan estimates

Refining the RD score – Defining the RD as the weighted RD

- 25 % **Snag resistance**
- 25 % **Bursting strength**
- 25 % **Hole enlargement**
- 25 % **Abrasion resistance**

Referred to hereafter as 'weighted RD' (wRD)

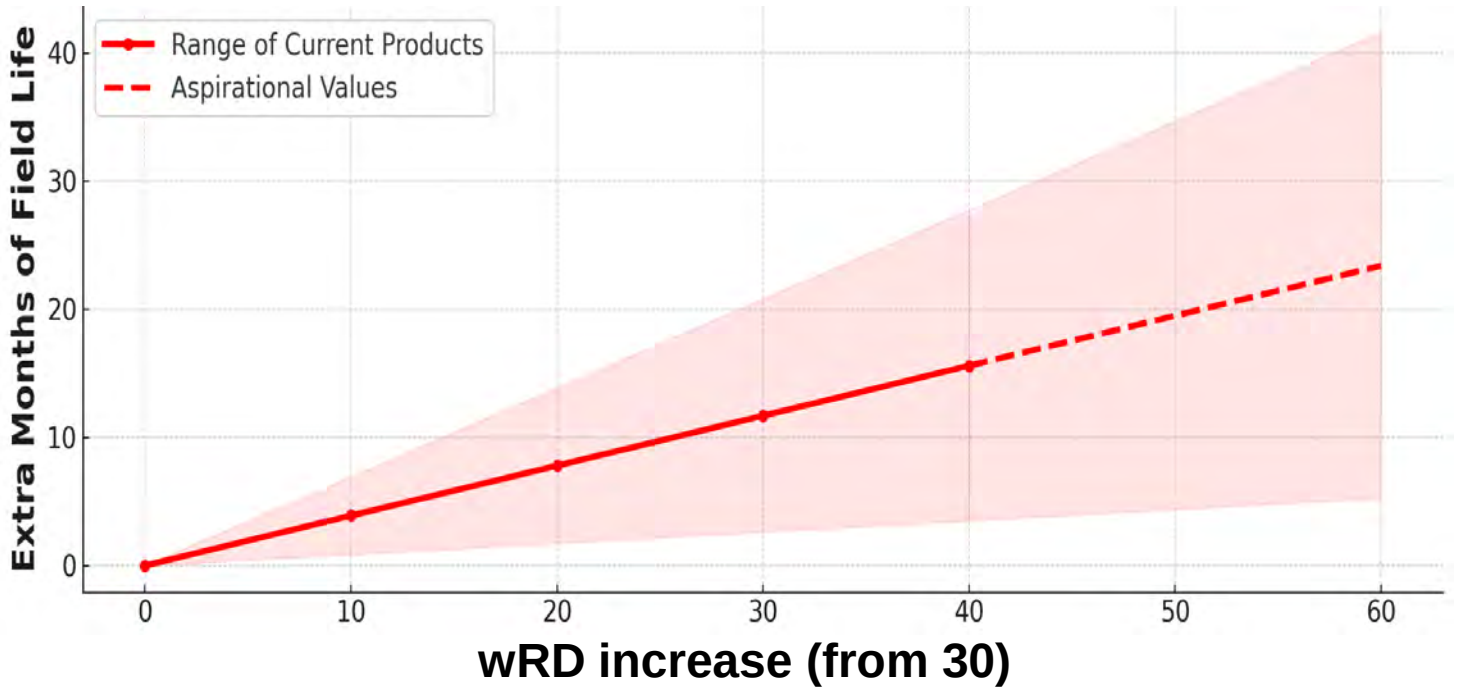
Refining the RD score – Range of wRD values



Note the bifurcation of wRD scores into two groups

Aspirational data coming from Malawi and Tanzania

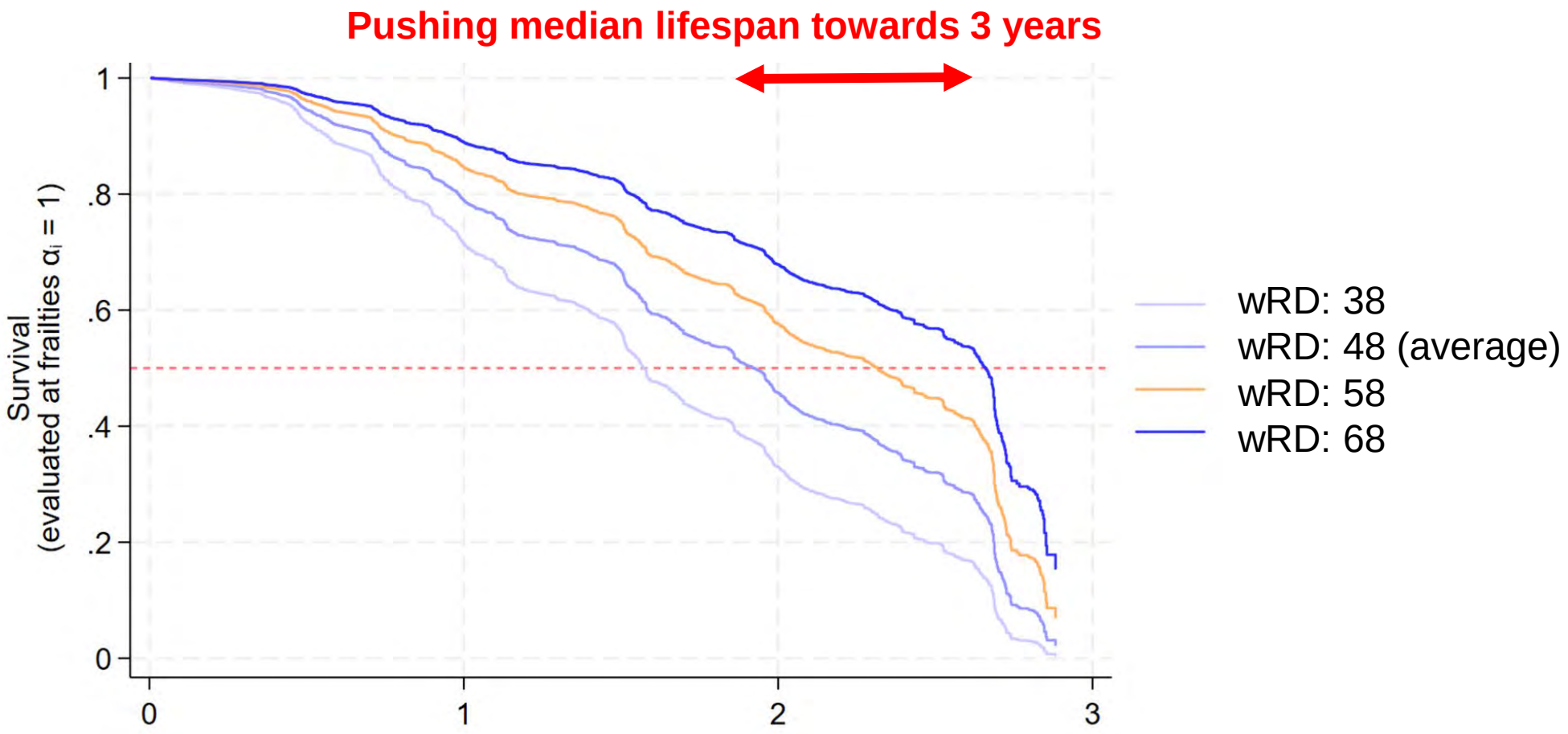
Refining the RD score – Generalising wRD (without country-specific data)



Increasing wRD from 30 to 65 increases median field life by **13.65 months** *(95% CI: 3.03-24.16)*

Error bar reflects country variation: *Effect will be larger in some countries than others*

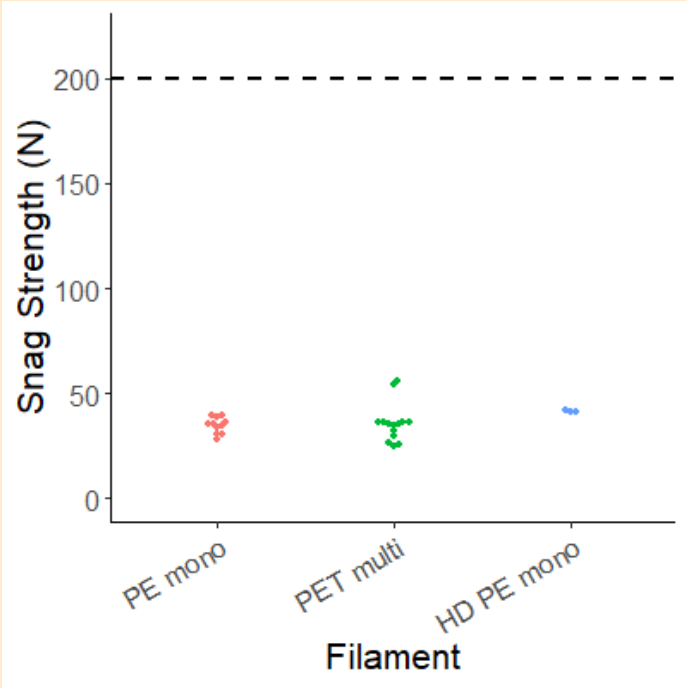
Refining the RD score – Pushing median lifespan to three years



Avenues to innovation - Physical characteristics of nets

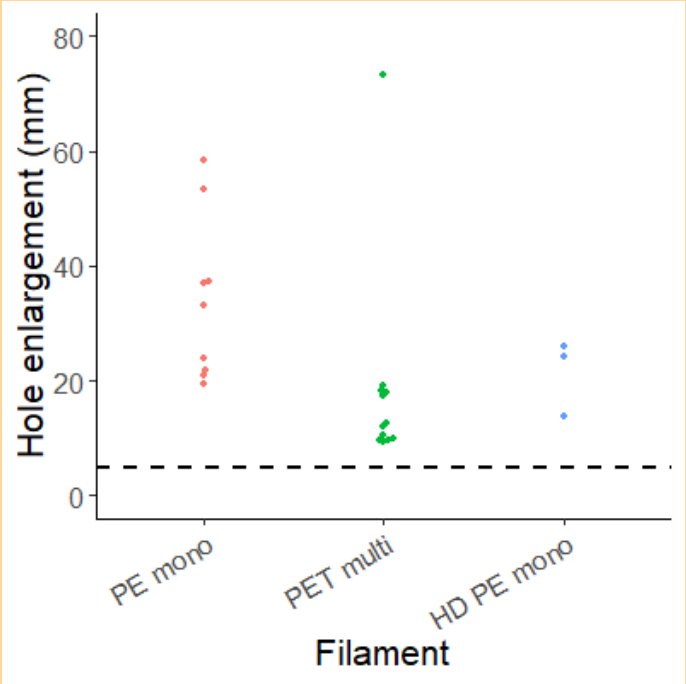
Holes formed

Increasing area density (fabric weight per unit area)?



Holes enlarged

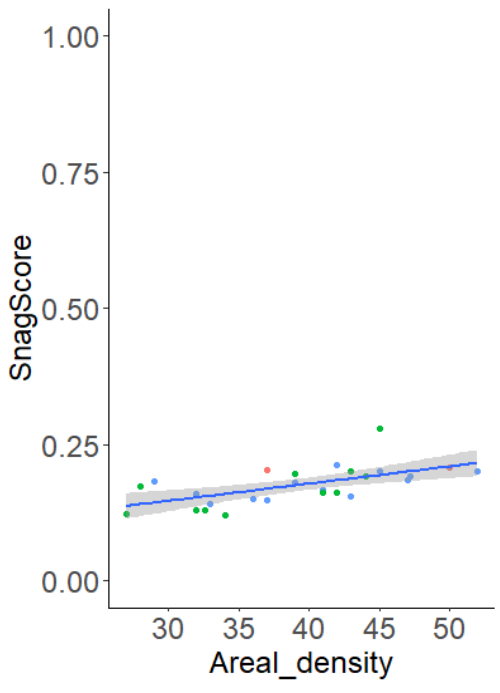
Increasing mesh count or changing knitting type?



Avenues to innovation - Physical characteristics of nets

Holes formed

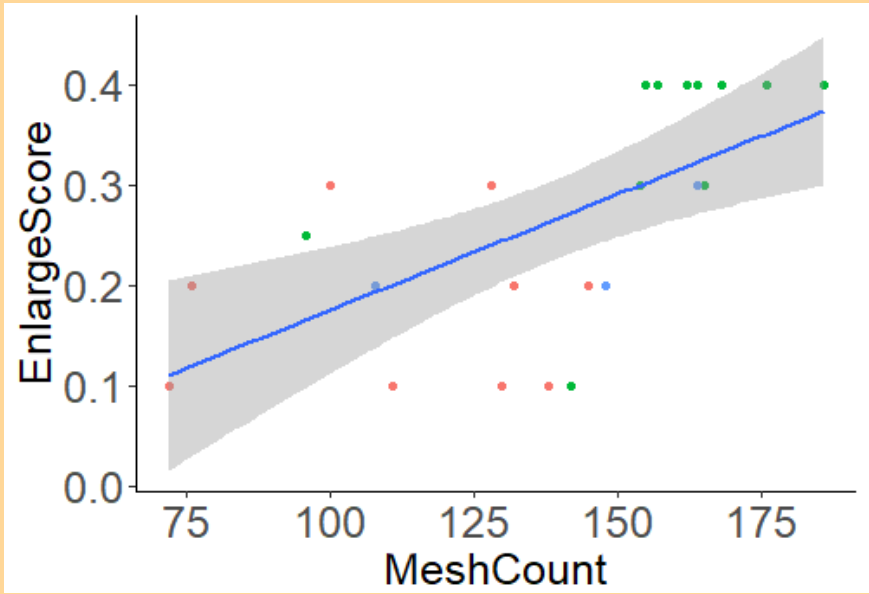
Increasing area density (fabric weight per unit area)?



Increasing fabric weight has negligible effect on snag strength

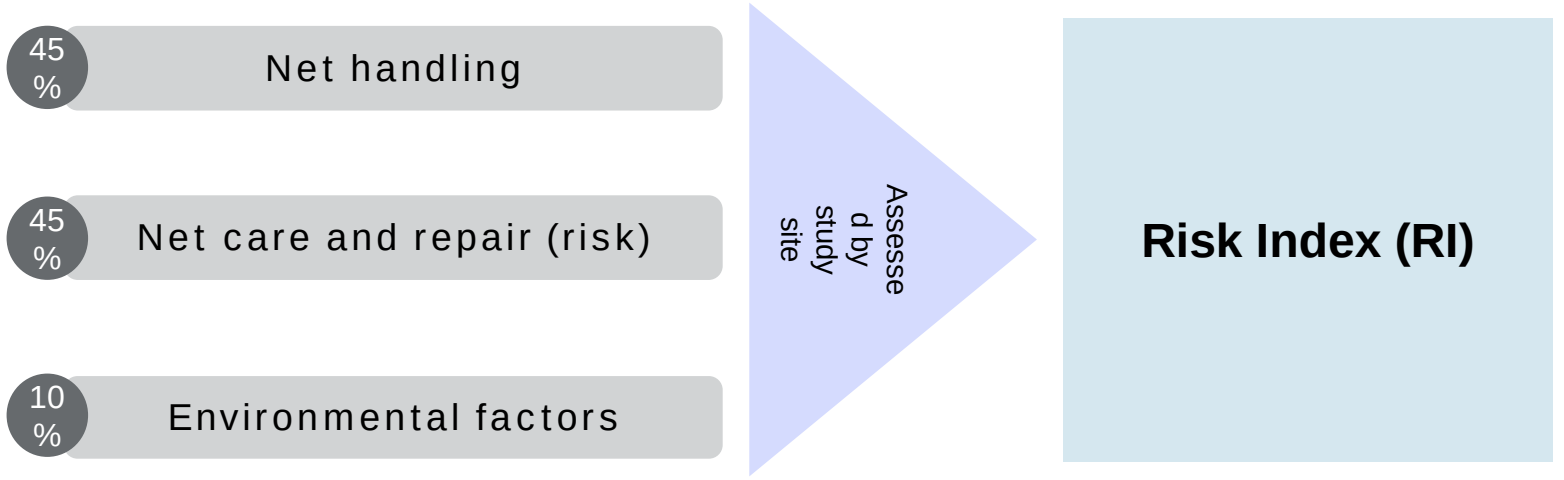
Holes enlarged

Increasing mesh count or changing knitting type?



Avenues to innovation – Refining

Error bar reflects country variation:
Effect will be larger in some countries than others



wRd score + **Risk Index (RI)**

Explain a very large proportion of ITN lifespan, $R^2 = \underline{0.76}$

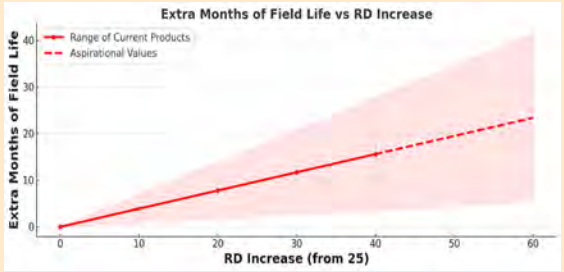
Avenues to innovation – Refining

Error bar reflects country variation:
Effect will be larger in some countries than others

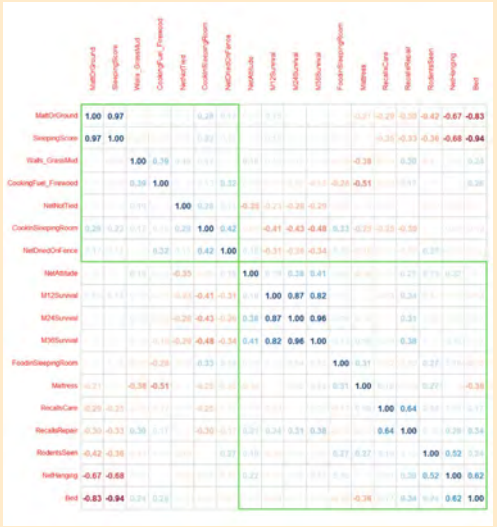
- 45 % Net handling
- 45 % Net care and repair (risk)
- 10 % Environmental factors

Assessed by study site

Risk Index (RI)



+



Explain a very large proportion of ITN lifespan, R^2 = 0.76

Key take home message

Increasing wRD from **30 to 65** increases median field life by **13.65 months**

*(10 point increase in wRD =**3.9 months**)*

Big thank you to Steve Poyer, Matt Worges, Eleanore Sternberg, Anna Trett, Tara Seethaler, Steve Russell and Angus Spiers

Julie-anne.tangena@lstmed.ac.uk

Frank.mechan@lstmed.ac.uk

Against Malaria Foundation (AMF) Procurement Highlights

2024 ITN Buyer & Seller Summit

9th December 2024

Ruth Hattersley, Senior Operations Manager, AMF

Outline

1. Intro: AMF procurement context
2. Net selection process & approach
3. AMF net requirements
4. Forecast net need 2025

1. Intro: The Against Malaria Foundation (AMF)

AMF is a malaria prevention charity focused on mass distribution of ITNs

- Founded in 2004
- Raising funds from the public, foundations and companies. No government funding
- 1.1 million donations from 220,000 donors in 189 countries. 170,000 donations in FY24
- USD 635 million raised to date
- 120 million nets distributed 2022-24
- Provides ITNs to fill gaps in mass campaigns in countries with high malaria burdens

1. Intro: AMF funds nets to fill gaps in high-burden mass campaigns

- AMF funds nets but also cares deeply about delivery accountability; works closely with in-country partners and focuses on data and monitoring
- Review funding requests from national malaria programs (NMPs) and agree together the net need, net type

Partnerships are central to AMF's contribution to the work against malaria

- **Co-funding** – Non-net costs of AMF-funded nets - Global Fund and/or PMI
- **Net distribution:** AMF works closely with NMPs and other partners on operations

AGAINST MALARIA FOUNDATION

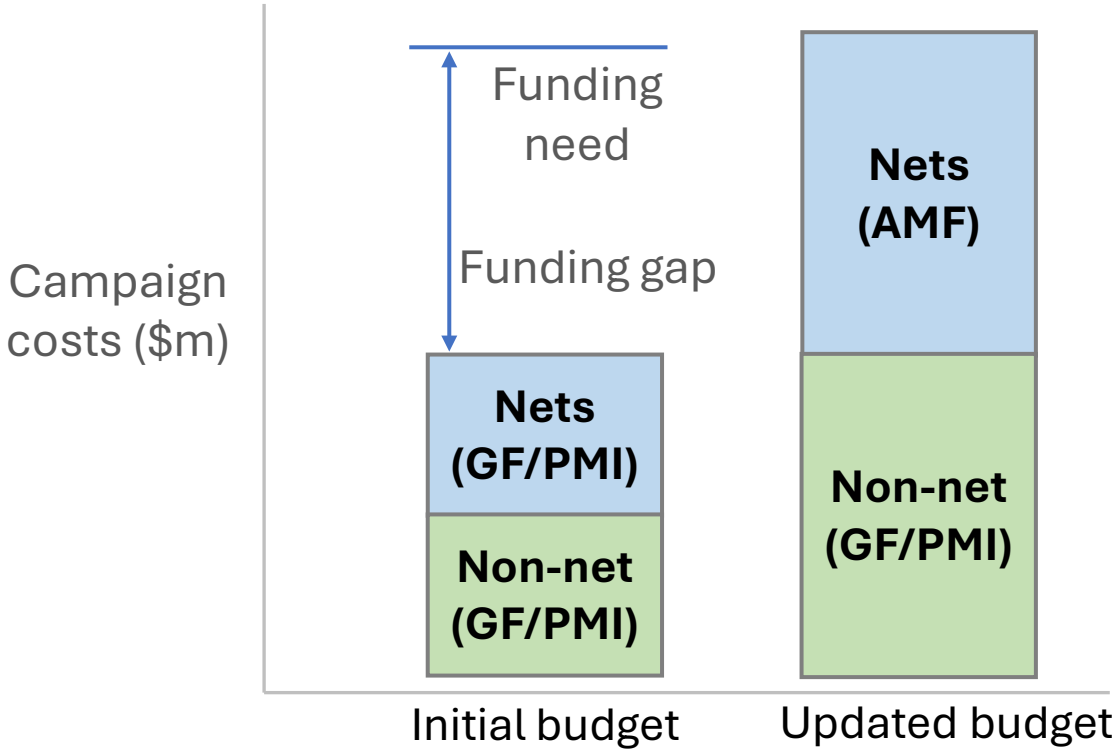
THE GLOBAL FUND

USAID FROM THE AMERICAN PEOPLE

CDC

U.S. President's Malaria Initiative

1. Intro: Working together to help countries to increase # of nets in mass campaigns

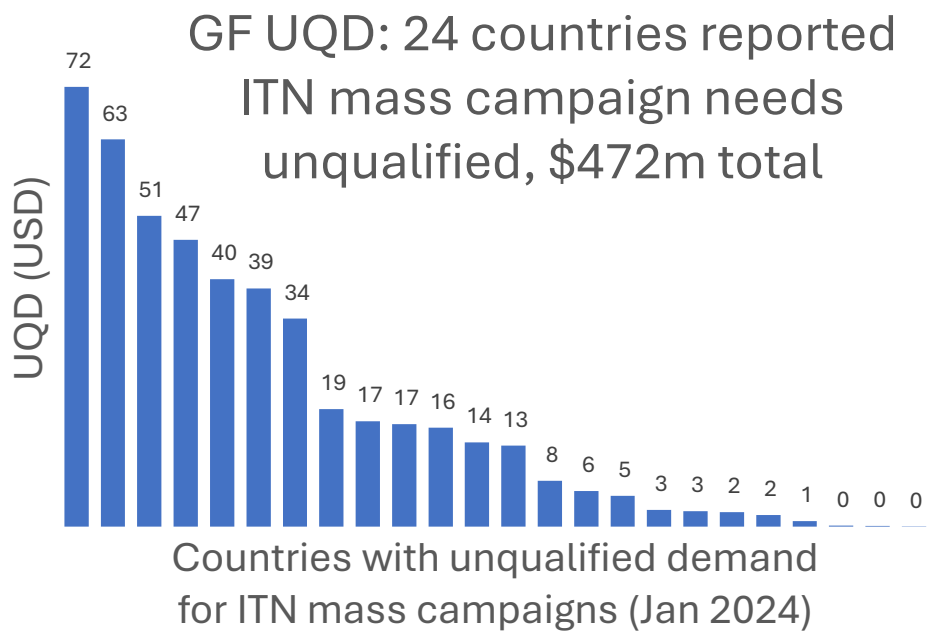


Simple example shown. In practice AMF/GF/PMI often co-fund nets.

Aim to help countries decrease funding gaps and achieve higher coverage

2. Net selection context: responding to gaps

Significant funding gaps for mass campaigns globally



Deploying most cost-effective nets means funds a) go furthest, b) have highest impact/$

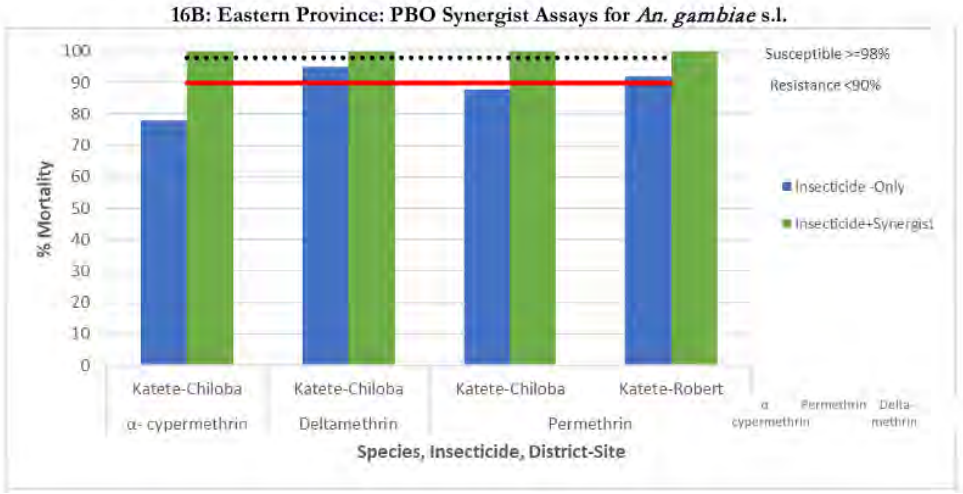
- Prioritising PBO and Dual AI nets according to resistance and malaria burden
- Selection process aims to gather and review relevant evidence; identify appropriate nets for each region

2. Net selection: Typical process & approach

1. Discussions with country
2. Analysis of malaria and entomology information
3. Analysis of net tendering information and supplier updates
4. Cost effectiveness estimates
5. Discussions with country and co-funding partners
6. Order confirmation

2. Net selection: Typical process & approach

- **Follow the data**; willing to invest additional funds where justified
- **Foster innovation** to help achieve a varied, forward-looking range of products available for deployment
- **Support data generation** and future research e.g. more entomology data, RD scores and alternative/less expensive monitoring, all to support decision making



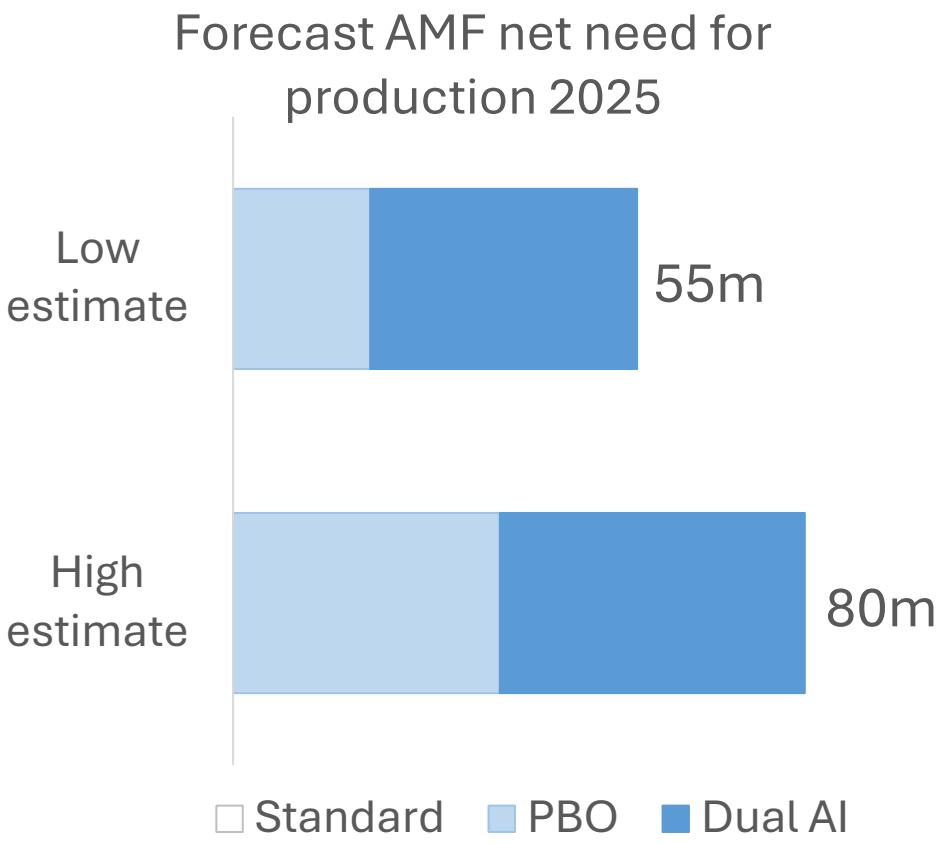
Example of bioassay results, PMI 2022

3. AMF net requirements

- Nets for high burden countries
- Increasing levels of resistance
- Increasing purchase of PBO and now Dual AI
- Last tender included:
  - WHO-PQ prequalified nets only
  - PBO & Dual AI nets only
  - White colour
  - 2 standard sizes
  - AMF label & GS1 barcodes

AMF-supported campaigns 2022-24

4. Forecast 2025 AMF net need & context

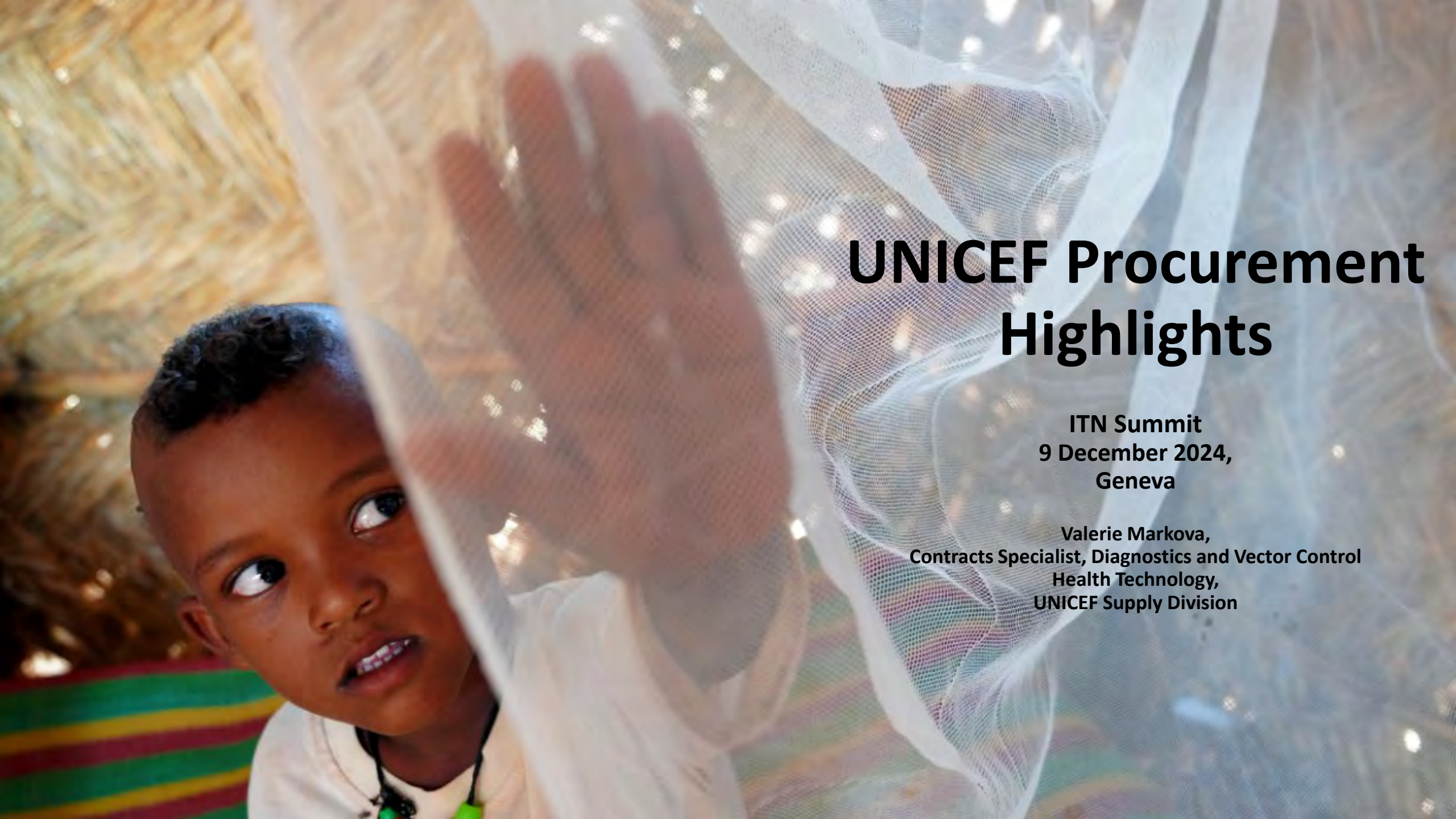


Context for forecast:

"Filling gaps" means funding commitments only once commitments of others are known

- Forecasts dynamic
- Net orders reflect final outcomes

Next tender planned Q1 2025



UNICEF Procurement Highlights

ITN Summit
9 December 2024,
Geneva

Valerie Markova,
Contracts Specialist, Diagnostics and Vector Control
Health Technology,
UNICEF Supply Division

UNICEF 2023-2028 Strategy positioning and alignment

UNICEF Strategic Plan
2022 - 2025
Goal 1:
Every child, including adolescents, to survive and thrive with access to quality primary health care

UNICEF Strategic Plan
2022 - 2025
Goal 4:
Every child, including adolescents, lives in a safe and sustainable climate and environment

UNICEF SD OMP
Strategic procurement and delivery

UNICEF SD OMP
Emergency preparedness and response

UNICEF SD OMP
2022 - 2025
Market influencing and innovation

UNICEF SD OMP
2022 - 2025
Sustainability

SDG 3: Ensure healthy lives and promote well-being for all at all ages.
Target 3.3: "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

UNICEF 2023-2028 Strategy Goal and Objectives

1 - To ensure a reliable access and uninterrupted supply of a wide range of quality assured, affordably priced ITNs of all types

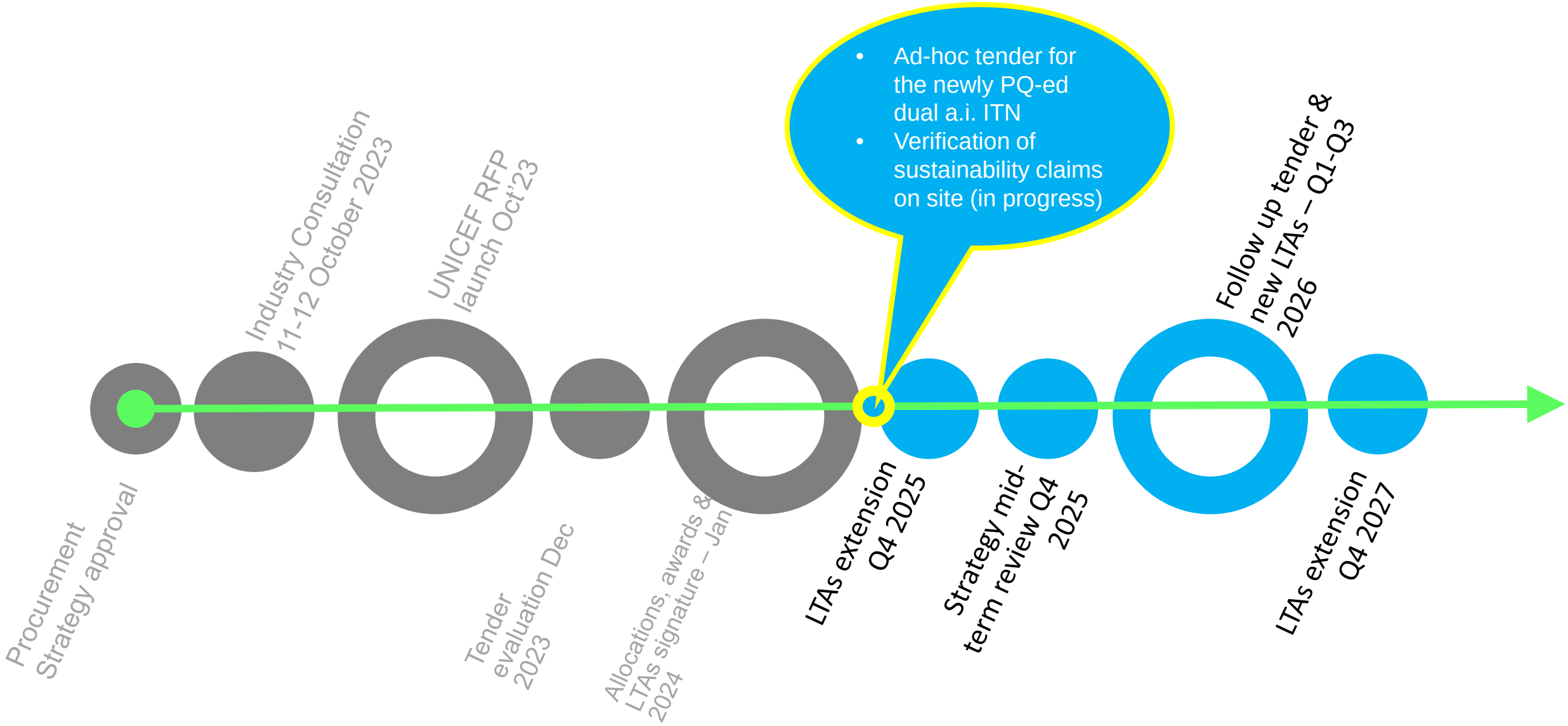
2 - To shape ITNs portfolio in a way that allows to increase a share of sustainably manufactured and procured ITNs

To support malaria eradication, reaching communities in need, by providing access to sustainably procured fit-for-purpose, quality-assured and cost-efficient ITNs

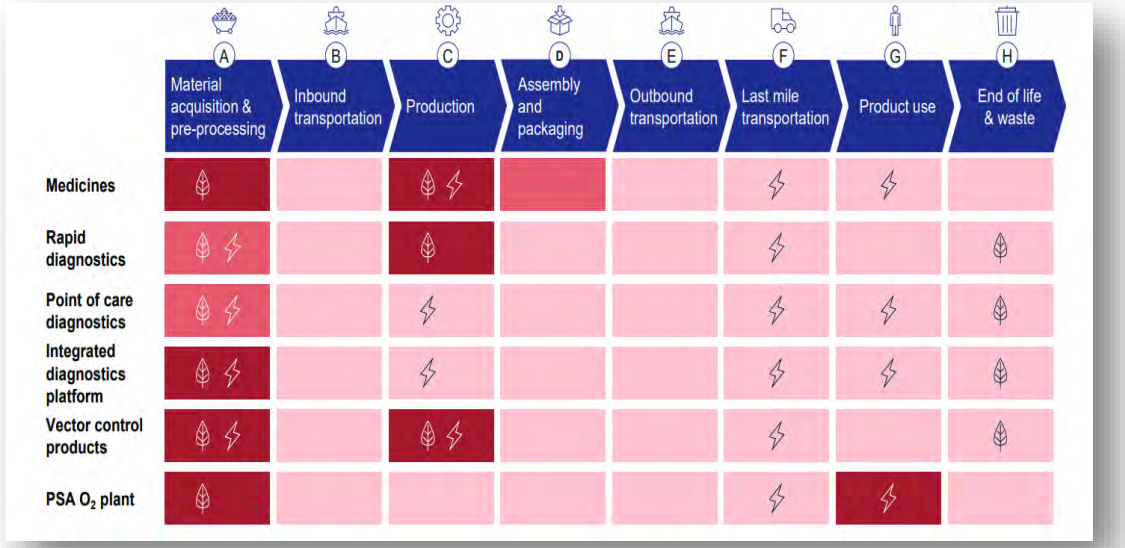
3 - To ensure efficient response to emergency needs for ITNs

4 - To improve affordability of PBO and Dual a.i. ITNs

UNICEF Strategy: Timelines and key milestones



THREE WAYS UNICEF REDUCES ITN GHG EMISSIONS



Source: Unitaid Report From milligrams to megatons: A climate and nature assessment of 10 key health products

Abatement lever 1: **Recycled plastic**

Recycled plastic in manufacture of ITNs can reduce product emissions by 32% while increasing product cost by less than 1%.

ITNs made of recycled plastic became available in UNICEF Supply Catalogue in 2024.

Abatement lever 2**: Alternative Products**

Use of novel vector control products can reduce emissions by up to 20%.

For example, SD explores spatial repellents / emanators. This product type has GHG reduction potential, fit for circular solutions. It can also become a key to an improved emergency response.

Abatement lever 3: **Bulk packaging**

Shift from individual to bulk packing in ITNs delivery reduces emissions while reducing product cost.

UNICEF 2023 – 2028 ITN Procurement Strategy requires that at least 80% of ITNs procured by UNICEF are bulk packed.

Reduction of plastic waste in deliveries of ITNs. Sustainability triple win

Clarifications on the shipment and storage regulations for dangerous goods are still ongoing.

Public Dashboard Reduction of plastic waste in deliveries of ITNs

Dashboard: Reduction of plastic waste in the delivery of insecticide-treated nets (ITNs) | UNICEF Supply Division

https://www.unicef.org/supply/dashboard-reduction-plastic-waste-delivery-insecticide-treated-nets-itns

New folder Service Gateway

unicef | for every child

Supply Division

EXPLORE UNICEF Press centre Donate

What we do For suppliers and service providers For governments and partners Stories Take action

Dashboard: Reduction of plastic waste in the delivery of insecticide-treated nets (ITNs)

How UNICEF is reducing plastic waste and saving money with bulk packing.

UNICEF is reducing plastic waste in the delivery of insecticide-treated nets (ITNs) by strategically shifting packaging requirements from individual plastic bags to bulk packing. This approach has prevented hundreds of tons of plastic waste, lowered procurement costs, and created opportunities for reinvestment.

The weekly updated dashboard above highlights the immediate benefits resulting from the reduction in plastic waste from ITN packaging.

Preventing mosquito-borne diseases

UNICEF is the largest procurement agency in the United Nations and, as part of its sustainability strategy, is exploring alternatives to make its supply chains more sustainable. Reducing plastic packaging and waste has been identified as an area that can have a significant impact.

ITNs are crucial for preventing mosquito-borne diseases and UNICEF is one of the world's

PMI | U.S. PRESIDENT'S MALARIA INITIATIVE
LED BY USAID FROM THE AMERICAN PEOPLE

THE GLOBAL FUND

Scanning Barcodes on ITNs and Bales "Lessons Learned"

Chris Warren, Senior Supply Chain Technical Advisor - President's Malaria Initiative
Parambir Gill, Specialist, Supply Chain Digitalization, The Global Fund

TraceNet - Background

PMI and GFATM co-convened:

- ITN manufacturers
- procurement agents, and
- implementing partners, including representatives from select donor-funded country programs.

TraceNet - Objectives

Data Carriers - Opportunity

There are opportunities to

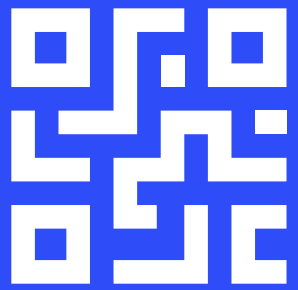
capture and **share information**

when ITNs change hands

from **the point of manufacture** through to
the **point where they are transferred to households**.

Data Carriers - Use Case Themes

EFFICIENCY



“Automate data capture”

ACCURACY

“Record reconciliation”

DATA EXCHANGE

“Share data with other systems”

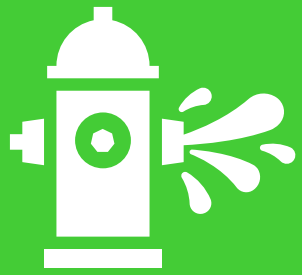
USE & MONITORING

“Plan for repurpose & end life”

INVENTORY MANAGEMENT

“Shelf-life management”

LEAKAGE



“Loss of goods”

Nigeria Implementation

Context

- ITNs for Cross River State in 2023 were serialized of which 157,738 were allotted to a scanning pilot,
- Used an existing ITN programming platform, for enabling Automatic Identification and Data Capture (AIDC)
- Increased understanding of how implementing barcode scanning can improve timeliness and accuracy of capturing campaign distribution data,
- product master-related information, including GTIN and transaction data (SSCC, SGTIN, batch, production data, and expiry data) supplied by manufacturer

Key Takeaways

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management (GHSC-PSM)

Quality

- Initial stages of the campaign detected illegible data carriers, which led to delays in distribution
- Specific barcode reading challenges include data carrier sizing; data carrier placement and damaged labels
- Duplication of serial numbers may have occurred

DRC Implementation

Context

- In DRC, in Bas-Uele province, IMA World Health scanned barcodes on nets at the point of dispense and then compared the number of nets scanned against number of nets dispensed, and expected to be dispensed (based on registration data)
- In total 674,373 nets were dispensed, of which only 353,979 (52.5%) were successfully scanned. The reasons for not being able to scan 47.5% of the nets are provided below and were largely consistent across health zones within the province.

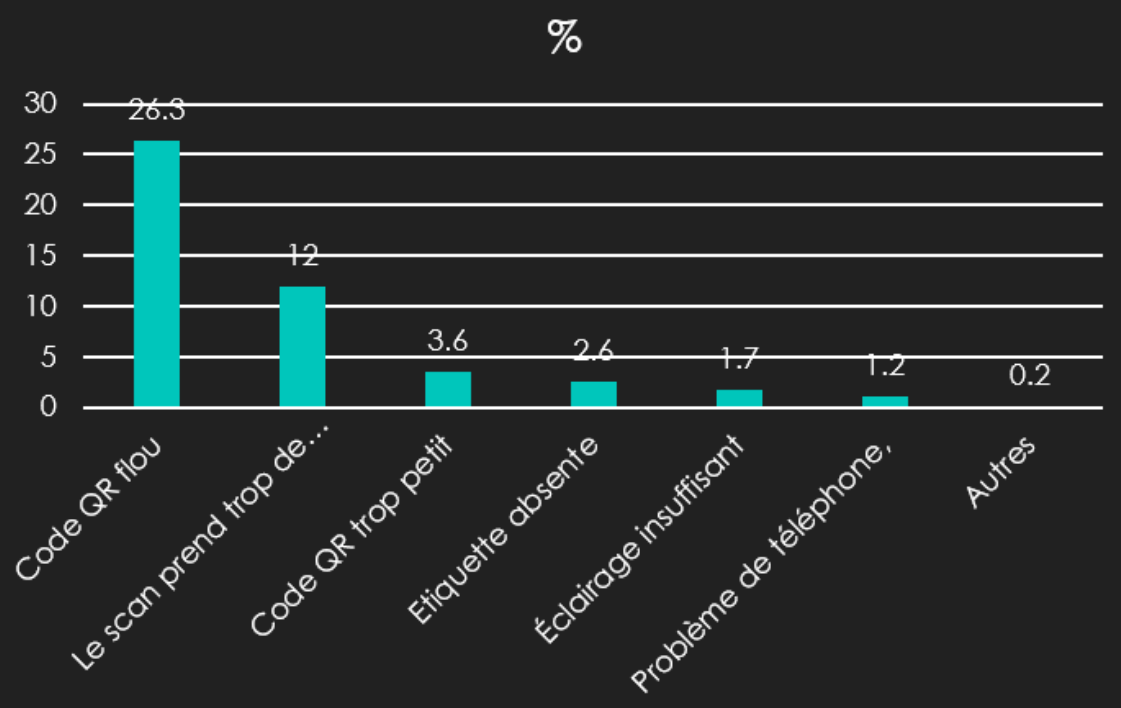
Key Takeaways

IMA WORLD HEALTH

Quality

- The top 4 reasons for the 47.5% of nets for which scans of the 2D data matrices on the nets were not able to be completed were:
  - **2D barcode is blurry (26.3%)**
  - **Scanning taking too long (12%)**
  - **2D barcode too small (3.6%)**
  - **Label missing (2.6%)**
- Together these reasons accounted for 94% of the nets that could not be scanned
- Duplicate codes and output data string length were also highlighted as issues for attention

	Reason for non-scanning	n=674373	%
1	Blurry QR Code	177,024	26.3
2	Scanning is taking too long	81 175	12.0
3	QR code too small	24 282	3.6
4	Label missing	17,564	2.6
5	Insufficient lighting	11,307	1.7
6	Phone problem,	7,828	1.2
7	Others	1,214	0.2



IMA WORLD HEALTH

Mozambique Implementation

Context

- Ability to scan nets at the time of distribution to enable traceability of nets was piloted as a part of the ITN campaign at Gaza province in Mozambique in November 2023
- This capability was initially planned to be built and rolled out on DIGIT HCM in April 2024 which was then pulled earlier when the opportunity to test emerged in Mozambique

Key Takeaways

egov. FOUNDATION

Quality

- Concerns raised with the susceptibility of the label content to damage (smearing) from abrasion with the textile of the ITN
- Some indications that the adhesiveness of the bale labels failed, rendering bales unscannable

Mozambique Implementation

Image of a front line worker scanning a net bag instead of net due to ineffective training

Image of a damaged code (code with net imprint / wrinkled barcode)

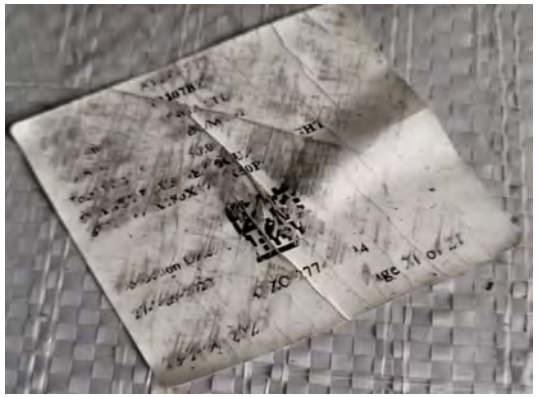


Image of a damaged and smudged barcode

Liberia Implementation

Context

- Liberia had a nation-wide bed net campaign planned in 2024 where they wanted to use the bales scanning functionality to trace the movement of bales from national warehouse to fixed posts
- Technical improvements in the DIGIT HCM platform were made to ensure that the scanners were able to read codes better and faster and the capability was made mandatory for all users. It is notable that in this implementation, 40 bales were scanned in a span of 5 minutes

Key Takeaways

Quality

- Quality of the bale barcodes - in terms of the print on the label and in terms of adhesives did not perform well in the Liberian context where adverse weather condition (rain) and basic bulk- material handling practices were frequently encountered.

Liberia Implementation

Image of warehouse workers moving bales from truck to the warehouse

Staging area where bales are scanned before moving into warehouse

Warehouse stacked with bales

Information for Manufacturers

Material handling of ITNs is typically different from that of other health commodities and this subjects ITN labels on bales and on nets to more instances of extreme handling and weather (heat and humidity)

Data Carriers on Nets

- ITN programming will benefit from individual ITN labels having **durability qualities** that facilitate a prolonged period of readability
- Protection from smudging and wrinkling / imprintment of net mesh pattern could be considered
- Aside from legibility, the individual ITN label needs to **be affixed (placement)** such that both scanning and reading is facilitated

Data Carriers on Bales

- Opportunity to **explore improvements in bale barcode placements** e.g. under flaps or parts less exposed to external contact & weather & away from other codes that may be present on bales
- Barcodes can be **affixed on multiple sides** to ensure that the warehouse managers can scan one of them even if others fall off / get damaged
- Early signals around label quality resulted in **TraceNet 2 recommendations specific to data carrier size, data carrier quantity and data carrier placement**
- Quality concerns, specific to ITN labels, were raised to the LQAG - further refinement of TraceNet recommendations to **include standard for ink quality, label adhesive and label material were explored but not pursued**.

- Pre-shipment physical inspection will assure for legibility / scannability at production stage
- Post-shipment monitoring will be able to inform on label durability

PMI ITN Procurement Highlights

2024 ITN Buyer Seller Summit

PMI deploys evidence-informed vector control tools

Based on

- Entomological data, including insecticide resistance and vector bionomics
- Human behaviors
- Community acceptance
- Programmatic Costs
- National strategies and policies

PMI | U.S. PRESIDENT'S MALARIA INITIATIVE

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CDC

Vector control currently accounts for a major share of PMI's budget

PMI deploys ITNs through integrated vector management strategies – providing effective vector control in the face of emerging insecticide resistance – a major threat to historical gains

PMI's ITN typically contribute towards Continuous Distribution rather than Campaigns

PMI recommends that partner countries transition to new types of ITNs (PBO) or dual-AI) where supported by insecticide resistance monitoring data

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CDC

PMI's ITN procurement policy requires that ITNs, at a minimum, be on the WHO PQ list of Prequalified Vector Control Products to be eligible for PMI procurement

PMI's procurement differs from Global Fund in that PMI will procure ITNs with a specified pyrethroid (if susceptibility testing data show a difference in mortality between the pyrethroids)

ITNs are procured via PMI's central procurement service agent : The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project

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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

PMI Procurement Highlights

2024 ITN Buyer Seller Summit

USAID FROM THE AMERICAN PEOPLE

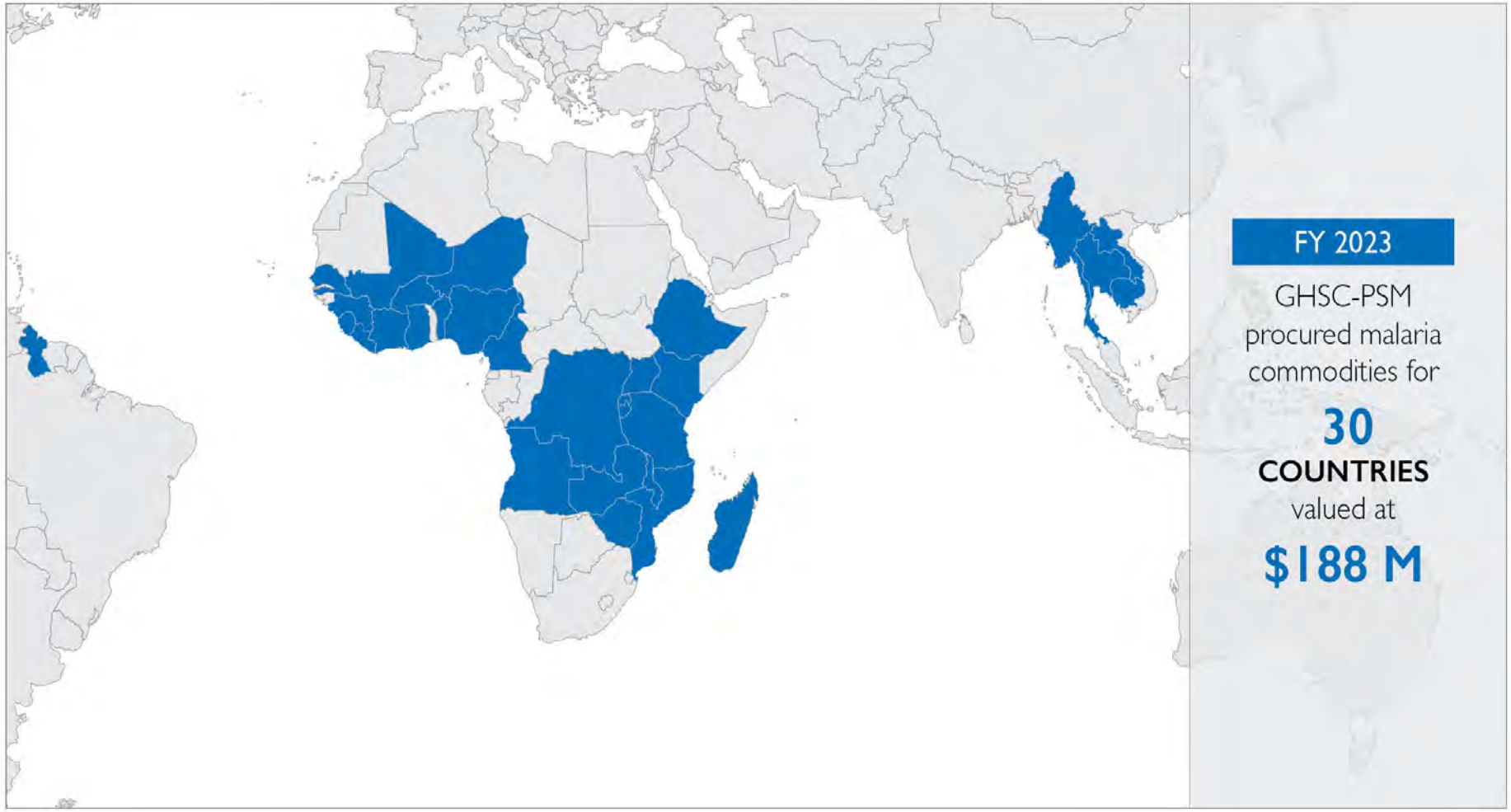
PEPFAR U.S. President's Emergency Plan for AIDS Relief

PMI U.S. PRESIDENT'S MALARIA INITIATIVE LED BY USAID FROM THE AMERICAN PEOPLE CDC

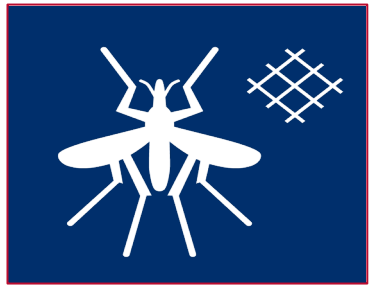
Presentation Outline

- Introduction to GHSC-PSM
- Overview of the GHSC-PSM Procurement Approach
- Quality Requirements for ITN Procurement

Global presence



In FY2023 PMI funded and provided



73m
people with access to mosquito nets

15m
people with insecticide for spraying their homes

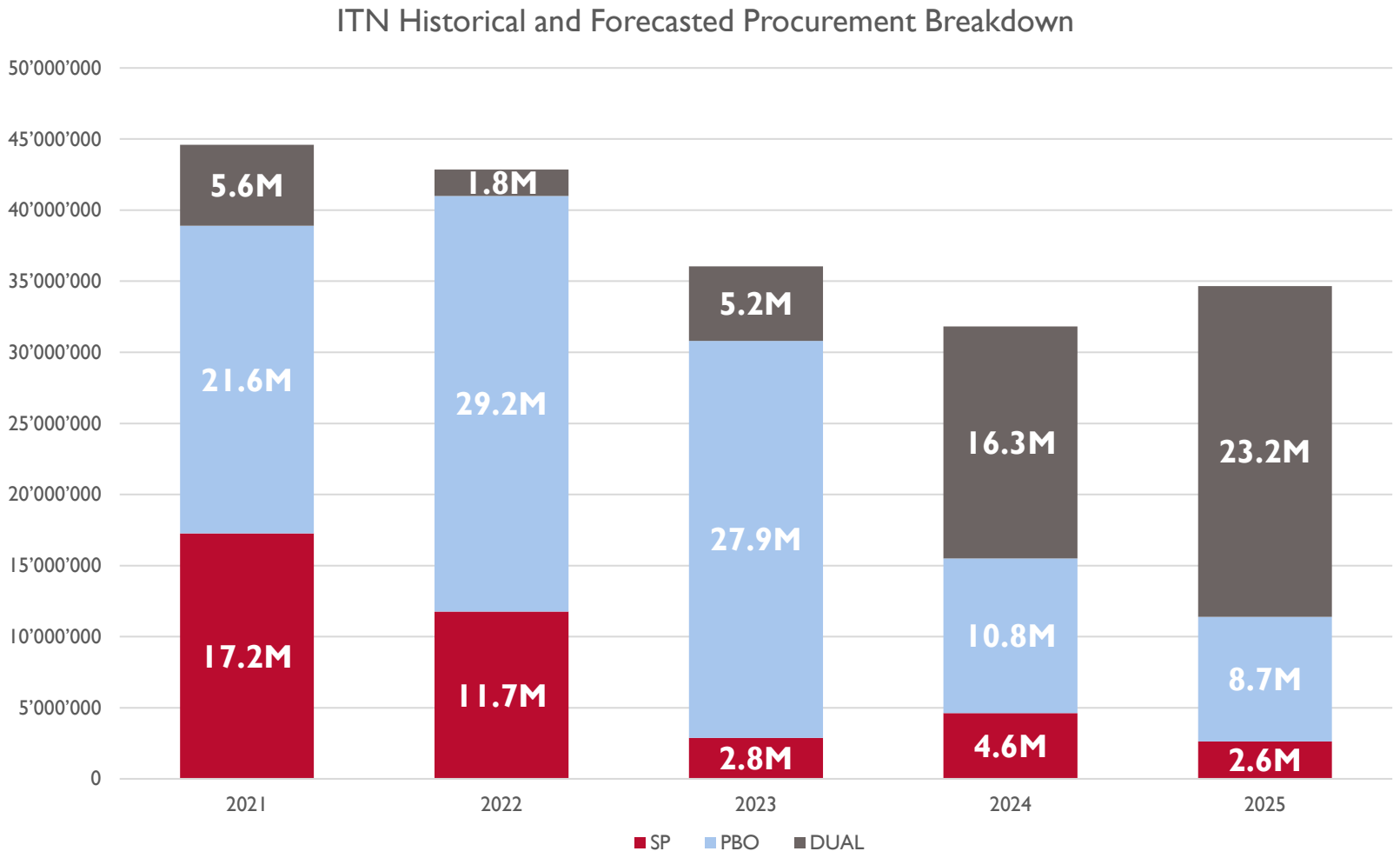
5m
pregnancies with preventive treatment

12m
young children with preventive treatment

102m
rapid diagnostic malaria tests

63m
fast-acting malaria treatments

PMI ITN demand has shifted towards Dual AI from 2021 - 2025



PMI's climate strategy embraces environmental sustainability

Optimized & Sustainable Packaging Innovations

- Reduced fuel consumption, lower emissions, less pollution throughout the entire supply chain
- Better recycling systems, improved disposal processes, supporting circular economy models for reduced environmental impact.

ESG Initiatives in Manufacturing

- Assess existing Environmental, Social, and Governance (ESG) initiatives by manufacturers to drive sustainable practices in production.

Sustainable Manufacturing Targets & Transparency

- Identify manufacturers' sustainability goals and evaluate the level of public disclosure of these targets.

GS1 remains a key requirement

- PMI has supplier requirements for implementing **GS1 standards** for different packaging levels
- Guidance and support is available on GS1 requirements and how to meet them

Coordination

LLIN Global Donors Meeting

- PSM coordinates with the Global Fund, UNICEF, and AMF regarding operational issues, market intelligence, and global supply planning

Procurement Partnership with AMF

- PSM performs quality testing and delivers orders procured by AMF on behalf of PMI

Procurement Approach

GHSC-PSM's tendering addresses multiple objectives and is transparent, systematic, and flexible

We take a strategic approach to sourcing that balances near-and long-term programmatic, market, and supply chain objectives

We contract and allocate orders based on holistic and rigorously determined overall best value evaluations

We communicate regularly with suppliers to provide detailed feedback on strengths and weaknesses, to articulate strategic priorities, and to receive feedback on our processes

We reward suppliers that invest in ways that contribute to our near and long-term objectives

Our processes are flexible and accommodate dynamic market, programmatic, and supply chain priorities

Allocations consider a sophisticated evaluation criteria to achieve "best value"

					
Total Landed Cost	**Supplier Performance**	**Quality Management**	**African Manufacturing**	**Innovation**	**ESG Initiatives**
Unit pricing, container loading efficiency, and estimated shipping costs from origin, when combined, present the opportunity to minimize costs and enable increased coverage of LLINs or other malaria commodities and programming	Inclusive of: • On-time goods availability • Quality control against product specifications • GS1 compliance • Qualitative performance feedback	Quality Management System - formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.	Inclusive of warehousing and both partial and full manufacturing. Diversifies the supply chain base, brings products closer to demand and thus reduces supply chain risk	Suppliers' investment in developing entirely new products. This is measured against specific milestones on the path for WHO PQ	Suppliers' investment in improving their impact on their surrounding ecosystems on both a global scale and within their local community

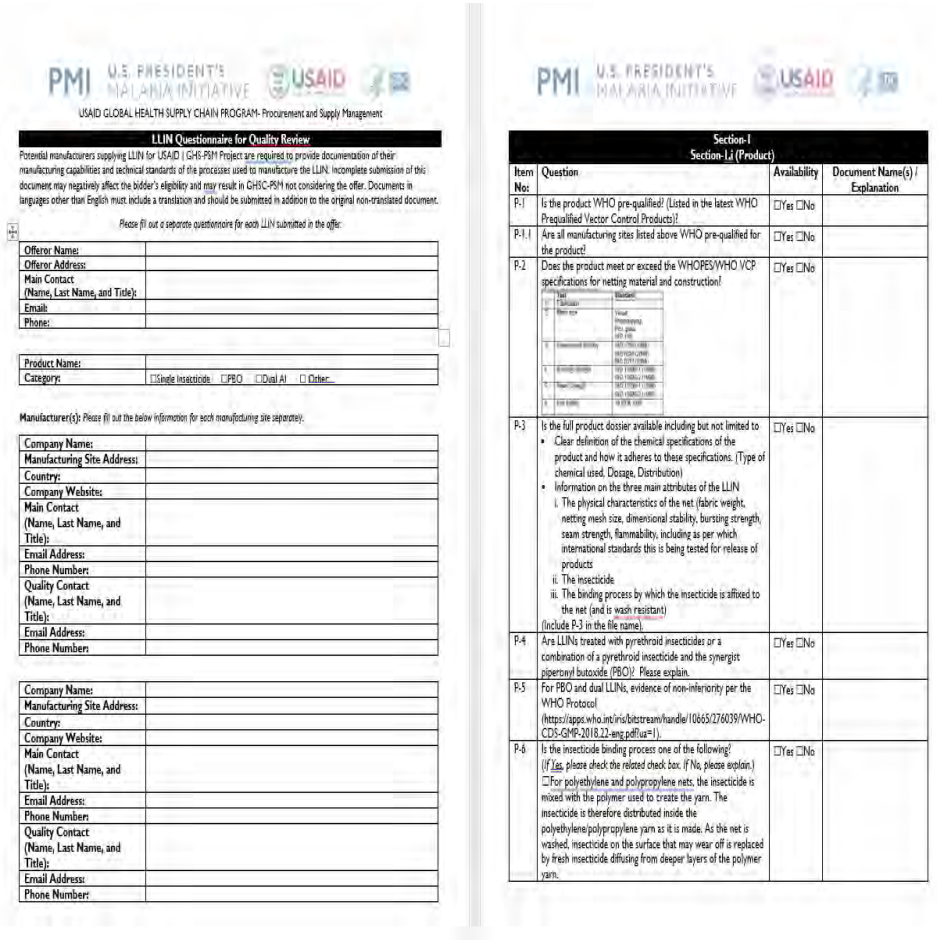
GHSC-PSM FY25 tendering approach

GHSC-PSM solicited offers from suppliers, in August 2024, requesting:

- Updated Pricing and Registration Coverage
- Container Loading Efficiency by net type and size
  - This information is used to determine the "total landed cost" of each item. "Total Landed Cost" is the estimated cost of the expenses associated with the delivery of one unit of product
- Innovation Efforts and Milestones (e.g. WHO Determination of Pathway, Dossier Approval, Hut Studies)
  - Points awarded for submission/initiation or approval/completion since close of the last tender
  - Dual AI is valued more than PBO
  - Pyriproxyfen-based nets were not considered for this category
- Environmental, Social, and Governance Initiatives
  - Emphasis was placed on rewarding suppliers with demonstrated ESG programs and ISO certifications in place
- Quality Questionnaire
  - Emphasis is placed on rewarding suppliers with the most robust quality control systems in place
  - Scoring is determined relative to responses from offering vendors, not a specified standard
- Quality Assurance Documentation (for new products)

Quality Requirements for LLIN Procurement

Quality review for tendering



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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM- Procurement and Supply Management

LLIN Questionnaire for Quality Review

Potential manufacturers supplying LLIN for USAID | GHS-PSM Project are required to provide documentation of their manufacturing capabilities and technical standards of the processes used to manufacture the LLIN. Incomplete submission of this document may negatively affect the bidder's eligibility and may result in GHSC-PSM not considering the offer. Documents in languages other than English must include a translation and should be submitted in addition to the original non-translated document.

Please fill out a separate questionnaire for each LLIN submitted in the offer.

Offeror Name:	
Offeror Address:	
Main Contact (Name, Last Name, and Title):	
Email:	
Phone:	

Product Name:	
Category:	☐Single Insecticide ☐PBO ☐Dual AI ☐ Other:...

Manufacturer(s): *Please fill out the below information for each manufacturing site separately.*

Company Name:	
Manufacturing Site Address:	
Country:	
Company Website:	
Main Contact (Name, Last Name, and Title):	
Email Address:	
Phone Number:	
Quality Contact (Name, Last Name, and Title):	
Email Address:	
Phone Number:	

Company Name:	
Manufacturing Site Address:	
Country:	
Company Website:	
Main Contact (Name, Last Name, and Title):	
Email Address:	
Phone Number:	
Quality Contact (Name, Last Name, and Title):	
Email Address:	
Phone Number:	

PMI U.S. PRESIDENT'S MALARIA INITIATIVE USAID

Section-I
Section-I.i (Product)

Item No:	Question	Availability	Document Name(s) / Explanation
P-1	Is the product WHO pre-qualified? (Listed in the latest WHO Prequalified Vector Control Products)?	☐Yes ☐No	
P-1.1	Are all manufacturing sites listed above WHO pre-qualified for the product?	☐Yes ☐No	
P-2	Does the product meet or exceed the WHOPES/WHO VCP specifications for netting material and construction?	☐Yes ☐No	
P-3	Is the full product dossier available including but not limited to • Clear definition of the chemical specifications of the product and how it adheres to these specifications. (Type of chemical used, Dosage, Distribution) • Information on the three main attributes of the LLIN i. The physical characteristics of the net (fabric weight, netting mesh size, dimensional stability, bursting strength, seam strength, flammability, including as per which international standards this is being tested for release of products ii. The insecticide iii. The binding process by which the insecticide is affixed to the net (and is wash resistant) (Include P-3 in the file name).	☐Yes ☐No	
P-4	Are LLINs treated with pyrethroid insecticides or a combination of a pyrethroid insecticide and the synergist piperonyl butoxide (PBO)? Please explain.	☐Yes ☐No	
P-5	For PBO and dual LLINs, evidence of non-inferiority per the WHO Protocol (https://apps.who.int/iris/bitstream/handle/10665/276039/WHO-CDS-GMP-2018.22-eng.pdf?ua=1).	☐Yes ☐No	
P-6	Is the insecticide binding process one of the following? (If Yes, please check the related check box. If No, please explain.) ☐For polyethylene and polypropylene nets, the insecticide is mixed with the polymer used to create the yarn. The insecticide is therefore distributed inside the polyethylene/polypropylene yarn as it is made. As the net is washed, insecticide on the surface that may wear off is replaced by fresh insecticide diffusing from deeper layers of the polymer yarn.	☐Yes ☐No	

Robust QA/QC

- Emphasis on robust quality control systems
- Learnings from previous areas of concern

QMS Review

- Manufacturing operations and controls
- QA processes
- QC and in-process checks

Other Quality related activities

- Stability studies – Real-time/accelerated
- Studies – transportation

PSM QA/QC process for procurement

Regulatory Compliance

✓WHO Prequalification

Documentation Review & Testing Compliance

✓Supplier Quality Management System (QMS) Assessment

✓Desk Review for ISO 9001 Compliance

✓Trial test

Risk-Based Quality Control (QC) Strategy

✓Proactive Risk Assessment

✓QC Testing & Monitoring

PSM QA/QC Process – upstream activities

Robust criteria prior to eligibility

- WHO PQ, Quality review (Quality questionnaire), Trial test

Inspections are conducted by an approved GHSC-PSM third-party agent

- Physical inspection of LLINs in accordance with ISO2859, Inspection Level 1
- Verification and documentation of quality, quantity, packing and marking/labelling (bales, bags and individual nets), as per (sub) contract/ PO
- Other requirements as per in PO e.g., country-specific labelling language, loading supervision, & container sealing

Sampling

- Representative samples are randomly obtained for each batch and sent to QC labs for testing

Testing occurs at approved PSM third-party labs

- Testing as per WHO specifications. All lots are tested, no randomization

Certificate of Conformance issued

- When documentation, inspections, and test results conform to specifications
- If a deviation is observed, QA performs an investigation

QA/QC Process – downstream and other activities

Product Complaints

- Investigations – post-shipment inspections, sampling and testing

In country QC

- Support – alignment with pre-shipment protocol.

Collaboration with global partners QA teams

- QA/QC process
- Best practices

Introduction of LQAG

Working Group

- The Global Fund (TGF)
- United Nations International Children's Emergency Fund (UNICEF)
- United States Agency for International Development (USAID) President's Malaria Initiative (PMI)
- Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM)
- Center for Disease Control (CDC)
- World Health Organization (WHO) Vector Control Team - Observer

Mission and Scope

- *The purpose of the LQAG is to provide a forum to monitor and communicate LLINs quality-related concerns and trends to facilitate and or implement activities to mitigate identified quality issues and potential risks. Inspections are conducted by an approved GHSC-PSM third-party agent*

Objectives and Goals

- *This working group aims to reinforce compliance of ITNs with established quality standards based on the WHO prequalification assessments, and to align quality assurance and quality control (QA/QC) processes within global procurers. To achieve these goals and objectives, procurers will discuss information that is deemed confidential and as such must be handled with the utmost discretion.*

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The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

Transforming Malaria Prevention

Kate Kolaczinski, Senior Specialist Malaria, the Global Fund
Clarisse Morris, Manager, Market Shaping and Partnership, the Global Fund

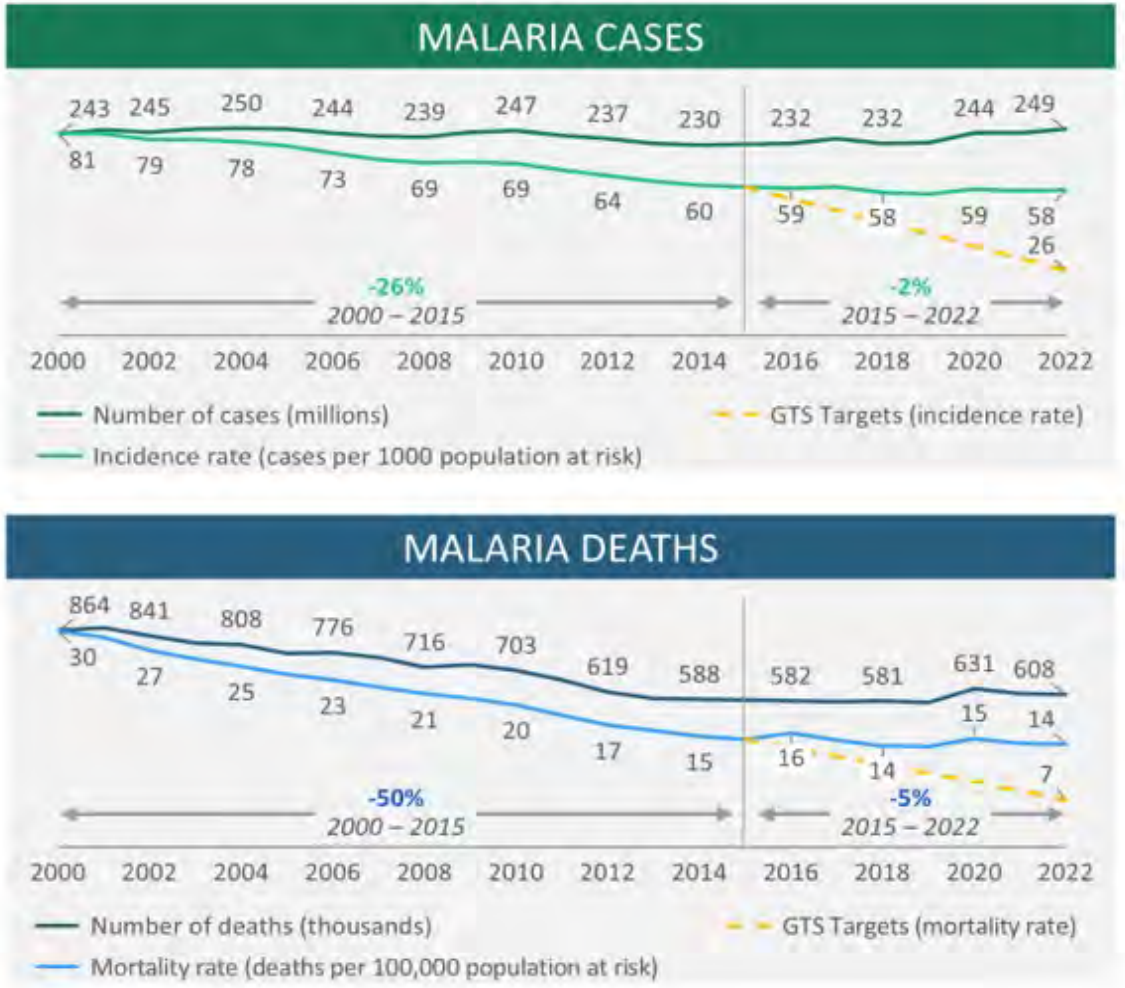
Content

The wider malaria control context

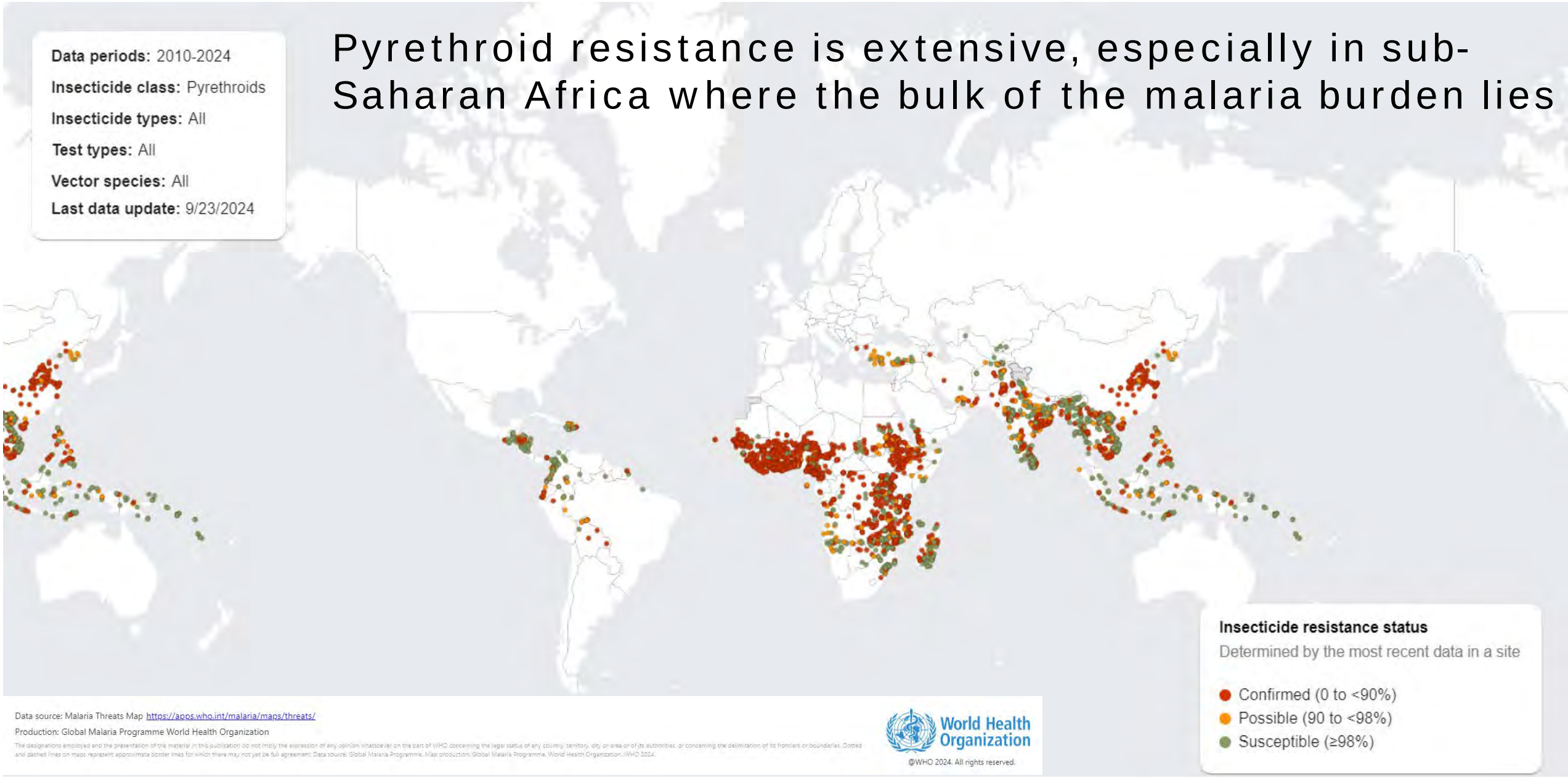
Following significant success for 15 years decreasing cases and deaths, progress has *stalled*

Why is progress at risk?

- Increasing **biologic threats**-insecticide/drug resistance, parasite deletions and emerging vectors
- Emerging **new tools are more effective but also more expensive** with limited or unstable supplier base; insufficient innovation pipeline
- Achieving and maintaining **coverage of effective tools is a multi-factor challenge**, hindered by limited resources to meet the prevention and treatment needs of growing at-risk populations
- **Implementing is more difficult and costly** in the settings of climate change/emergencies and insecurity

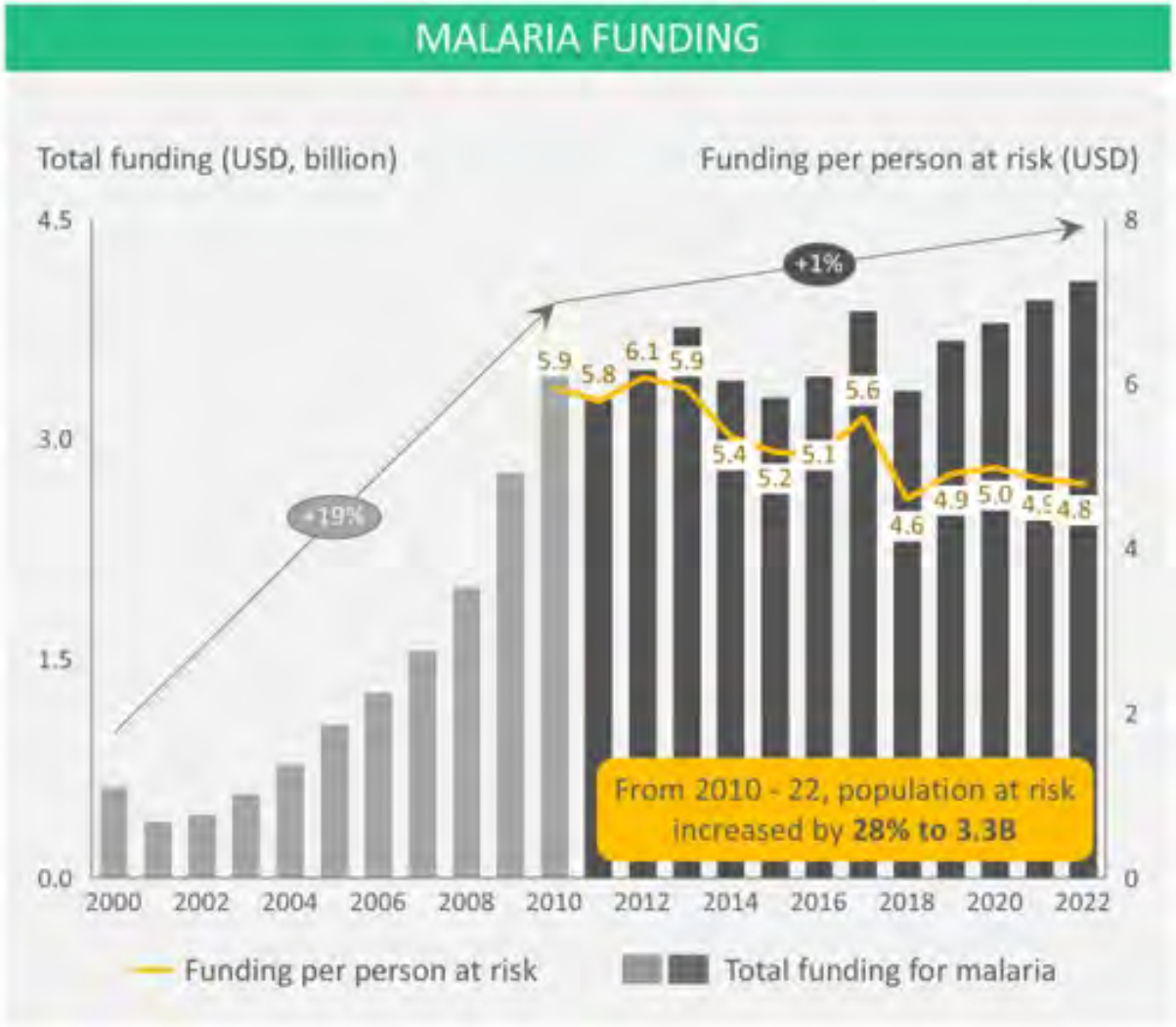


Pyrethroid resistance is extensive, especially in sub-Saharan Africa where the bulk of the malaria burden lies



And the threats facing malaria go *beyond* the GF partnership model

- **Population growth** - 41% population growth in Global Fund supported countries since 2002
- **Climate change** - Overlap between areas of highest malaria and highest sensitivity to climate change impact (efforts underway with CxH)
- **Insecurity** - 44% (24) of HI/core portfolios are classified as COE and home to 76% of global malaria cases
- **Financing** - Unprecedented fiscal pressure faced by countries – in particular, low-income countries in Africa where malaria is concentrated



*In totality, this **increases the number of people at risk** with cascading impacts on service delivery across contexts*

Countries are facing difficult prioritization decisions

- Balance across the 3 diseases and health systems strengthening needs
- Within a disease – how much for prevention versus care?
- Public vs private vs community balance
- Coverage decisions – deprioritize areas?
- Intervention type decisions – varying costs, effectiveness and cost-effectiveness

Malaria Prevention is in transition as programmes adapt to changing context and challenges

Current shifts being seen

- Maximising impactful tools at expense of coverage
  - Some countries are opting to buy only PBO or CFP nets; but leave some at risk populations uncovered
- Maximizing coverage at the expense of ‘upgrading’ to better tools
  - Several programmes include pyrethroid only nets in areas of pyrethroid resistance, as the way to ensure as many ITNs as possible can be procured
- Some programmes have gaps in both type of net *and* geographical coverage
- Prioritizing ITN campaigns and leaving gaps in routine nets, SMC or other grant areas

Potential future context

- Per capita funding may be lower
- Moves to more sub-nationally tailored approaches, and an expanding vector control toolbox may influence the ITN context:
  - Likely that ITNs will remain a core tools
  - Likely increase shift towards non-pyrethroid nets in pyrethroid resistant areas
  - May see more nuanced decisions around how to maintain coverage – more targeted campaigns but higher throughput distribution?
  - Other tools – IRS, LSM esp. in urban areas, newer VC tools
- Insecticide resistance management remains important will continue to be a concern – partnership to consider appropriate response

ITN type decisions are driven by WHO guidance

Pyrethroid-chlorfenapyr vs pyrethroid-only ITNs

Pyrethroid-chlorfenapyr ITNs should be deployed instead of pyrethroid-only LLINs for prevention of malaria in adults and children in areas with pyrethroid resistance.

Strong | For

Pyrethroid-PBO vs pyrethroid-only ITNs

Pyrethroid-PBO ITNs can be deployed instead of pyrethroid-only ITNs for the prevention and control of malaria in children and adults in areas with pyrethroid resistance

Conditional | For

Pyrethroid-chlorfenapyr vs pyrethroid-PBO ITNs

Pyrethroid-chlorfenapyr ITNs can be deployed instead of pyrethroid-PBO ITNs for prevention of malaria in adults and children in areas with pyrethroid resistance.

Conditional | For

Pyrethroid-pyriproxyfen vs pyrethroid-PBO ITNs : Pyrethroid-pyriproxyfen ITNs are not recommended for deployment over pyrethroid-PBO ITNs for prevention of malaria in adults and children in areas with pyrethroid resistance

Conditional | Against

Pyrethroid-pyriproxyfen vs pyrethroid-only ITNs: Pyrethroid-pyriproxyfen ITNs can be deployed instead of pyrethroid-only LLINs for prevention of malaria in adults and children in areas with pyrethroid resistance.

Conditional | For

- Based on the results of 2 randomised controlled trials which showed **a strong and consistent impact from the pyrethroid-chlorfenapyr IG2 ITNs compared to pyrethroid-only ITNs in areas of pyrethroid resistance**:
- Tanzania: **IG2 net areas had 55% lower prevalence and 44% fewer cases than standard net areas;**
- Benin: **IG2 net areas had 46% lower prevalence and 46% fewer cases than standard net areas**[1]

To maximise cost-effectiveness, Global Fund encourages:

- In pyrethroid resistant areas, strive to deploy CFP nets
- Consider pyrethroid-PBO ITNs as the alternative
- Strive not to deploy pyrethroid-only nets in areas of pyrethroid resistance
- Do not revert to pyrethroid-only nets once an area has moved to more effective net

Pricing - and a background of catalytic support – has been vital to enable this encouraged shift to Dual AI despite funding challenges

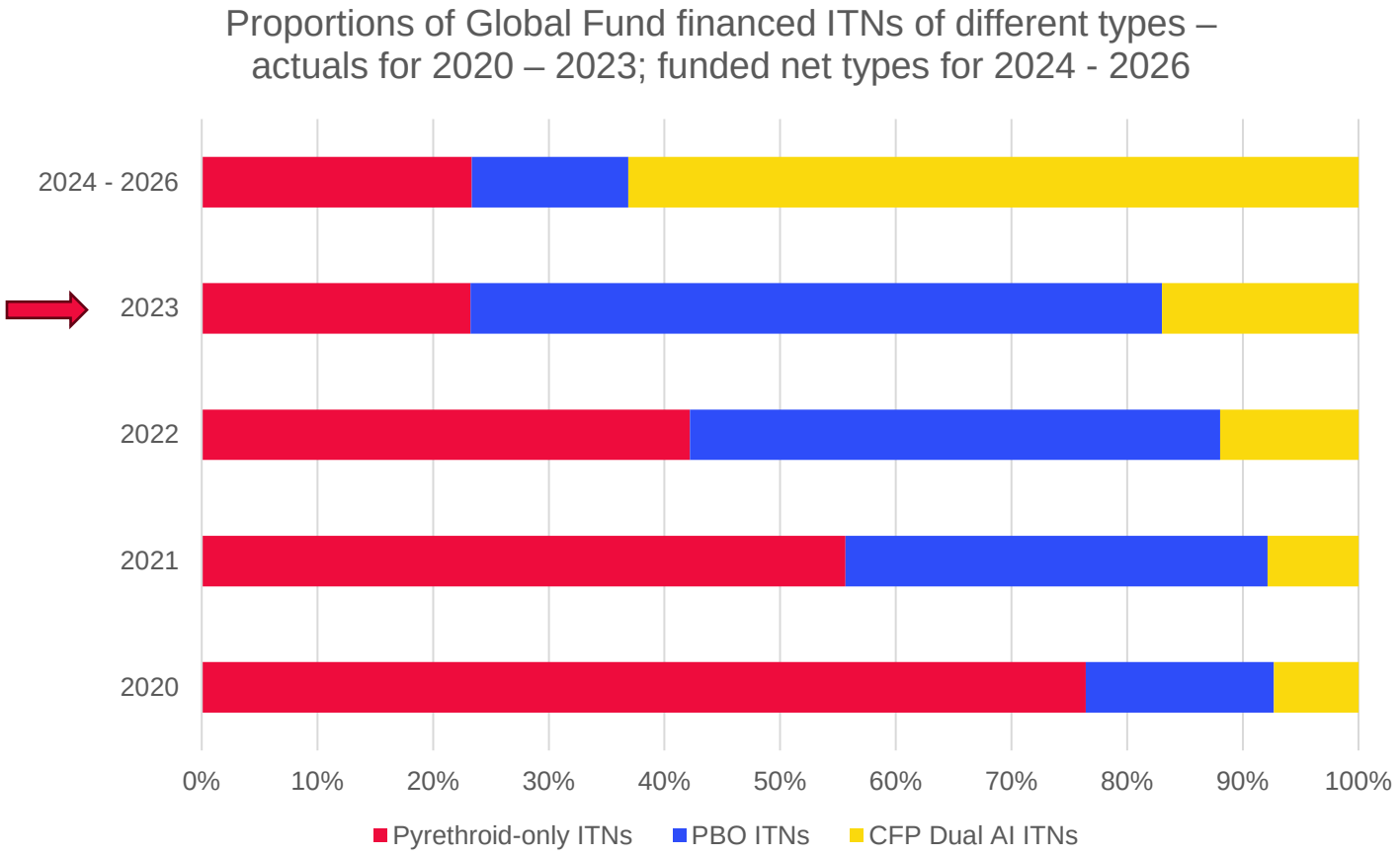
8-years of catalytic support

2024 – 2026
NextGen Market Shaping SI – Revolving Facility (Global Fund and partners including Gates, Vestergaard, BASF)

2022 – 2024
Net Transition Initiative (Global Fund and partners including BASF)

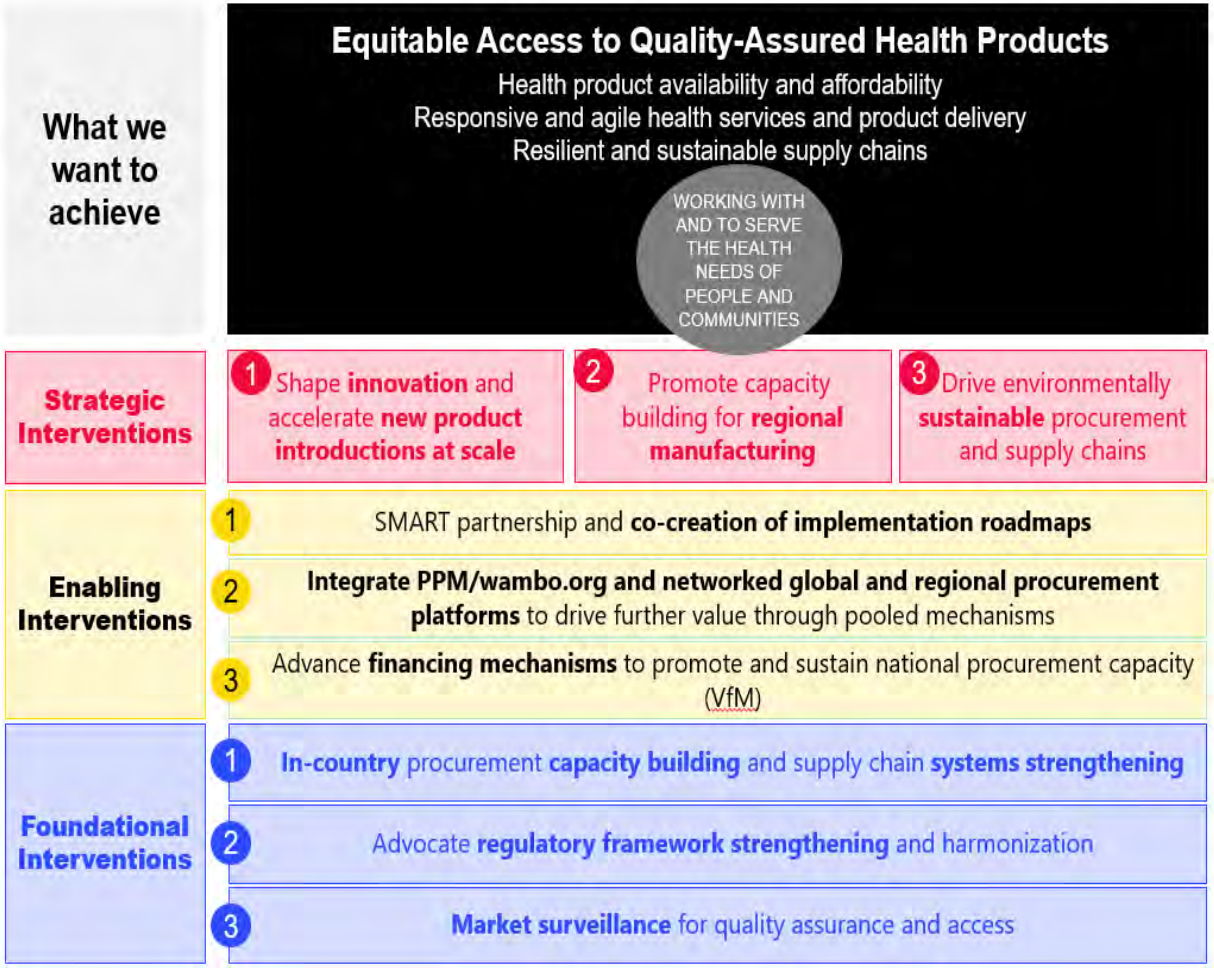
2018 – 2022
New Nets Project (Unitaid, Global Fund – IVCC and partners including BASF)

WHO recommendation, based on LSHTM led studies in Tanzania and Benin



NextGen Market Shaping Approach aims to drive equitable access to quality assured health products in support of the Global Fund 2023 - 2028 Strategy

Download NextGen Market Shaping Overview



Global

1. Work with industry and partners to drive innovation that is accessible to LMICs
2. Secure supply that is affordable, available, quality and responsiveness
3. Foster South-to-South collaboration

Regional

1. Leverage PPM / wambo.org to collaborate with partners to build regional procurement capacities
2. Stimulate and sustain regional manufacturing capacity building

National

1. Use grant investments and country partners to strengthen in-country supply chain systems
2. Ensure quality assured health products will be distributed effectively and efficiently to communities and people we serve

NextGen Market Shaping Strategic Initiative was created to catalyze impact across the three diseases in Grant Cycle 7

Global Fund 2023 - 2028 Vision and Strategy Implementation

NextGen Market Shaping SI

Drive equitable access to quality-assured HIV, TB and malaria products to meet the needs of the people and communities we serve

1	2	3
Accelerate **Health Product Introductions** at scale	Promote capacity-building for **regional manufacturing**	Drive **in-country supply chain systems strengthening**
Accelerate the introduction and scale-up of new, more effective health products to increase availability, affordability and uptake of the best health products on the market, working with suppliers and country teams.	Promote health product manufacturing close to where products are used, building capacity among manufacturers, regional procurement platforms and regulatory processes to reduce impact from global supply chain disruptions.	Strengthen systems and in-country capacity for procurement and supply chain to improve availability of commodities through efficient supply chain design and operations.
Market-, disease- & country-facing approach	Regional approach	Country-facing approach

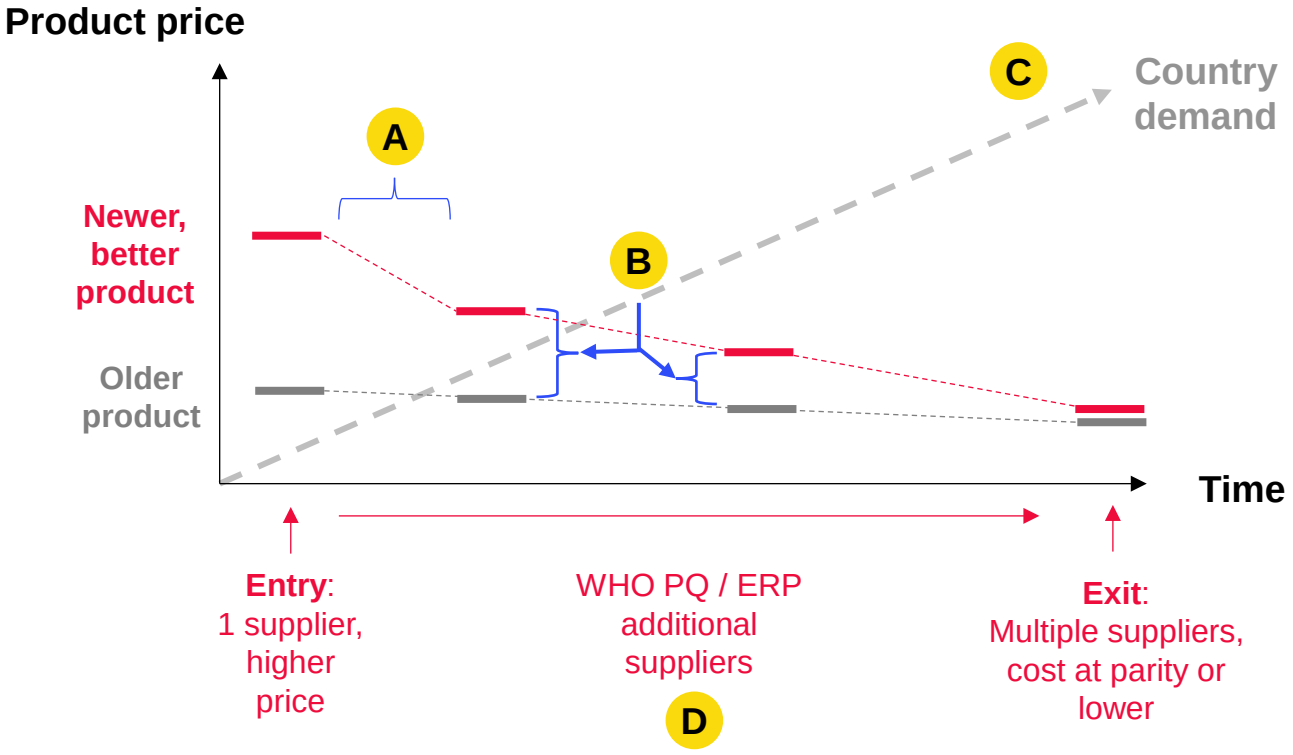
Key Partners*

Unitaid, IVCC (Building Partnerships Creating Solutions Saving Lives), PEPFAR, PMI U.S. President's Malaria Initiative, MMV Medicines for Malaria Venture, FIND Diagnosis for all, Bill & Melinda Gates Foundation, World Health Organization, Africa CDC, The World Bank

* Illustrative

Health product introduction interventions intend to address barriers to timely, scaled uptake of new health products

Simplified / Illustrative Market Dynamic Diagram for Health Product Introductions



A **Advance volume commitments** to secure lower pricing at market entry, increased capacity and shorter lead times

B **Access support** to co-finance product costs for country programs and build demand to achieve economies of scale to drive down prices

C **Demand mobilization and country readiness** to ensure national programs and affected communities are prepared to rapidly adopt, introduce, and scale product use

D **Regulatory interventions** aim to accelerate robust approvals for new introductions

***Note:** not all innovations enter market at higher cost nor do all innovations replace older offerings (e.g., current PrEP innovations will add to package of HIV prevention offerings); market intervention levers are not required for all innovations (will vary based on product and market dynamics)

Ensuring Excellence: Quality Assurance

Olivier Ducamp, Senior Manager, Quality Assurance & Compliance, the Global Fund

Content

QA Policy for VCPs:
Second and Final Step in the Review/Update of TGF QA Policies

1 SC23/B50

- Update the **QA Policy for Pharmaceutical Products**
- Amend the QA Policy for Diagnostics Products, to incorporate diagnostic products/in-vitro diagnostics and Personal Protective Equipment (PPE) and become the Amended and Restated **QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core PPE**

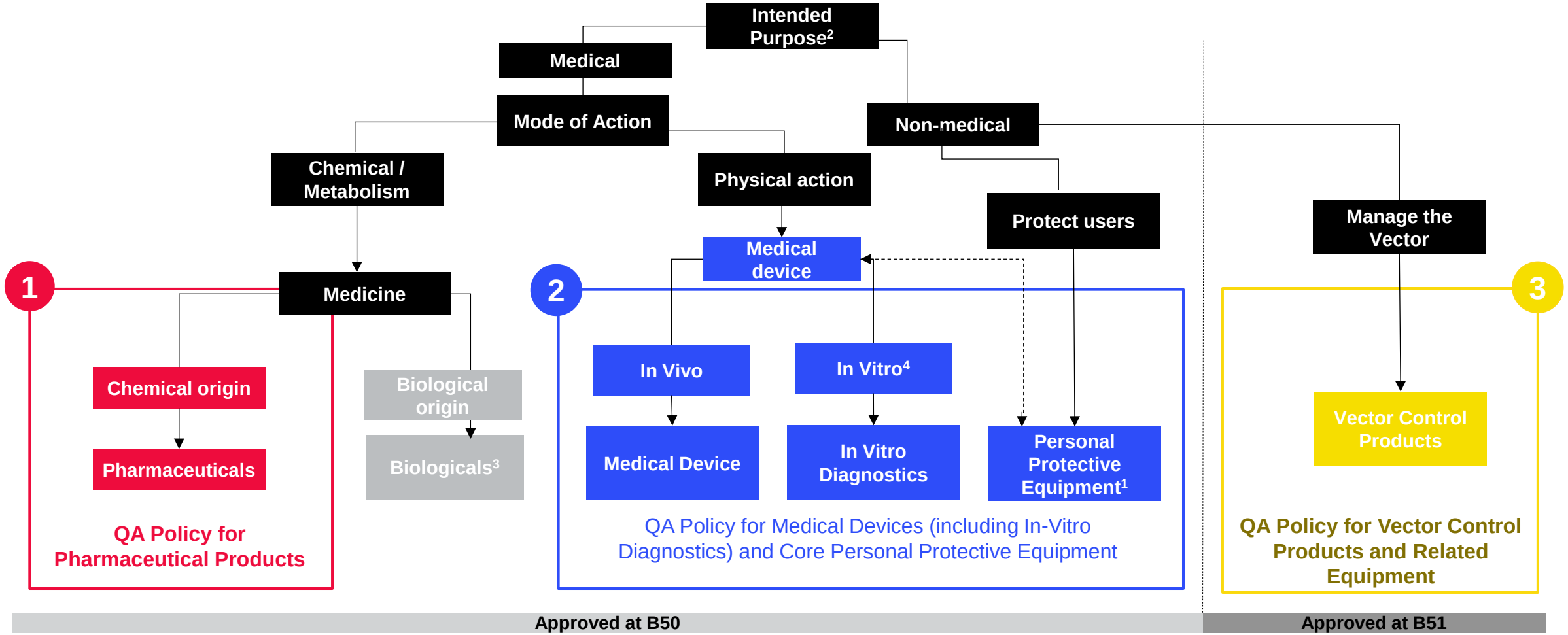
2 SC24/B51

- Develop a **QA Policy for Vector Control Products and Related Equipment**, including insecticide treated nets, indoor residual spraying and other vector control products

The launch of Step 2 was **contingent on the release of WHO guidance** on quality assurance of vector control products (**issued in December 2023)**

The QA Policy Framework Covers the Range of Global Fund-Financed Health Products

Schematic Representation of Health Product Categories[1]



[1] Simplified overview. For more detail, please refer to the standardized definition of each health product category
[2] Some products may meet the conditions for more than one product category. In such cases, quality assurance requirements for both categories apply
[3] Current TGF spend on Biologicals is negligible and thus does not warrant development of a QA policy to date
[4] On samples taken from the human body

Approach for Developing the QA Policy for VCPs & Related Equipment

Policy development

There was **no existing QA Policy for Vector Control Products**. Unlike the QA requirements for other health products, the Global Fund's QA requirements for Vector Control Products were managed at the operational level

The QA Policy has therefore been developed from scratch by:

Elevating requirements from existing operational guidance, which will help to ensure there is smooth implementation of the Policy

Aligning requirements to other QA Policies, where appropriate, maintaining some key differences to reflect the nuances of vector control products (see table)

Enhancing requirements where needed, to ensure Global Fund's response is fit-for-purpose

Key differences from other QA Policies

Difference	Rationale
WHO-Listed Authorities and Emergency Use Listing (EUL) not included	Not established timeline to date for extending the WLA framework to VCPs; EUL is not an available modality for VCPs
Stronger guidance on storage and waste management	The safe storage and waste management of VCPs is important for minimizing health risks for handlers, protecting the environment and preserving pesticide effectiveness. Many jurisdictions have regulations to be complied with
Additional recommendations on traceability, and resistance monitoring	More explicit traceability requirements can help address post-market surveillance and other supply chain requirements and centralized monitoring activities organized or endorsed by the Global Fund (e.g., as partnership efforts are advancing to ensure field performance of ITNs). A stronger emphasis on insecticide resistance monitoring is critical in light of increasing biological threats to insecticide effectiveness

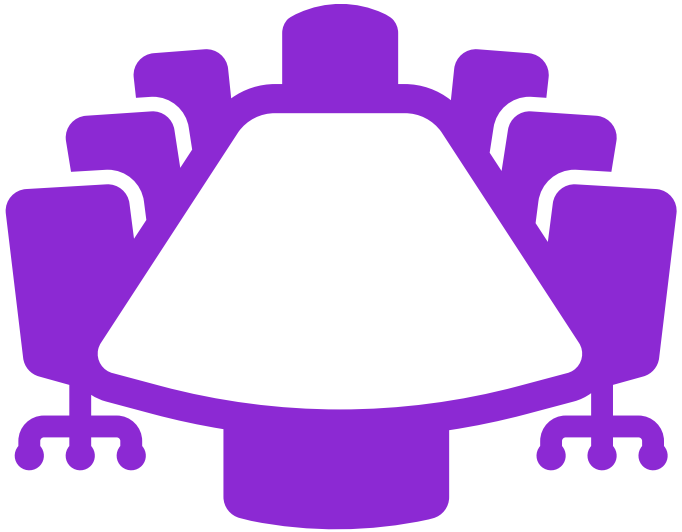
Quality Assurance Requirements - Upstream

Reference	*Requirement (QA Policy for VCPs and Related Equipment)*
Clinical Standards	National or regional malaria vector control guideline / strategy OR WHO guidelines for malaria OR WHO rapid communication on Malaria
Quality Standards & Authorizations	1. Compliance with: • Applicable laws and regulations AND • Authorized by NRA in the country of use 2. (i) Prequalified by the WHO Prequalification Programme; or (ii) Recommended for use by the ERP. 3. (i) Related equipment comply with WHO specifications (ii) Related PPE comply with QA policy for MDs (including IVDs) and core PPE
Selection	• If 2 or more WHO PQ'ed VCPs available → select WHO PQ'ed VCP • If none or only 1 WHO PQ'ed VCP available → selection of ERP VCP can be envisaged • Approval of procurement of ERP products required
Monitoring Product Quality (Pre-shipment inspection, sampling and testing)	Inspection and Sampling (Risk based / Independent sampling agent / Per WHO or internationally recognized standards) Testing (Independent laboratory with testing methods in the scope of accreditation, in accordance with ISO 17025 OR GLPs certified / Testing conducted in accordance to methods and specifications approved by WHO PQ or ERP)

Quality Assurance Requirements - Downstream/In-Country

Reference	*Requirement (QA Policy for VCPs and Related Equipment)*
Transportation, storage and distribution	• WHO or internationally recognized guidance for good transportation, storage and distribution practices • Traceability mechanisms encouraged
Monitoring Product Quality (Throughout the Supply chain)	• Monitoring plan and implementation done in collaboration with NRA • Per WHO / internationally recognized guidelines • Results submitted to stakeholders including TGF *Principles for consideration:* • *Risk-based approach for products identification and verification activities* • *Verification activities strategies (visual inspection, partial or full testing) to ensure that the high costly activities have the best chances to provide meaningful results* • *Costs related to the quality control activities and technical assistance to strengthen NRA capacities on this matter may be considered in TGF grant*
Monitoring Insecticide resistance	• PRs Implement insecticide resistance surveillance plan • Use of insecticide susceptibility test kits and impregnated papers per WHO recommendations
Incidents & Product non-compliance	• PRs develop and maintain a reporting system • Reporting per NRA requirements • Communication with stakeholders
Waste management	• Done in line with National / regional guidelines OR • Global Fund, WHO or FAO issued guidance

Establishment of an Expert Review Panel for VCPs



- ERP for VCPs will **allow the Global Fund to make risk-informed decisions to accelerate the introduction and scale up of innovative products**, while awaiting their full review and approval through required mechanisms (i.e. WHO's pre-qualification program)
- The ERP is a group of independent experts that reviews the potential risks and benefits associated with the use of health products that do not yet have the required regulatory approval required by TGF, but which have a demonstrated public health value
- Accelerated introduction of new VCPs is critical to mitigate and manage the risks associated with increasing insecticide resistance, and ensure the ongoing response is effective. ERP for VCP will follow same process like for the other healthcare products (pharma & diagnostics)

The Global Fund Secretariat is working with WHO to establish the Terms of Reference for the ERP for VCPs

Expert Review Panel (ERP)

Process Steps

KEY DELIVERABLES

- Stakeholders' consultations
- Finalized scope of product categories to accept EoI

- "Invitation for EoI" published on TGF website
- Manufacturer submit an EoI (questionnaire & supporting documentation)

- Manufacturers are informed about the screening outcome of the Product Questionnaire

- ERP Meetings/ Review
- TGF receives the outcome of the ERP Review

- Inform manufacturer on the ERP Review outcome and decision
- Update TGF List of products
- Request Additional Data
- Implement Risk mitigations if applicable

- Transfer of additional data from manufacturer for ERP Review

- ERP Review of additional data
- TGF receives ERP Reports

- Inform manufacturer on the ERP Review outcome and decision
- Update of TGF List of products
- Implement Risk mitigations if applicable

Operationalization of the QA Policy

By design changes initiated by the QA Policies are to be translated into the lower levels of TGF documentation

QA Policy
approved by TGF Board provides high level QA requirements for products and practices

Health Products Guide*
approved by TGF EGMC recalls high level requirements along with additional detailed requirements

Other Internationally recognized **guidance, norms and standards** issued by WHO, ISO or Others

QA Briefing Notes
issued by TGF QA & Compliance Team (in consultation with internal/external stakeholders) provide operational guidance to facilitate the implementation of the quality requirements from the QA Policy. **Two Briefing Notes in Place –Visual Inspection of ITNs and Sampling , Testing and reporting results of ITNs. Being reviewed to include IRS products**

Signals, accidents, OOS…

QA Information Notices
issued by TGF QA & Compliance Team to inform about specific risks and necessary mitigations measures

Monitoring Product Quality
Recipients to monitor quality and performance of VCP along the supply chain

Other Quality Assurance Documents:

Issued by TGF QA & Compliance Team (in consultation with internal/external stakeholders) provide operational guidance to facilitate the implementation of the quality requirements

***The "Guide to Global Fund Policies on Procurement and Supply Management of Health Products" is sometimes referred to as the "PSM Guide" or, in Global Fund Grant Regulations, as the "Health Products Guide"**

Recommendations for manufacturers

- Registration/marketing authorization in the country of use: Synchronize market clearance activities for new product introduction and benefit from WHO-PQ approval reliance
- Change management: Anticipate as much as possible necessary post-approval changes with WHO-PQ (and inform The Global Fund accordingly)
- Continuous improvement: learn from nonconformities and mitigate risks… due root cause analysis resulting in effective CAPA (<30-day submission requirement)
- ERP: Consider using the mechanism once operationalized
- Keep in mind! Manufacturing sites to comply with ISO 9001 standard on QMS requirements / Third-party warehouses/additional storage sites to comply with national regulations, covered by ISO 9001 standard on QMS requirements or Good Storage and Distribution Practices (GSDP)

Navigating the Future of ITNs

Moses Muputisi, Manager, Demand and Planning, the Global Fund

Eric Nyiligira, Manager, Health Product Management, the Global Fund

Lin Li, Senior Manager, Direct Sourcing, the Global Fund

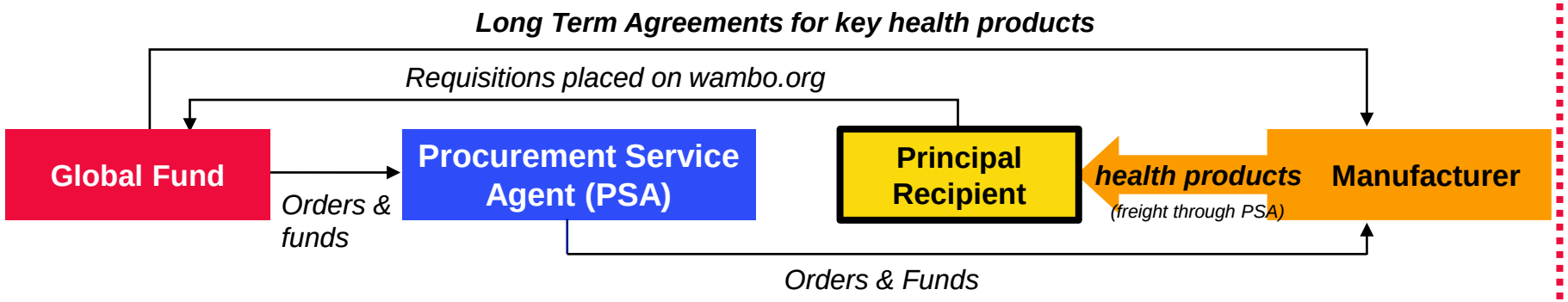
Anne-Sophie Briand, Senior Specialist Vector Control, the Global Fund

Procurement Channels and Routes to Market

Every year about $ 2-3 billion or more of the Global Fund's grant financing is used for procurement of health products with the Global Funds Pooled Procurement Mechanism (PPM) being the largest channel, representing around 50-60% health product spend depending on the category.

Three types of channel that implementing countries use for the procurement of health products

1. Pooled Procurement Mechanism (PPM/wambo) Managed by Supply Operations Department in the Global Fund Secretariat
   (50-60% by value)



2. National Procurement Mechanisms

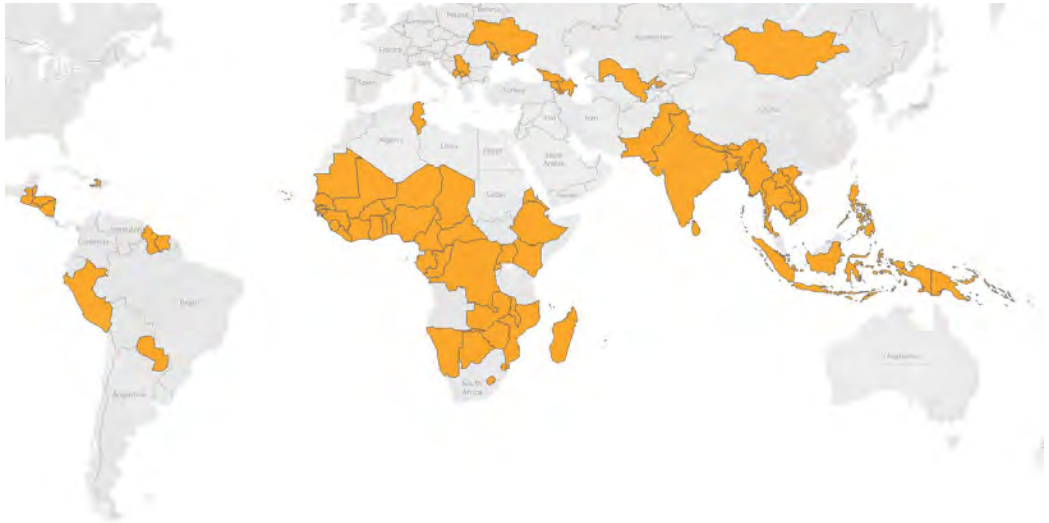
3. Other Procurement Agents (e.g., UN agencies when they are PR); Stop TB's Global Drug Facility*

* Recipients of Global Fund funding for TB often procure medicines & may procure other health products for TB through the Stop TB Partnership's Global Drug Facility (GDF).

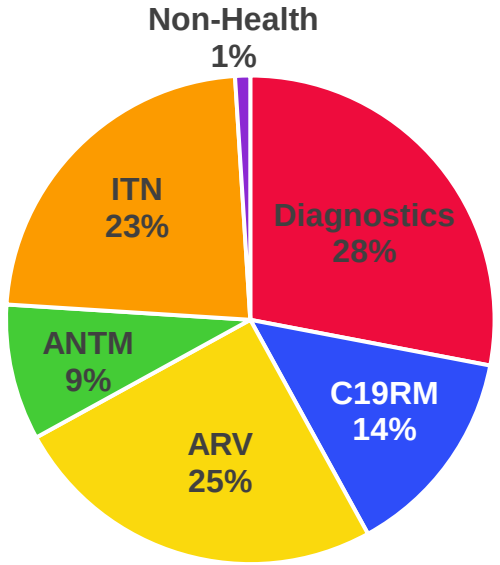
US$1.34 billion orders placed in 2023 through PPM

Nearly 5,000 shipments of needed health products reliably delivered despite global supply chain disruptions

PPM through its wambo.org platform connected **452 PR users** from **108 organizations** in **81 countries**



Processed 1,367 Purchase Orders for a total value of US$1.34 billion



Product category spend (US$)

Diagnostics: diagnostic and lab consumables and equipment

C19RM: pandemic preparedness through the Global Fund's C19RM financing

ARV: antiretrovirals

ANTM: antimalarials

ITN: Insecticide-treated nets

Environmental sustainability: Increased shipment by sea to mitigate carbon footprint associated with delivery.

79% by value

95% by volume

We have long supported regional diversification of the supply base and are committed to doing more

African sourcing outcomes – 2022

~98%
of co-trimoxazole
(an essential medicine) PPM volumes produced in Africa

~19%
of insecticide-treated nets
PPM volumes produced in Africa for Africa

~17%
of artemether/lumefantrine (an antimalarial medicine) PPM volumes produced in Africa

11%
of AQSP for 2025 SMC campaign

Priority Global Fund interventions to build capacity for regional manufacturing

The Global Fund will deliver complementary, sustainable interventions through its **NextGen Market Shaping approach** to accelerate equitable access to quality-assured health products, both grant-funded and non-grant funded.

1. Support accelerated product qualification and country demand forecasting
2. Engage with regional procurement platforms and consortiums to increase sustainable capacity
3. Build inter-agency efforts and partner and country engagement to identify key priorities
4. Support regional regulatory framework strengthening and harmonization
5. Advocate for technology transfers & know-how upstream

THE GLOBAL FUND

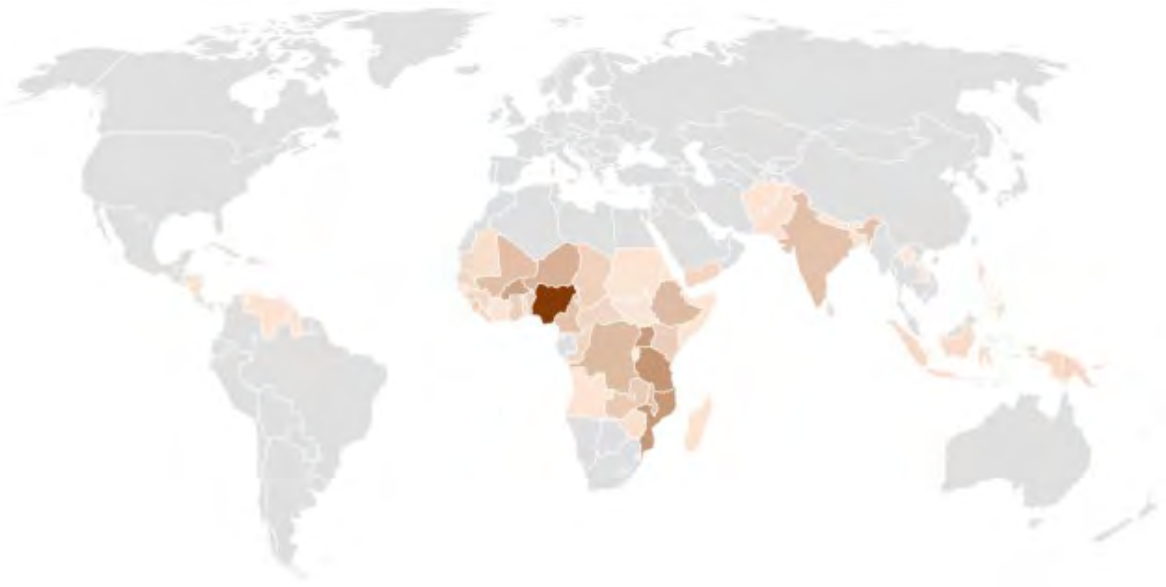
Source: Global Fund Results Report 2023

Addressing Challenges and Opportunities in Dual AI Transition

PPM ITN demand is driven by countries with the highest malaria burden

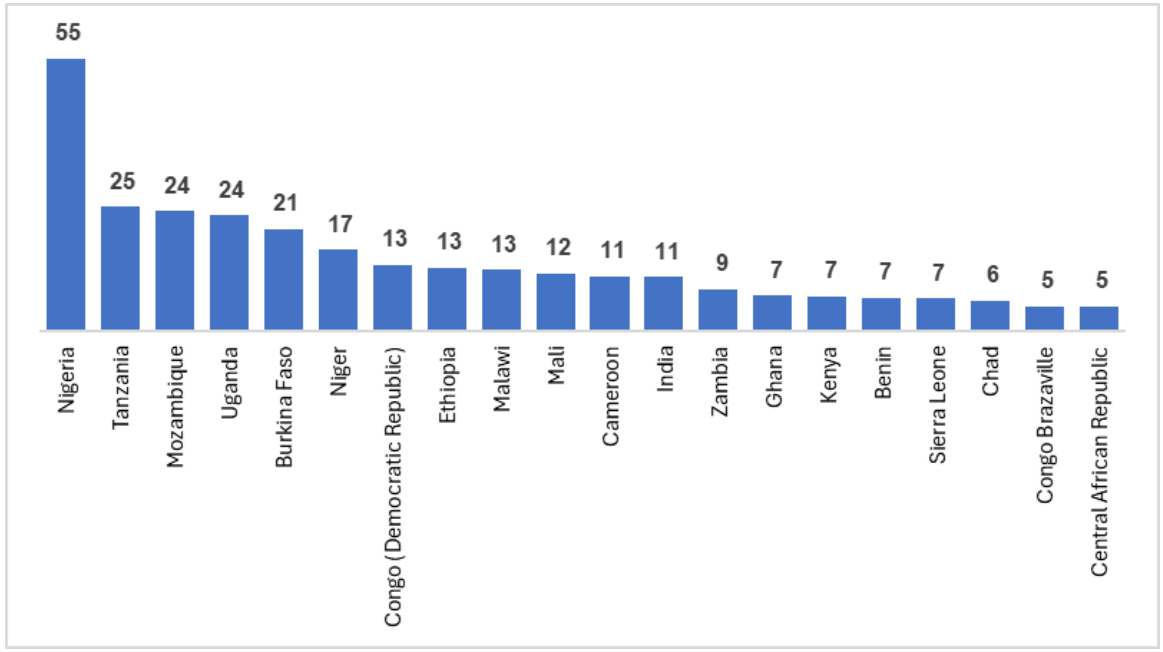
Nigeria, DR Congo, Uganda and Mozambique alone represent ~50% of malaria cases worldwide

PPM planned deliveries of 328 million nets to 46 countries from 2024 to 2026



Bangladesh, Benin, Bhutan, Burkina Faso, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo (Democratic Republic), Congo Brazzaville, Eswatini, Ethiopia, Gambia, Ghana, Guinea, Guyana, Honduras, India, Indonesia, Kenya, Liberia, Malawi, Mali, Mauritania, Mozambique, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Tanzania, Timor-Leste, Togo, Uganda, Yemen, Zambia, Zanzibar, Zimbabwe

Top 20 countries represent 90% of the ITN total PPM demand from 2024 - 2026

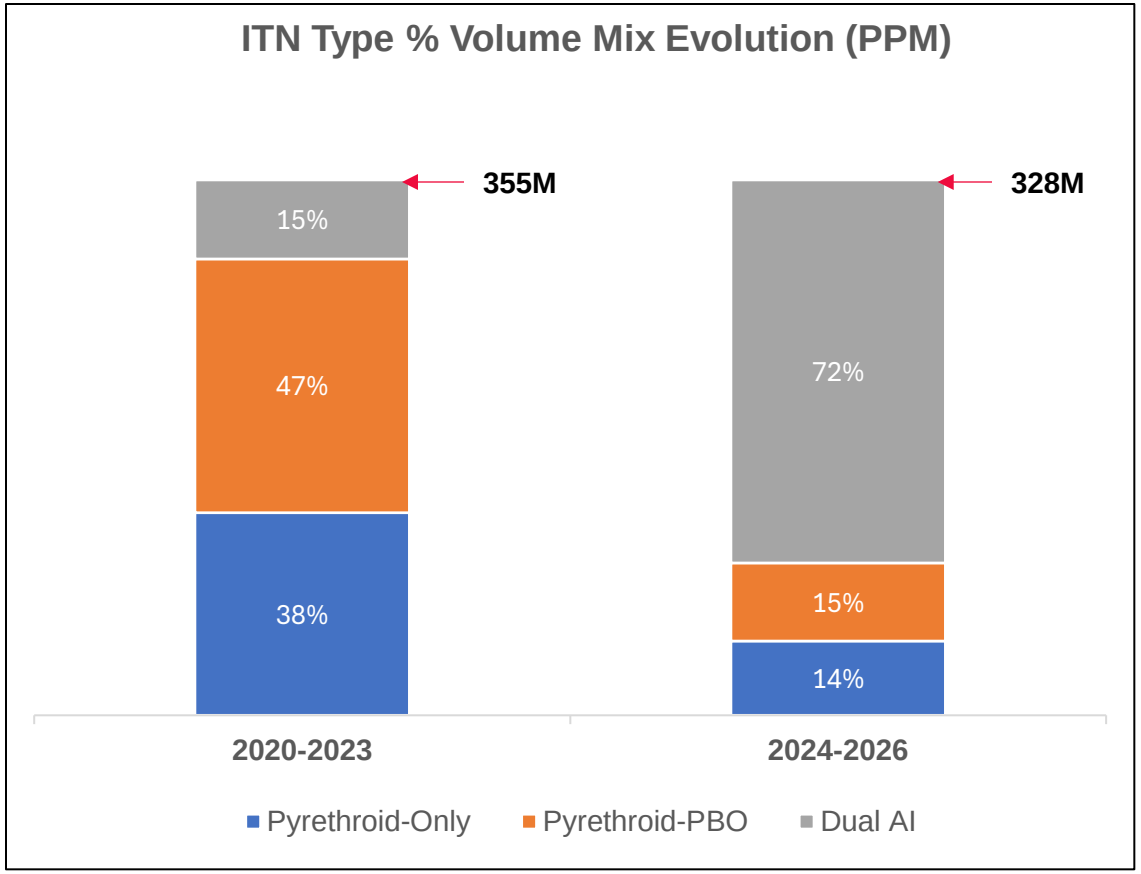


Figures include all net types procured or planned
PPM classification based on 2020-2023 period

Demand Conversion to Dual AI

Considering the increasing biologic threats and the impact of climate change, accelerating dual AI net introduction in the current grant cycle (2024-2026) is a critical part of the Global Fund's ITN procurement strategy.

- Rapid shift to dual AI in 2024-2026 period compared to 2021-2023.
  - Dual AI now contributing 72% of PPM volumes, up from 15% in 2020-2023.
  - Growth of dual AI volumes comes at the expense of both Pyrethroid Only and Pyrethroid PBO net types. PBO net type has contributed more to the dual AI growth than Pyrethroid Only.
- Overall reduction in PPM volumes between the two periods from 355M to 328M although some changes are still expected in the 2024-2026 volumes.
  - Lower PPM volumes in current cycle partly due to less affordability of dual AI.
  - Affordability is still an important factor for improved access of dual AI nets.
- Including non-PPM volumes (total of ~400M) dual AI nets still projected at over 60% (254M) of total Global Fund funded volumes.
  - Dual AI nets funded by the Global Fund estimated at 80% - 90% of current international funded dual AI nets.



Dual AI volumes in 2021-2023 are from the New Net Project

PPM Dual AI projected demand

The GF PPM accelerated the dual AI roll-out at scale in the last 18 months, thanks to the WHO recommendation and demand mobilization by the Global Fund Country Teams. Projected PPM Dual AI demand increased from April 2023 estimates of ~30% to 72% as of November 2024

April 2023

Product	Year 2024 *	2025	2026
Pyrethroid-only	15 - 34M	30 - 39M	3 - 4M
Pyrethroid-PBO	24 - 40M	30 - 66M	3 - 13M
Dual A.I.	38 - 74M	41 - 86M	11 - 22M
TOTAL	**110 - 120M**	**140 - 150M**	**30 - 40M**

NOTE: This is based on available information as of April 2023. Additionaly updates will occur during 2023 as new Global Fund GC7 grants are made and approved during Q2 and Q3 2023. In particular, 2026 aggregate demand is expected to be further refined in subsequent iterations based upon GC7 grant making.

Forecast figures are based on PO placement date.

** Includes "advanced procurement" for about 42M of orders to be placed during 2023 for deliveries in 2024, and which are to be funded by GC7.*

November 2024

Year 2024*	2025	2026	TOTAL
19.7M	10.7M	19.8M	**50.3M**
23.6M	14.0M	4.9M	**42.5M**
42.9M	115.5M	76.7M	**235.1M**
86.2M	**140.3M**	**101.5M**	**327.9M**

- Increase in total volume between Apr 2023 and Nov 2024 (~20M) driven by some countries switching from non-PPM to PPM.
- Accelerated conversion from both Pyrethroid Only and Pyrethroid PBO to dual AI during 2024 leads to big variances by net type.

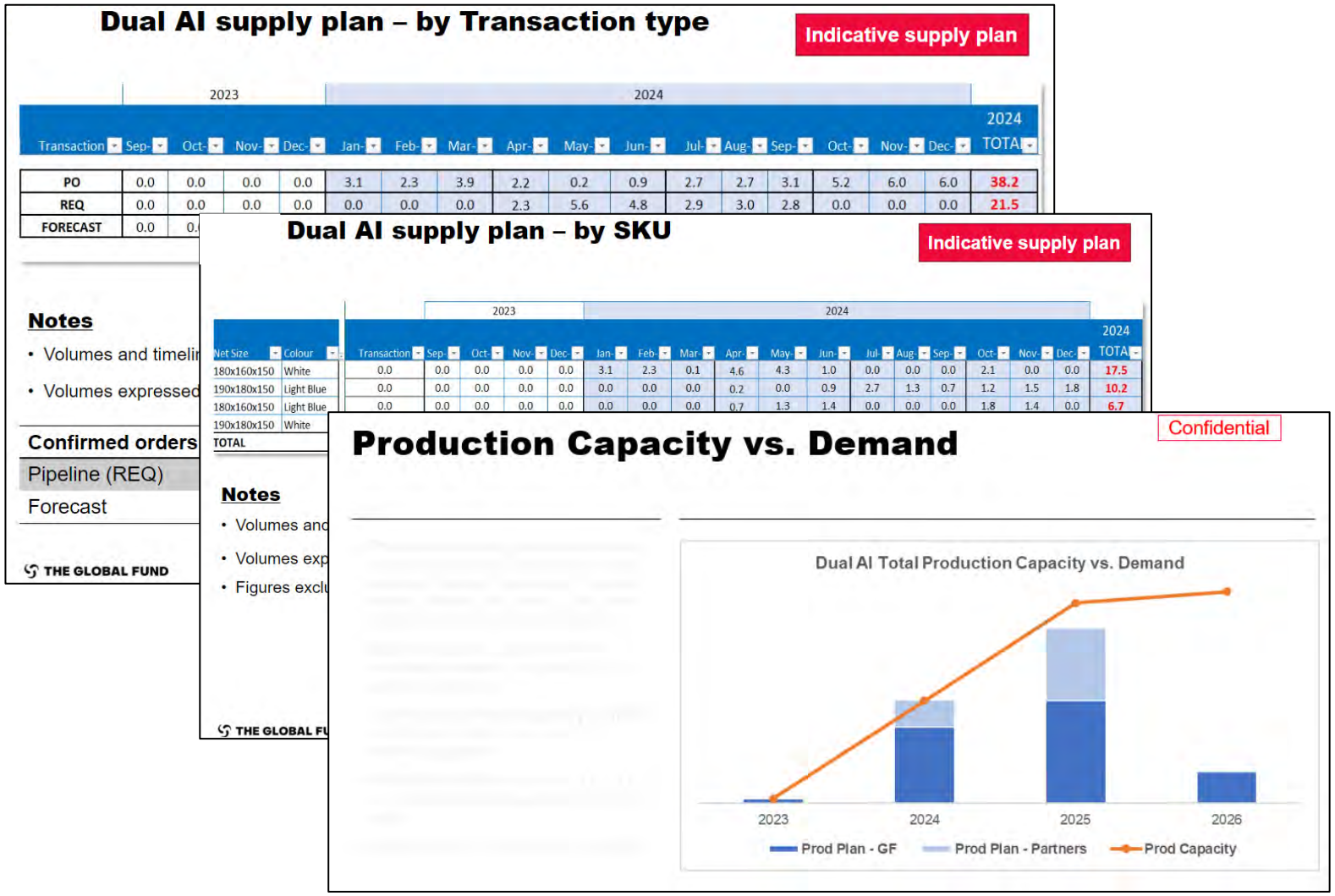
Key Features - Dual AI operational model (2023-2026)

Monthly capacity and production scheduling: Align production capacity with monthly demand to optimize resources, avoid bottlenecks, and ensure timely production and delivery of ITNs.

Restricting to 4 SKUs: Reducing SKUs simplifies manufacturing, quality control, and shipping, leading to faster production, better planning, and lower unit costs through economies of scale.

Supply planning: Provides manufacturers with forward visibility of demand over a 12-month period to assess and validate capacity and other resources availability to meet demand.

Strong Partner Coordination on Demand: Close coordination between the Global Fund and partners ensures accurate demand forecasts and aligned production schedules.



Operational challenges in Shipment and Logistics

Pre-testing shipment process: Delayed documents, changing inspection sites, unavailable inspectors, and goods stored in multiple warehouses increase time, resources, and costs.

Loading capacity limitations at the manufacturer level: Container capacity discrepancies cause booking delays, higher freight costs, and inefficiencies. Warehouse management issues limit loading, while discrepancies in loaded/offloaded quantities persist, with inconsistent third-party inspections. Container stuffing often deviates from POs for multi-destination shipments.

Any other freight or logistical issues: Vessel rollovers and blank sailings cause booking delays; force majeure events and port congestion, extend lead times. Red Sea issues contribute to rising prices.

ITN Market Dynamics

Actual Supplier Overview

WHO Prequalified ITN Supply Base

Supplier4	Pyrethroid nets	PBO nets	Dual ai nets
A to Z Textile Mills	X	X	(X)*
BASF	X		X
Disease Control Technologies			
Fujian Yamei	X	X	
Life Ideas	X		
Mainpol	X	X	X
PPP Hollandi	X	X	
Real Relief	X		
Shobikaa	X	X	
Sumitomo Chemical	X	X	
Vestergaard	X	X	X
V.K.A. Polymers	X	X	(X)*
Yorkool	X	X	X
Total	**12**	**9**	**4 (2)**

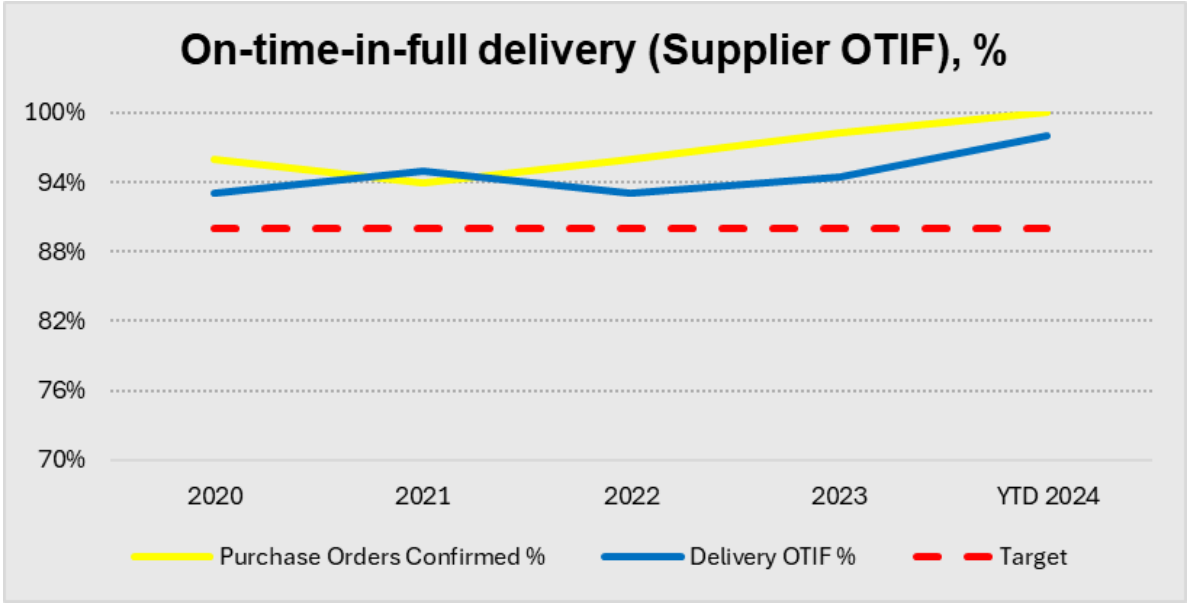
- Need to **expand supplier base** on Dual AI nets and regional manufacturing
- Encourage suppliers to **invest in their production development**
- Encourage **technical transfer and licensing** to accelerate the regional manufacturing

Source: WHO Prequalified Vector Control Products list, status as of 6 December 2023
*Source: WHO Vector Control Products Pipeline, status as of 6 December 2023

Consistently high supplier delivery performance

Despite global challenges, on-time, in-full delivery (OTIF) performance remained at or above the 90% minimum target. Global Fund is grateful for the industry's commitment and agility, especially during the Dual AI nets transition.

- **Regular communication with suppliers to** provide visibility and timely PO placement
- **Effective Supply Chain Planning:** timely demand forecasting and close engagement with countries and GF CTs.
- **Strong collaboration across stakeholders** is key to managing the surge demand situation(dual a.i ITN) and ensuring supply; as such, Global Fund actively engages with partners to coordinate the demand planning and capacity uptake
- **Contingency Planning:** Preparing for potential disruptions such as transportation delays or geopolitical events.



- Performance Measurement is based on the principle of comparing the number of supplier shipments delivered "On Time in Full" (OTIF) against the total number of Supplier shipments made. The measurement point shall be the point at which the Supplier has fulfilled their obligations to the PSA regarding the Committed Delivery Date.
- Only PPM shipments are included.

Data Source: Global Fund Procurement Service Agent

Market Observations 1/2

The Global Fund has identified several developments in the ITN sector which directly impact the ITN strategy

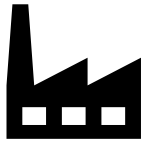
- Climate change poses a “substantial risk” to progress being made to fight malaria.
- To safeguard current vector control tools, there is a need to **continue innovation** and **introduce ITNs with different insecticides.**
- There is a lot of **geopolitical uncertainty** including the level of funding available to fight malaria. Our level of success at the Replenishment will play a key role in determining what we'll be able to afford in the next grant implementation cycle 2027-2029. It will put further **pressure on the cost of dual a.i ITN in the next grant cycle**.
- **Freight issues, inflation, and raw material price increases** may threaten equitable access to ITNs.
- The global focus on climate change is driving manufacturers, buyers, and regulators to adopt practices that **reduce environmental impact across End-to-End ITN supply chain**

Market Observations 2/2

The Global Fund has identified several developments in the ITN sector which directly impact the ITN strategy

- The **rapid transition to dual AI ITNs** has resulted in a limited-capacity ITN supply base, while there remains excess capacity for PYR-only and PBO ITNs. This shift, combined with the updated WHO PQ requirements, may influence the dynamics of the supplier base over time.
- **Expansion** of the **Dual AI nets supplier base** is key to sustaining dual a.i ITN roll-out.
- **Supporting regional manufacturing** to reduce lead times, mitigate supply chain risks, and enhance resilient supply chain.
- Clarities on contract and subcontract manufacturing arrangements and product ownership are essential to **prevent anti-competitive practices and ensure product quality**.
- **There are some outstanding issues to be further addressed**, including material preference, durability, waste management, and emerging topics such as bulk packaging delivery complies with Land and Marine transport regulation

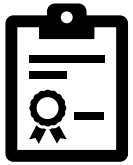
Key enablers for expanding Regional Manufacturing



Regional Manufacturing Expansion: Develop local production facilities and upgrade infrastructure in malaria-endemic regions to ensure cost-effective, quality assured production of insecticide-treated nets (ITNs).

Technical Transfer and Training: Facilitate the transfer of manufacturing knowledge and technology from global experts to regional manufacturers, along with capacity building and training to ensure quality standards.

Licensing and Intellectual Property: Negotiate licensing agreements and accelerate regional manufacturers' access to the technology for producing dual A.I. ITNs at scale.

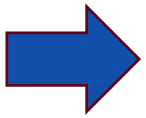


Quality Control and Regulatory Compliance: Align regional manufacturing with international standards for quality assurance, ensuring products meet WHO prequalification and national regulatory requirements for safety and efficacy.

Public-Private Partnerships and Sustainability: Foster collaborations between governments, NGOs, and the private sector to scale up production, ensure affordable distribution, and promote the use of sustainable materials and manufacturing processes.

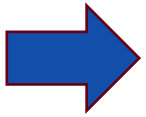
Outstanding challenges observed

- **MATERIAL PREFERENCE:** some user preference for polyester ITNs over polyethylene. Currently, no data or studies have demonstrated that polyester ITNs are superior to polyethylene ITNs in terms of efficacy, durability, or user acceptance.



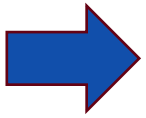
Commitment to Evidence-Based Policy: The Global Fund remains committed to evidence-based decisions and will transparently engage with manufacturers and stakeholders to address this observation.

- **DURABILITY:** Potential variations in durability across suppliers' ITNs, which could result in differing overall effectiveness of the nets over time.



Balancing Sustainability and Cost Impact: The Global Fund recognizes the importance of more durable ITNs but remains mindful of the cost implications, requiring a careful balance between durability and affordability.

- **BULK PACKAGING**: Due to differing interpretations of dangerous goods regulations for transporting bulk ITNs, the Global Fund adjusts ITN deliveries in individual bags to maintain standardization for the dual a.i. ITN, while actively seeking regulatory clarification.



Balancing Compliance and Environmental Impact: The Global Fund strives to comply with regulations on environmental risks, such as marine pollution, while remaining mindful of the waste management challenges individual bags may pose at the country level.

Common Perspectives & Closing Remarks

Lisa Hare, Chief, Malaria Supply Chain Branch, USAID

Lin Li, Direct Sourcing Manager, the Global Fund

Key take away messages

1) INNOVATION: To fight against the malaria bio-efficacy resistance issue, we encourage suppliers to innovate and invest in new product development.

2) PROMOTE REGIONAL MANUFACTURING: Expand/accelerate regional manufacturing footprint through direct investment, technical transfer, or licensing via a partnership.

3) ENHANCE AFFORDABILITY: There are uncertainties ahead, but further improving the affordability of quality-assured dual AI ITNs is crucial to ensuring coverage and fighting bio-efficacy resistance.

4) LEVEL-UP: Embrace the updated WHO PQ requirement to enhance the quality-assured supply base.

5) BUSINESS INTEGRITY: Concerns exist about business practices and subcontracting/contracting arrangements. We are closely monitoring the situation and its development.

Together, we can win the fight against malaria

THANK YOU