
Long-lasting Insecticidal Nets Supplier & Partner Consultative Meeting

26 September 2019

Singapore

LLIN Supplier & Partner Consultative Meeting Agenda

1. ITN Policy Update
2. WHO Prequalification Vector Control Update & Progress
3. Global Fund Responsible Procurement Update
4. Global Fund, PMI, UNICEF LLIN QMS: Collaborative Expectations
5. IVCC Vector Control Product Development Pipeline
6. UNICEF Procurement Update
7. PMI LLIN Sourcing & Procurement Update
8. Global Fund LLIN Procurement Strategy



ITN policy update

Dr. Kate Kolaczinski
Malaria Team, The Global Fund
LLIN suppliers meeting, Singapore, September 2019

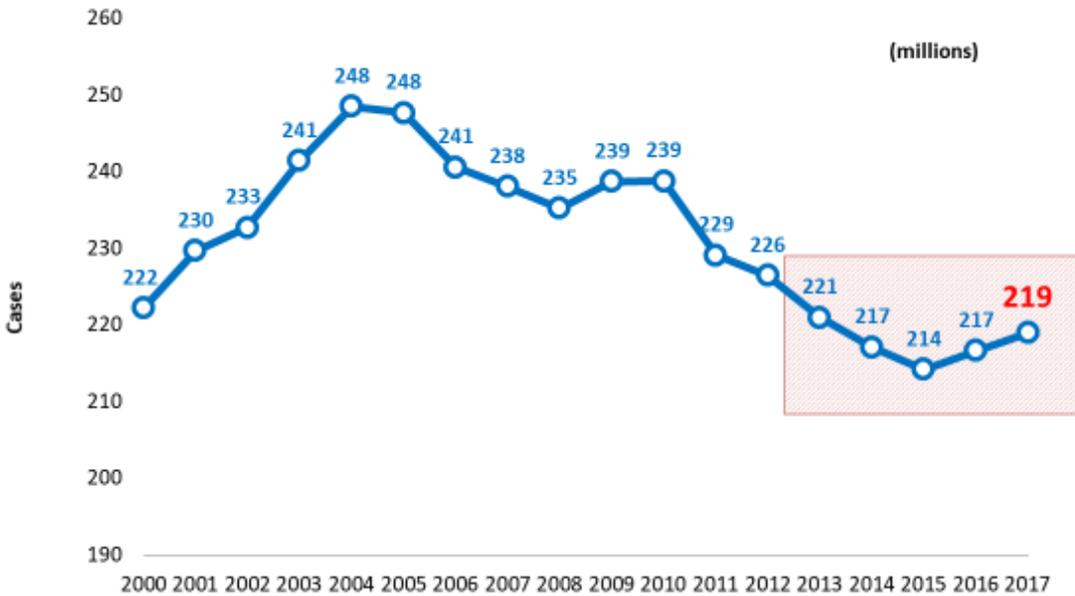
Outline

1. Malaria and funding landscape
2. ITN policy landscape
3. Global Fund approach to funding ITN interventions
4. Question and answer

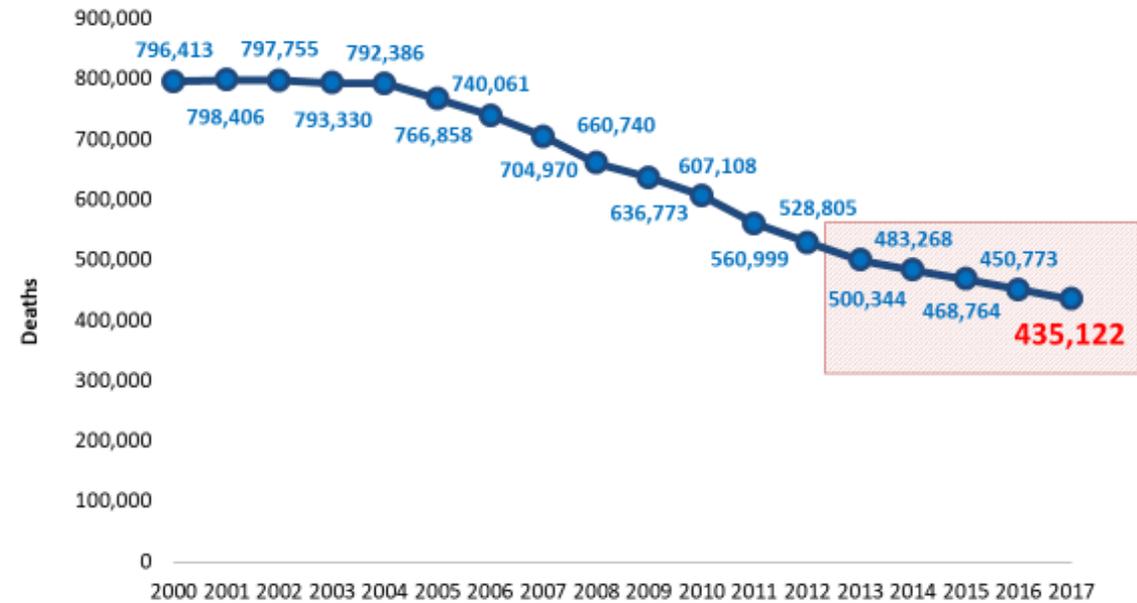
1. Malaria and funding landscape

Worldwide malaria progress: 2000–17

Number of malaria cases



Number of malaria deaths



Figures: Alastair Robb, Global Malaria Programme, WHO

ITN ownership and coverage (Sub-Saharan Africa), 2010–17

Percentage of population at risk with access to an ITN and sleeping under an ITN, and percentage of households with at least one ITN and enough ITNs for all occupants, sub-Saharan Africa, 2010–2017 *Source: ITN coverage model from MAP.^a*

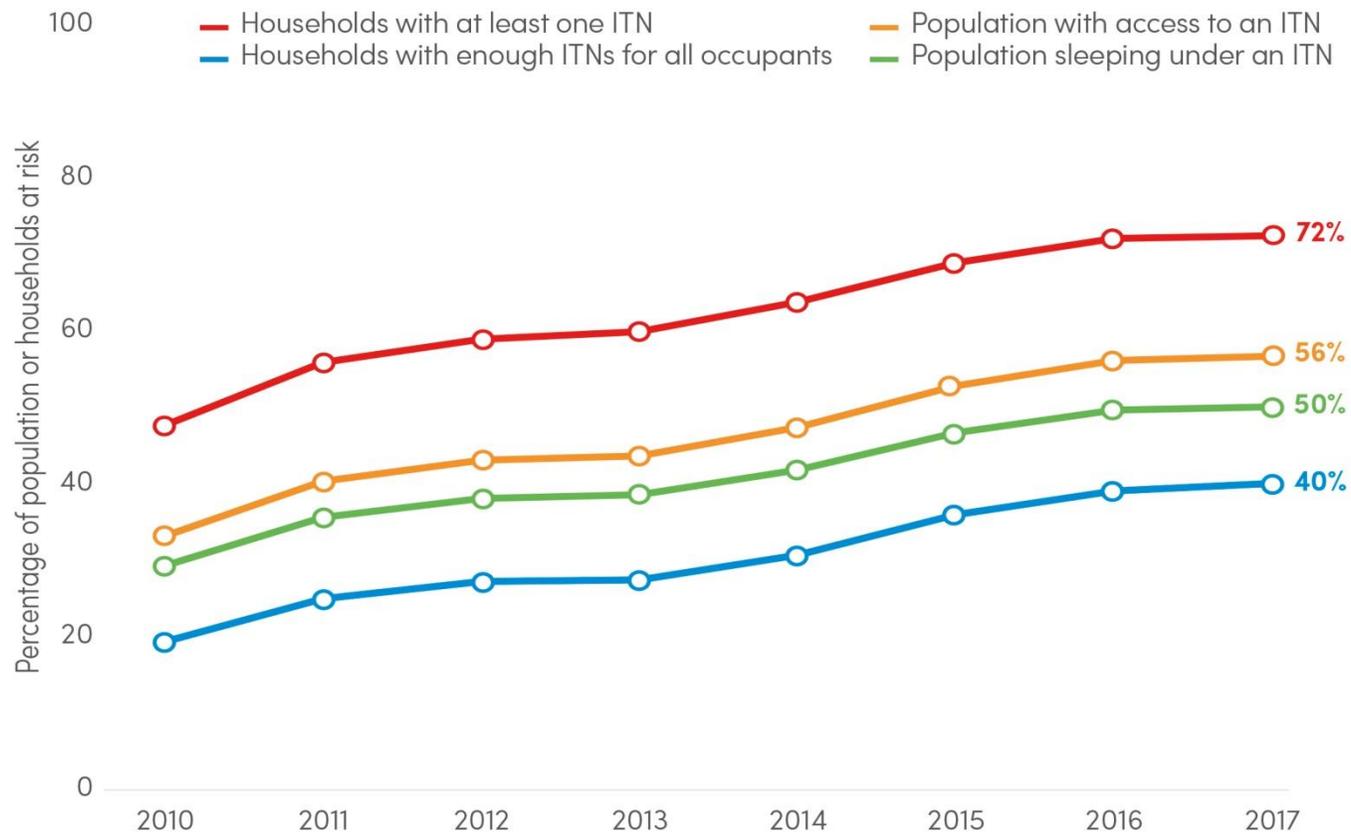


Figure: World Malaria Report, 2018

ITN: insecticide-treated mosquito net; MAP: Malaria Atlas Project.

^a <http://www.map.ox.ac.uk/>

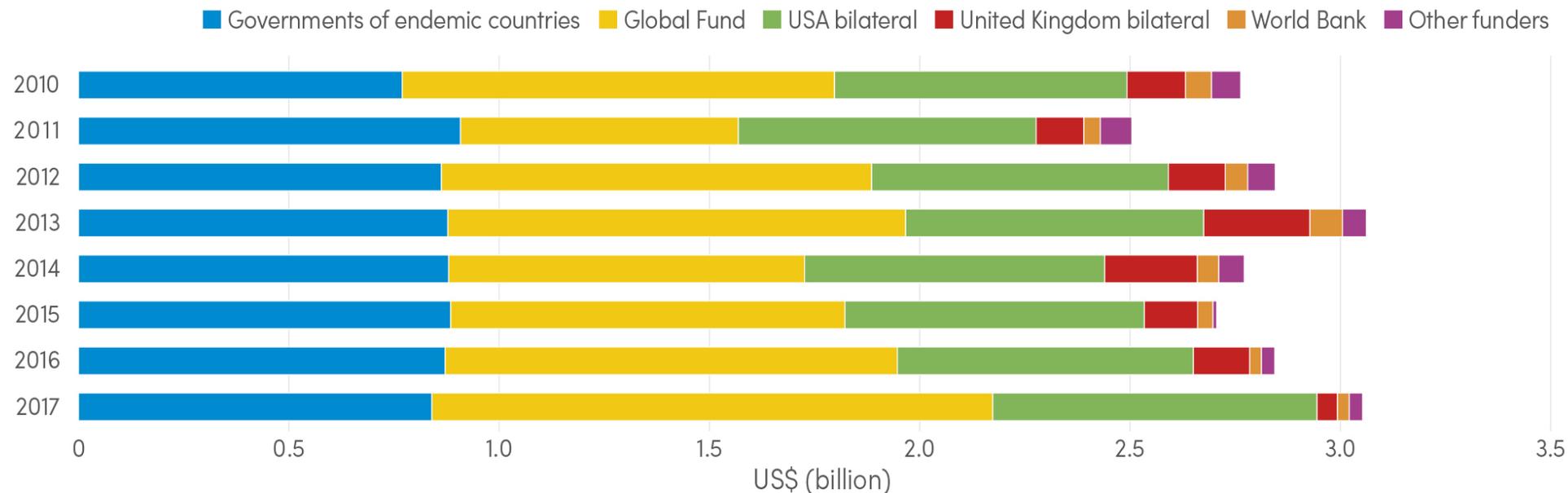
Barriers to progress

- Biological challenges
 - Insecticide resistance
 - Drug resistance
- Tools challenges
 - Durability
 - Efficacy
 - Residual transmission
- Systemic and contextual challenges
 - Health systems
 - Economic environments
 - Climate and climate change?
 - Insufficient funding for full needs

Stagnation in funding levels since 2010

FIG. 2.3.

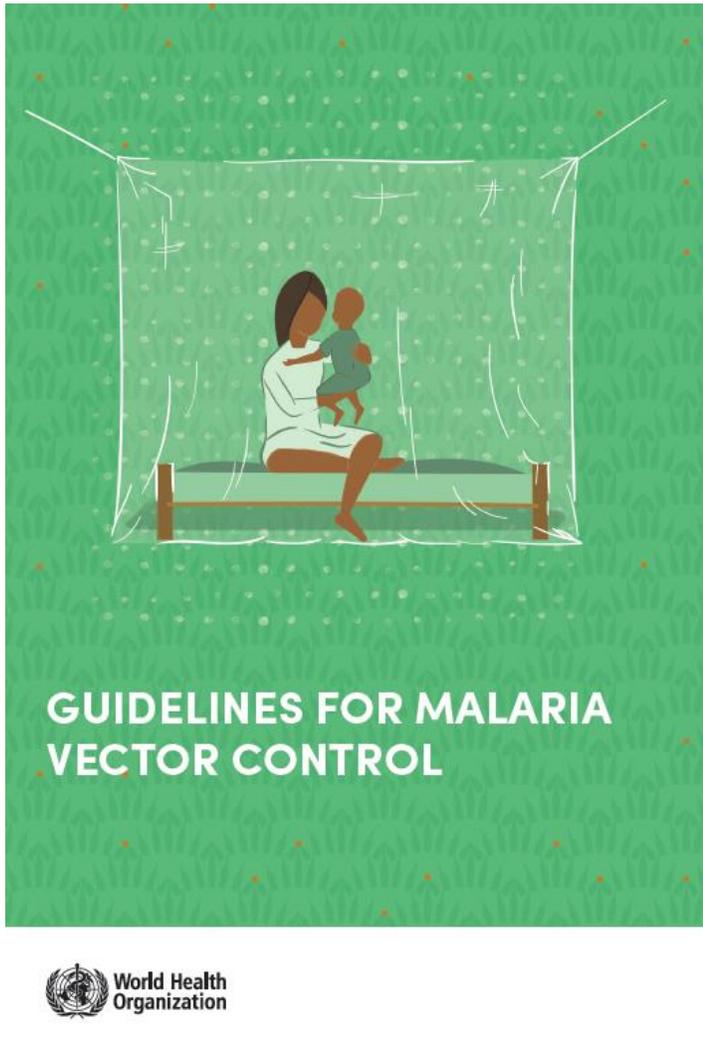
Funding for malaria control and elimination 2010–2017, by channel (constant 2017 US\$) Sources: ForeignAssistance.gov, United Kingdom Department for International Development, Global Fund, NMP reports, OECD creditor reporting system database, the World Bank Data Bank and WHO estimates.



NMP: national malaria programme; OECD: Organisation for Economic Co-operation and Development; USA: United States of America; WHO: World Health Organization.

Figure: World Malaria Report, 2018

2. ITN policy landscape



- WHO Guidelines for malaria vector control
- New document published in mid 2019
- Combines all guidelines on different vector control interventions in once place
- Operational manuals remain separate

MALARIA BURDEN REDUCTION AND ELIMINATION

Universal coverage with effective vector control using a core intervention (ITN or IRS) is recommended for all populations at risk of malaria in most epidemiological and ecological settings.

Good practice statement

Priority should be given to delivering either ITNs or IRS at high coverage and to a high standard, rather than introducing the second intervention as a means to compensate for deficiencies in the implementation of the first intervention.

Conditional recommendation



- Universal coverage of populations at risk with at least one core intervention
- Core vector control interventions:
 - IRS
 - ITNs
- Supplementary interventions recommended only in specific defined contexts
- Combining ITNs and IRS recommended under specific conditions only

INSECTICIDE-TREATED NETS

Pyrethroid-only LLINs prequalified by WHO are recommended for deployment as a core intervention in all malaria-endemic settings.

Strong recommendation as an intervention with public health value, high- certainty evidence

Pyrethroid-PBO nets prequalified by WHO are conditionally recommended for deployment instead of pyrethroid-only LLINs where the principal malaria vector(s) exhibit pyrethroid resistance that is: a) confirmed, b) of intermediate level, and c) conferred (at least in part) by a monooxygenase-based resistance mechanism, as determined by standard procedures.

Conditional recommendation as an intervention with public health value, moderate-certainty evidence



- Pyrethroid-only LLINs recommended as a malaria control tool in all areas
- Pyrethroid-PBO nets recommended in areas:
 - with specific IR context
 - where increased cost won't lead to coverage gaps
- No policy recommendation yet for dual ai nets

3. Global Fund approach



Vector Control

General guidance given to countries:

All country requests for funding should be grounded in a national vector control strategy which is:

- Evidence based: entomologic and epidemiologic data
- In line with WHO global guidance
 - or with clear explanations if local decisions differ
- Aims to ensuring universal coverage of at risk populations with at least one core vector control intervention (IRS or ITNs)
 - While embracing the flexibilities needed to appropriately allocate limited resources to maximize impact



Vector Control

Intervention specific guidance given to countries:

Insecticide treated nets:

- Strong focus on maximizing coverage and use in at risk populations
- Pyrethroid-only LLINs:
 - procurement will continue to follow WHO guidance
- PBO nets:
 - procurement will continue to follow WHO guidance, specific IR and operational conditions to be met if price is higher
- Other prequalified nets that do not have a WHO policy (e.g. dual a.i nets):
 - continue to be available through the New Nets Project pilots only
- Countries deploying PBO nets (or dual a.i nets as pilots) are recommended to not revert back to pyrethroid-only nets in future
- No change to net characteristics policy (size, shape, colour etc) from current cycle
- More funding for net durability and efficacy monitoring likely



Vector Control

Intervention specific guidance given to countries:

Indoor residual spraying and Insecticide treated nets:

- IRS continues to be supported as an effective malaria control intervention
- Countries recommended to maintain coverage in previously GF-supported IRS areas
- Must demonstrate sound insecticide-resistance management strategy and routine monitoring of the quality and coverage of IRS.
- TGF will consider funding ITNs and IRS in the same geographic areas if:
 1. Universal coverage of at risk populations with one method of vector control is ensured
 2. High coverage and utilization/acceptance of the first method
 3. Combination is proposed for the management of insecticide resistance and is proposed as a part of a national insecticide resistance monitoring and management plan.

Questions?

WHO Prequalification Vector Control

Update and Progress

Marion Law, Group Lead
WHO Prequalification – Vector Control

Prequalification process: Application Statistics

Total prequalified products – 77

- ✓ Converted - 71
- ✓ Prequalified - 6

Requests for Determination of Pathway

- ✓ 116 actions to date

Pre submission meetings - many

New applications -23

Change applications - 39

Protocol reviews - 27

Prequalification – VC applications

Prequalified

- ✓ SumiShield 50WG
- ✓ Cielo ULV
- ✓ Fludora Fusion
- ✓ Aquatain AMF
- ✓ Royal Sentry 2.0
- ✓ Royal Guard

Under Assessment

- ✓ Aquastrike
- ✓ Sylando 240 SC
- ✓ Tsara
- ✓ MkitoNet
- ✓ Axient 440EW
- ✓ In2Care Mosquito Trap
- ✓ Imergard

Outputs and ongoing work from Assessment Sessions

Policies

- ✓ Product Labelling
- ✓ Accepting publicly available information to support applications
- ✓ Re-evaluation of active ingredients

Activities

- ✓ Risk assessment models review
- ✓ Label improvement plan
- ✓ Comprehensive Review of Chlorpyrifos
- ✓ Product review of combination of active ingredients in bednets
- ✓ Planning a re-evaluation program for PQ listed products.
- ✓ Regulatory framework - for a gene drive mosquito interventions /products

PQT-VC Assessment Sessions Arusha, Tanzania 2018



PQT-VC Assessment Sessions Arusha, Tanzania 2018



PQT-VC Assessment Sessions Rome, Italy, December 2018



PQT-VC Assessment Sessions

Rome, Italy, December 2018



PQT-VC Assessment Sessions

Dakar, Senegal May 2019



PQT- VC Priorities for 2019

Application assessment (new applications, protocols, changes)

- ✓ Assessor's sessions

Post market activities

- ✓ Implementation of label improvement plan
- ✓ Complaint Process
- ✓ Targeted oversight-surveillance & monitoring
- ✓ Post-market product review

JMPS

- ✓ Continue the integration of processes

Capacity building in countries- fact finding

Guideline review

Opportunity

Build a system, i.e., WHO Vector Control evaluation process, that is robust and ensures access to safe, effective and high quality products throughout their life-cycle and at the same time flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs.

Thank You

Questions / Comments?

Appendix 1

Guiding Principles

Engagement with colleagues, partners, all stakeholders

- ✓ Practice openness and transparency
- ✓ Collaborate, engage and listen through proactive/constructive 2-way communication
- ✓ Demonstrate integrity (judgement/confidentiality/tact/consistency)
- ✓ Be respectful and demonstrate respect

Process and Decision Making

- ✓ Action oriented, i.e., value-added processes which focus on end user access to products
- ✓ Evidence-based
- ✓ Adhere to established roles and responsibilities
- ✓ Transparent
- ✓ Timely
- ✓ Well documented policies and decisions
- ✓ Continuous evaluation and process improvement

Broader Impact

- ✓ Embrace innovation and creativity (Nick Hammon, Innovative Vector Control Consortium)
- ✓ Apply a global perspective to meet varying geographic and disease needs
- ✓ Monitor and evaluate current approaches to meet changing global needs, i.e., remain relevant

Responsible procurement

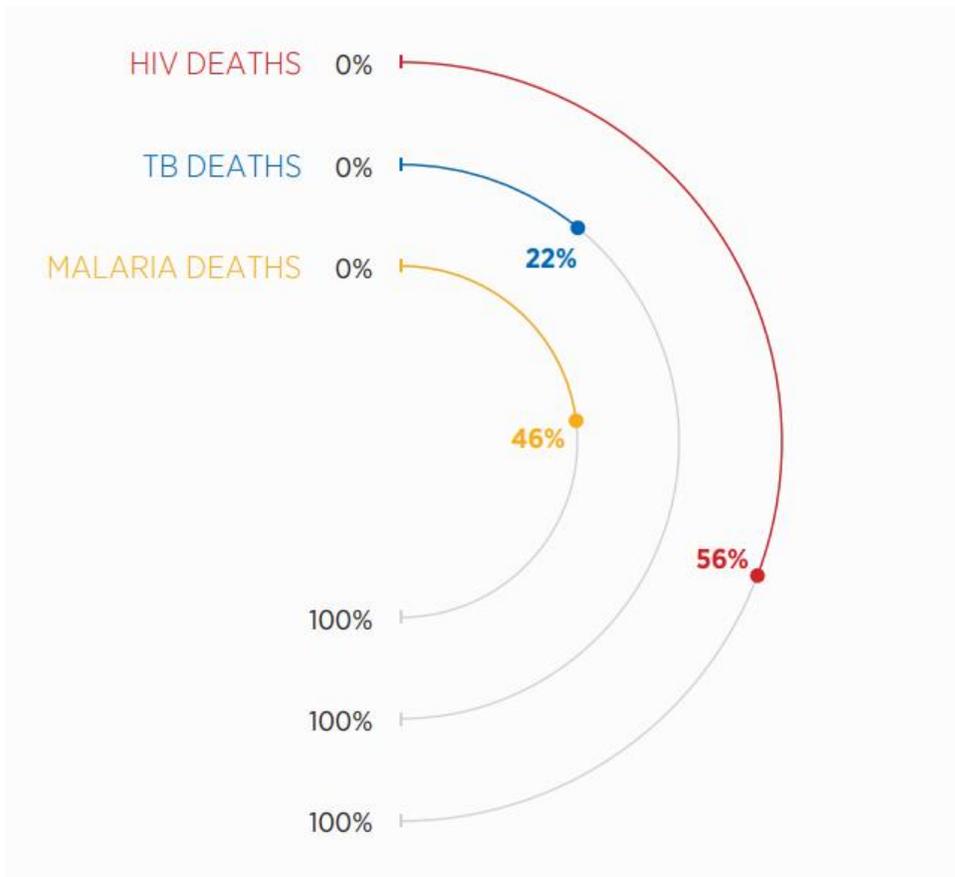
26 SEPTEMBER 2019, SINGAPORE

Global Fund Mission:

Investing the world's money to defeat AIDS, TB & Malaria

32 million
lives saved

40% decline in deaths from three diseases



Ending the epidemics & promoting human rights: Considering the total cost to human well-being



Source: www.cfp.cn



Source: davidmixner.typepad.com



Source: Human Rights Watch (www.hrw.org)

Our values and what they mean for LLIN suppliers

Dignity and respect

Working conditions:

- Labour rights
- Fair bargaining
- Health and safety
- No slavery
- No child labour
- No discrimination
- Gender-consciousness:
 - No harassment
 - No exploitation

Environmental respect:

- Protection from hazards
- Waste management
- Emissions scrubbing
- Waste minimization
- Re-use and recycling

Integrity

- Taking the total cost
- No corruption
- Managing conflicts of interest
- No anti-competitive practices
- Sustainability

Accountability

- Fair, honest and correct information
- Rules-based procurement
- Continuous improvement
- Third-party management
- Prompt disclosure
- Supply chain visibility

Duty of care

- Full and accurate records
- Performance & compliance systems
- Access and audits

We will invest in suppliers who share our values and who in turn invest in meeting these standards

Making Ethics work at the Global Fund



- Accepted in 2014 by the Board
- Defines values and assigns roles
- Unifies codes and policies

- **Ethics Officer**
- **Specialists:**
 - Conflict of interest
 - Counter-fraud & anti-corruption
 - Integrity due diligence

Taking responsibility for LLIN manufacturing

**Market-shaping
strategy**

Integrity pact

Responsible Procurement

Global Fund:

- Revised codes of conduct
- Clear direction
- Strengthened monitoring
- Enhanced disclosures
- Material encouragement
- Continuous engagement

Suppliers:

- Environmental and occupational health certification
- Accountability for full supply chain
- 'Race-to-the-top' innovation
- Responsiveness to raised issues

Specific steps for procuring LLINs responsibly

STANDARDS & CERTIFICATION

Suppliers encouraged to take proactive steps to obtain the EMS and OHS certifications, or work towards fulfilling specific criteria

SUPPLY CHAIN DISCLOSURE

Each supplier must demonstrate the extent of **ownership** and **flexibility** over the entire supply chain, which allows to effect change

ENHANCED DUE DILIGENCE

The Global Fund will be aligning with partners to conduct site reviews, undertake testing and strengthen integrity risk management

LLIN QMS: collaborative expectations

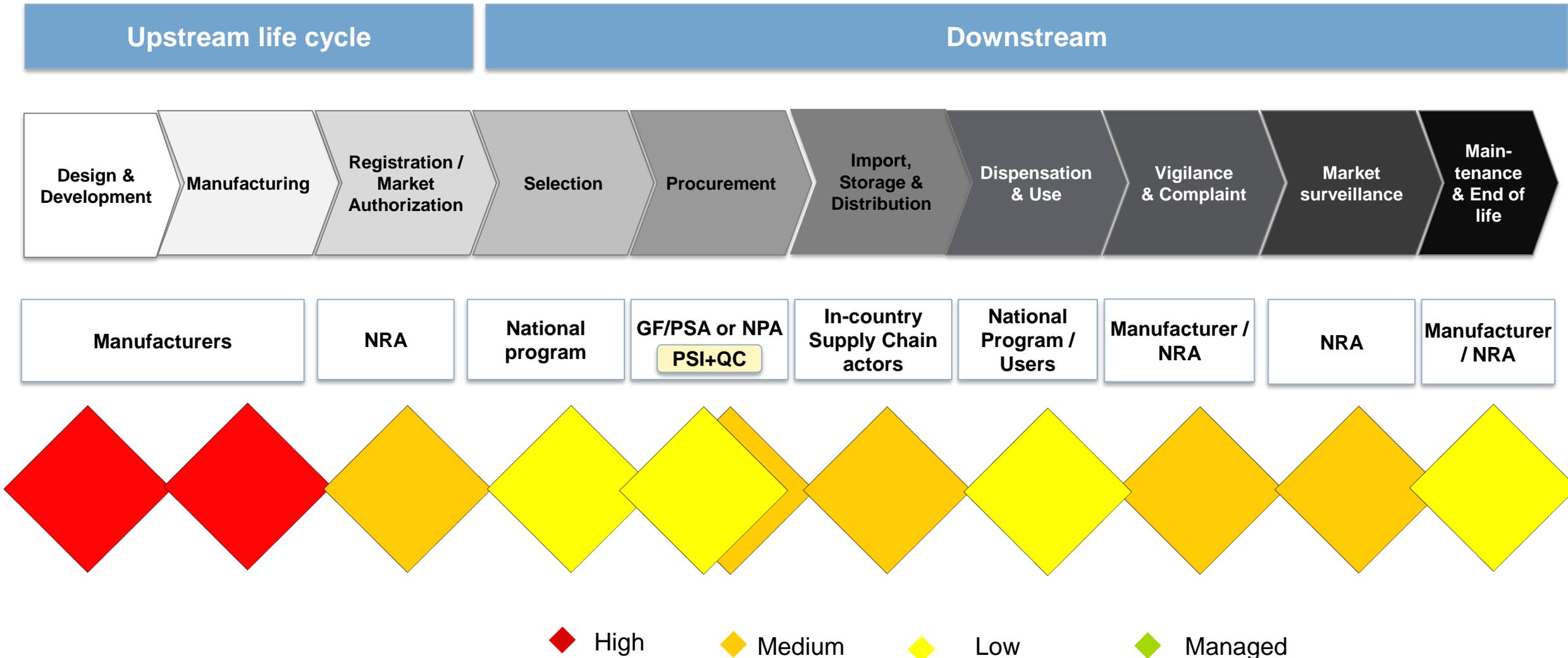
Stuart Turner & Jennifer Wray
on behalf of
The Global Fund, UNICEF & PMI

26 September 2019 – Singapore

PMI-specific QMS enhancements

- Revised contractual requirements from procurement agent
 - Record & product retention
 - Definition of batch
 - Long-term agreements
 - WHO PQ
 - Desk audit - QMS review, in-place SOPs, ISO-9001 & cert documentation, etc
 - Environmental safety clauses
- Physical inspection & quality control testing continued
 - Alignment with GF/UNICEF on physical inspection
 - HPLC,GC on API; bursting strength; seam strength; etc
- LLIN durability monitoring continued
- Post-marketing surveillance – TBD
 - Influence on existing/future contracts and eligibility
 - Donor-level & WHO PQ data exchange
- Evolving as procurement evolves (e.g., PBO & dual AI)

GF estimated Risk Profile along the Product life cycle (qual.)



Overview of QA related requirements in manufacturer agreement

SCOPE	GF/UNICEF	USAID
Product Requirements	<ul style="list-style-type: none"> • Reference to PSM Guide / QA Policy • Packaging Requirements <ul style="list-style-type: none"> • Packing for shipment • Packaging & Labelling Requirements • To ensure supplier product registration 	<ul style="list-style-type: none"> • QA Policy: WHO Vector Control prequalified as minimum. Added testing and monitoring. QMS requirements.
Supplier related obligations	<ul style="list-style-type: none"> • To designate a Responsible person for QA • To convey same obligation to supplier • To ensure compliance with Authorization • To ensure compliance with QMS /GMP standards • To ensure compliance with GDP Standards • To notify any change that may impact the quality 	<ul style="list-style-type: none"> • Supplier to provide documentation & evidence of compliance with GMP. • Assess impact of all changes (materials and process) on quality. • PMI notified of any change requests to WHO PQ.
Regulatory Authority & Audit	<ul style="list-style-type: none"> • To provide report of Regulatory Authority inspection • To notify in case of Warning letter • To accept GF audit 	<ul style="list-style-type: none"> • Notification of regulatory action within 2 business days.
Verification and control activities	<ul style="list-style-type: none"> • To retain samples • To allow GF to test retained samples 	<ul style="list-style-type: none"> • Retain samples from every order, one-year past expiration.
Documentation	<ul style="list-style-type: none"> • To retain records technical files, manufacturing files and distribution files for traceability 	<ul style="list-style-type: none"> • To maintain records one-year past expiration

Overview of QA related requirements in manufacturer agreement

SCOPE	GF/UNICEF	USAID
Deviations & Out of specifications	<ul style="list-style-type: none"> To inform in case of quality incidents, Out of specifications (internal) To engage in investigations /root cause analysis 	<ul style="list-style-type: none"> Maintain records of all in-process check test results including OOS. Analyze/trend OOS result for root cause analysis. Continuous improvement. Implement resolutions
Quality Defect & Recall	<ul style="list-style-type: none"> To inform GF of serious quality defect (external) and recall To allow GF to recall a batch in case of serious risk for patient 	<ul style="list-style-type: none"> Define serious risk; active/insecticide content (efficacy), physical characteristics (efficacy) contaminant (health and safety)
Specifications and analytical methods	<ul style="list-style-type: none"> To share specifications and analytical methods To provide if not commercially available, the reference standards 	
Shelf –Life & Sales	<ul style="list-style-type: none"> To ensure remaining shelf-life To provide data on sales 	<ul style="list-style-type: none"> Ensure shelf-life along production/freight continuum (e.g., integrity of product during shipping)
Vigilance	<ul style="list-style-type: none"> To designate a qualified person and a system in place To submit to the relevant authority To inform of any safety communication 	

Considerations

- **Responsibility for timely transparency**
 - Donors and vendors to provide data/info to WHO PQ
 - Mechanism? Type of data? Frequency?
 - Upstream subcontractor management?
- **Dual API + pyrethroid**
 - Procurement currently through NPP due in part to global volume supply
- **PBO**
 - PMI: 2/5 eligible; future volumes contingent on internal VC considerations on acceptable standardization
 - On-going ento/epi data collection to inform future procurements
- **High-level donor transparency**
 - Sharing of data, pre- & post-shipment

GF NC & OOS Data Base

- ✓ From February 2015 to Date
- ✓ 35 Events
- ✓ 17 Manufacturing sites
- ✓ More than 50 consignments / ??? batches

✓ Main deficiencies identified

- ✓ Data Integrity / Data Manipulation
- ✓ Poor documentation practices
- ✓ Poor manufacturing practices
- ✓ Not authorized Variation in Design / manufacturing process / Testing Specifications
- ✓ Lack of efficacy (**under investigations**)
- ✓ Inadequate labelling and packaging
- ✓ Poor management of critical sub-contractors
- ✓ Poor practices in managing complaint

✓ Areas of improvement

- ✓ Quality Management System (QMS)
- ✓ Registration / variations
- ✓ Complaint & Vigilance
- ✓ Design Verification / Validation
- ✓ Storage, distribution & transportation Practices

Proposed Future UNICEF QC Activity

- Ongoing QA collaboration with all procurement agencies – i.e. Durability studies
- Continue PDI to verify AI and Mechanical properties
- Surveillance on batches within lots
- Retain batch samples of all PO's
- Critical Review and Revision of the standard PDI Guidelines to support proposed QMS enhancements.
- Provide data on complaints or any post market activity findings to PQ
- Initiate closer relationship with Vector Control PQ team by quarterly calls and an annual face to face (possibly in parallel with regular VCWG Meeting in Geneva)

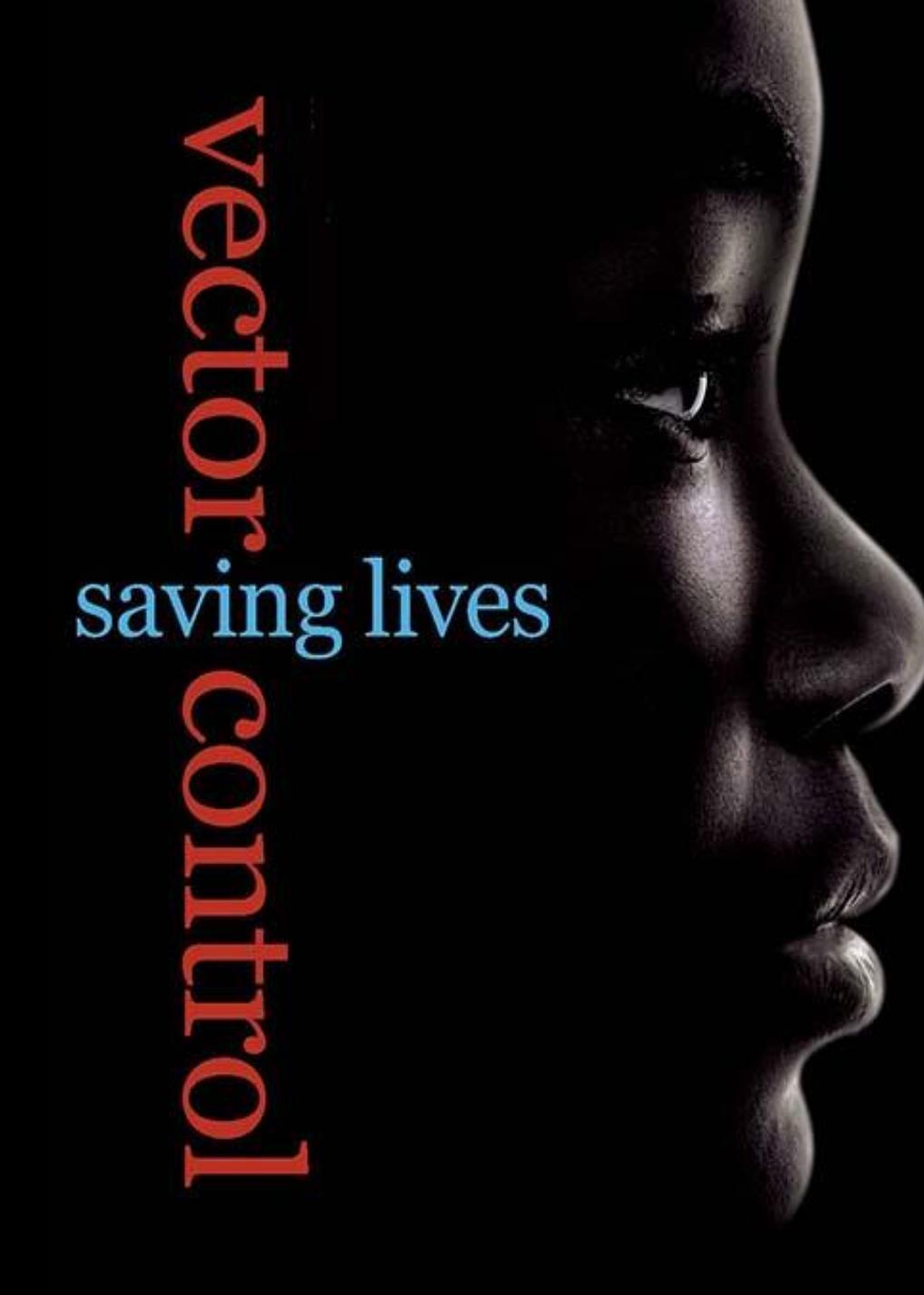
Thank you!



USAID
FROM THE AMERICAN PEOPLE

PRESIDENT'S MALARIA INITIATIVE





vector
saving lives
control

Vector Control Product Development Pipeline

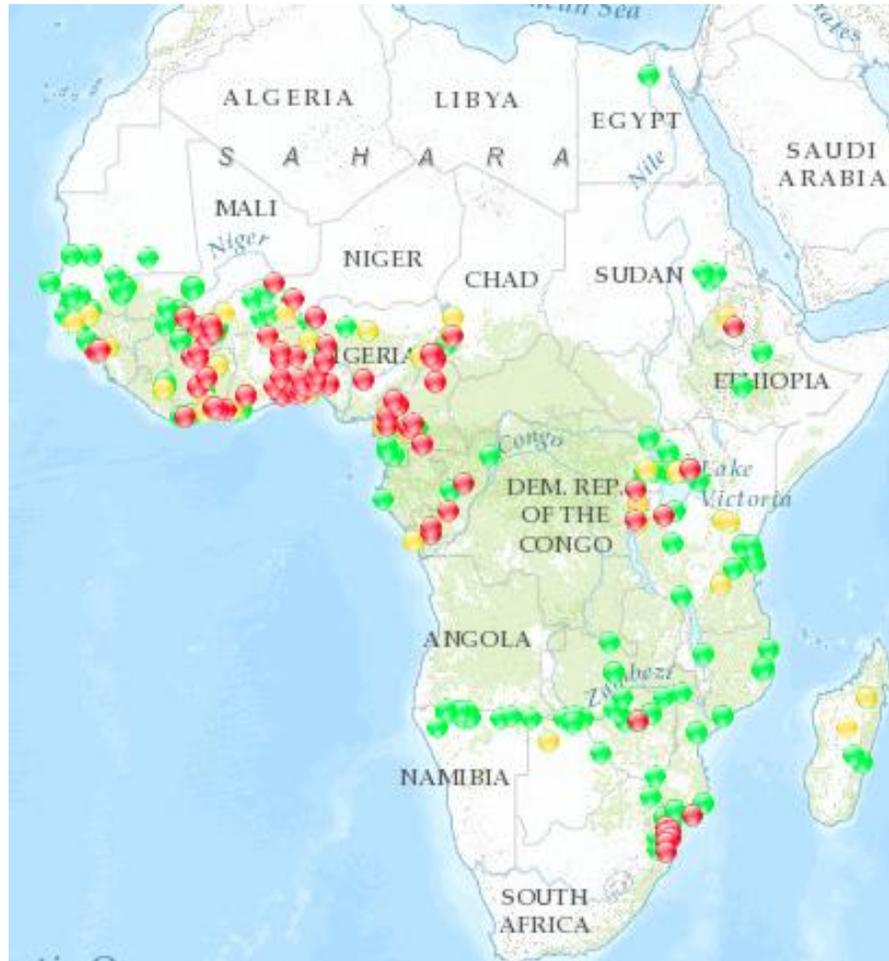
John Vasanthan Paul

September 2019

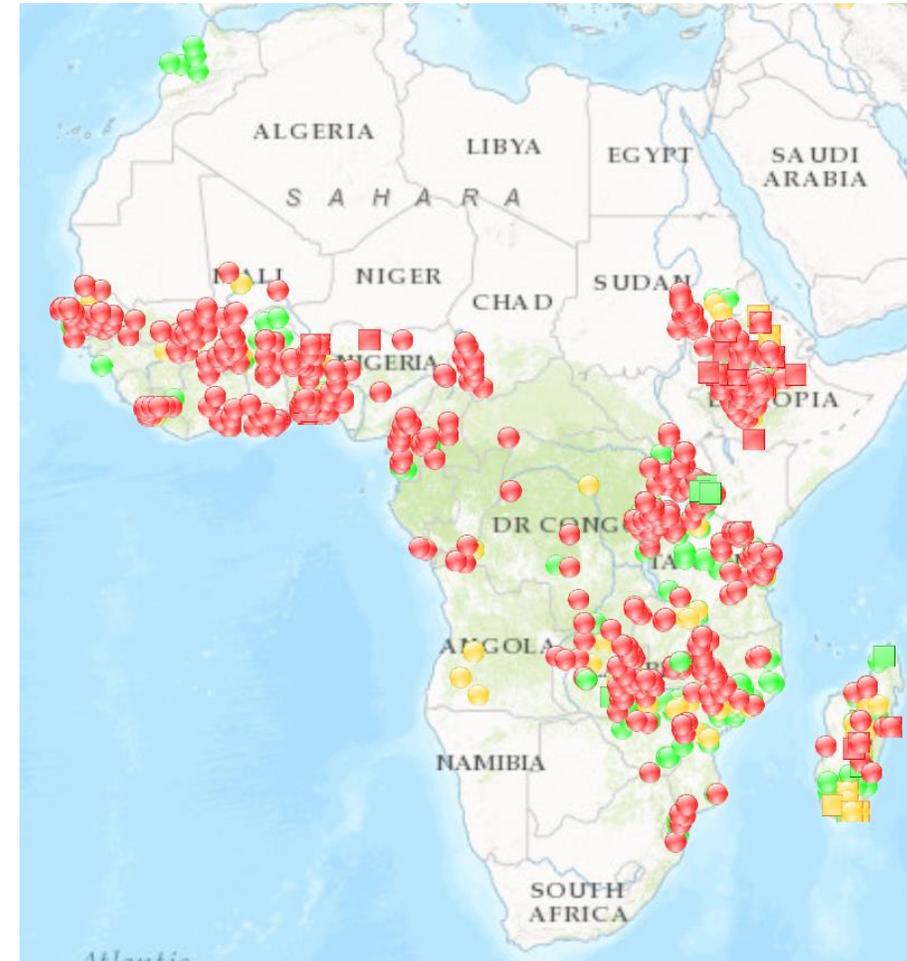


- What do we need from the vector control product development pipeline
- How does IVCC develop products
- What is the pipeline for IRS and LLINs
- New Nets Project Market intervention to enable the Dual AI net market.
- What else is in the pipeline
- What are the key barriers to bringing these products into beneficial use.

Resistance increasing in distribution and intensity



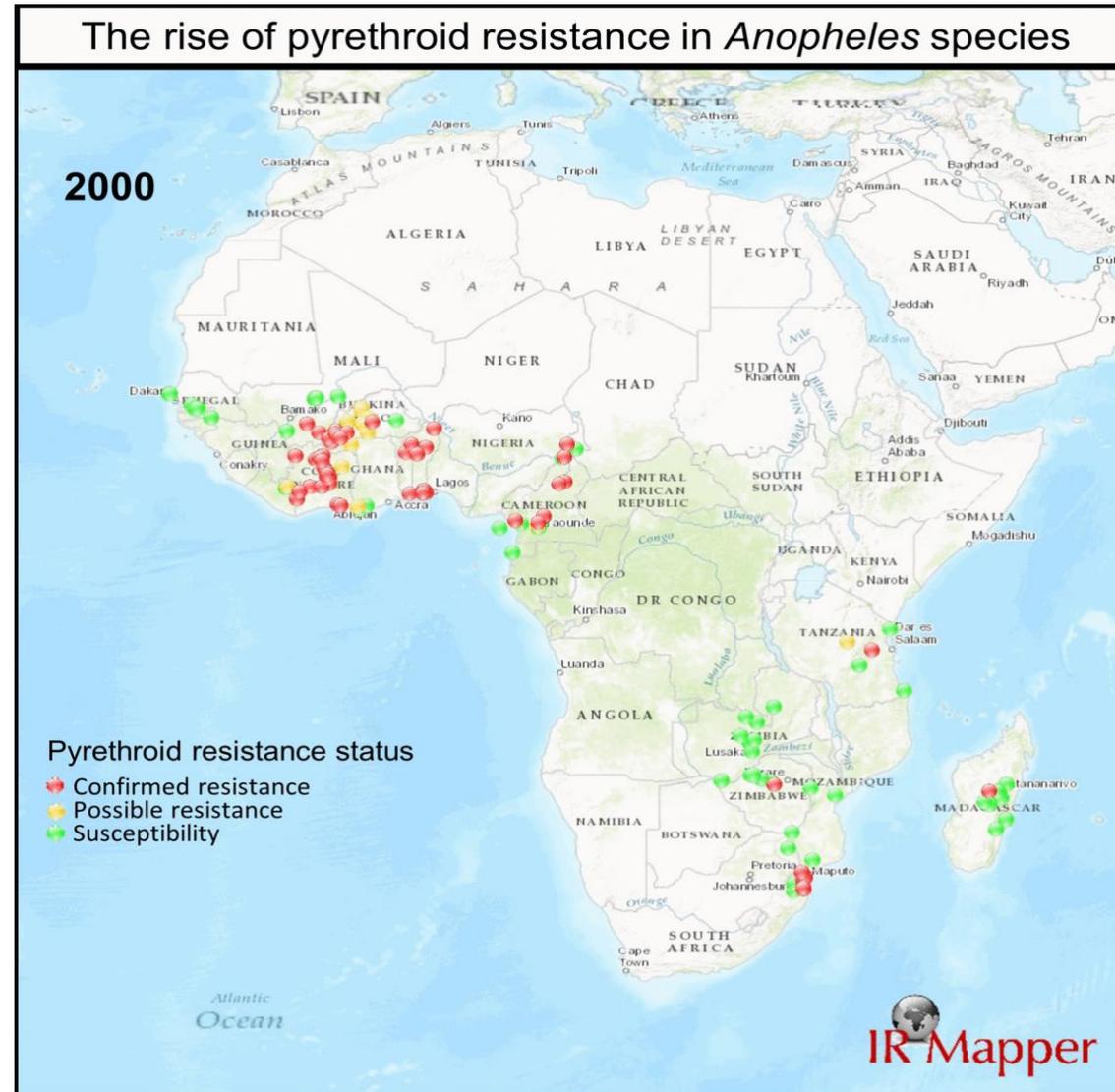
2000-2005



2005-2016

Source: IR Mapper (www.irmapper.com) June 2016

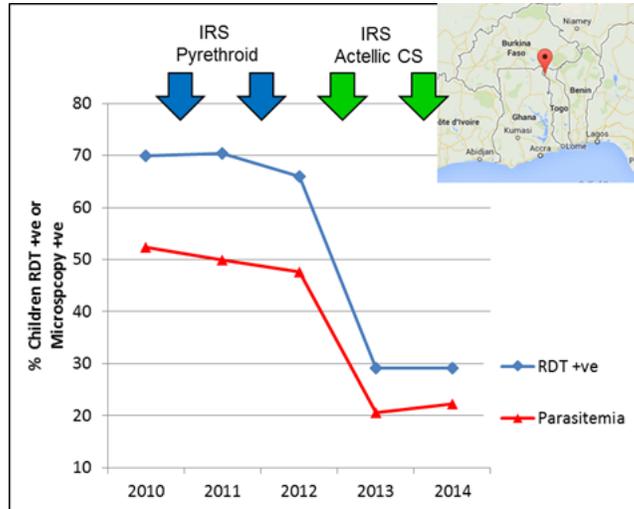
Rise in pyrethroid resistance



Restoring mosquito mortality improves vector control



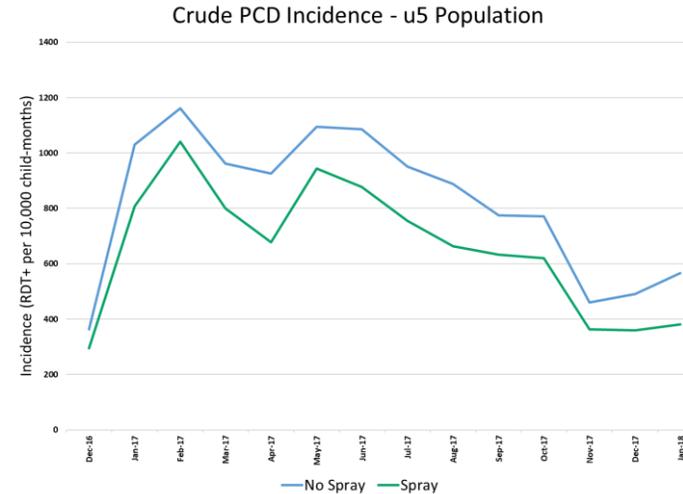
First Programme use of Actellic Ghana 2012



Bunkpurugu - Yunyoo district, Northern Ghana

- Mosquitoes Susceptible in 2010 Resistant by 2012
- Surveys of 824 children under-five.
- Data collected on IRS, ITN ownership and usage, fever in children under-five and anti-malarial treatment.

Cluster randomised trial of Actellic Mozambique 2017



- An. funestus densities were **reduced by 50%**
- Passive case incidence of under 5-year old RDT+ malaria **reduced by 20%** (RR 0.81; 0.79 – 0.83)

Cluster randomised trial of PBO nets Tanzania 2015

Result year 1: Malaria prevalence



Arm	N	June-2015-4 months post intervention				Dec 2015- 9 months post intervention				
		% prevalence	OR	95%CI	p	% prevalence	OR	95%CI	p	
LN-S	997	55.5	1			932	55.3	1		
LN-PBO	971	45.8	0.68	0.39 - 1.18	0.163	883	31.1	0.37	0.21 - 0.65	0.001
LN-S & IRS	994	38.5	0.50	0.31 - 0.82	0.007	877	28.7	0.33	0.19 - 0.55	<0.001
LN-PBO & IRS	955	37.0	0.47	0.28 - 0.79	0.005	969	26.4	0.29	0.17 - 0.49	<0.001

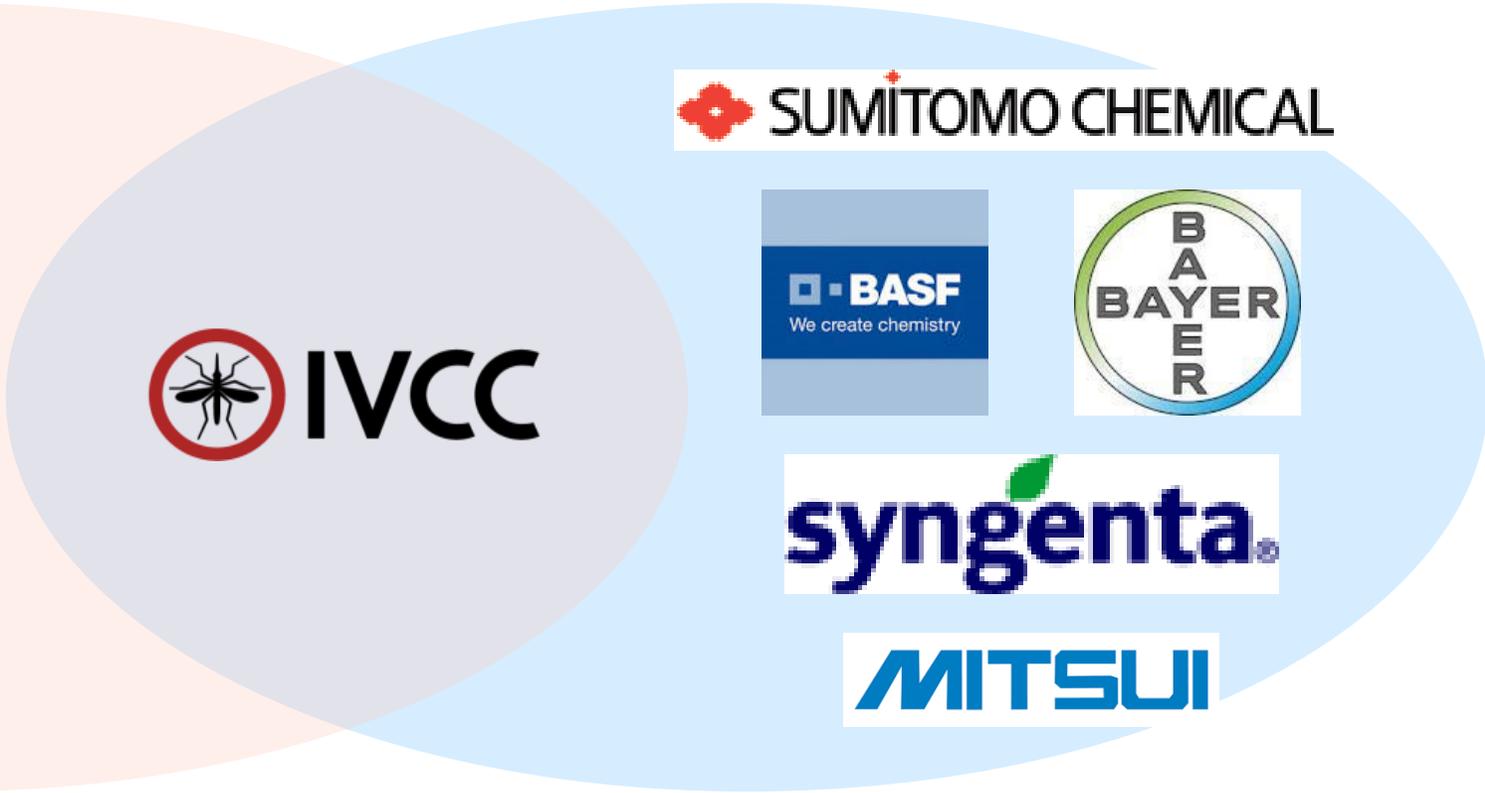
Standard LLIN: LN-S (Olyset Net), LLIN with PBO (Olyset plus) : LN-PBO, Pirimiphos Methyl : IRS

- 4 months post intervention: Reduction in prevalence in all intervention arms but significant difference only for the two IRS arms.
- After 9 months : reduction in prevalence (protective efficacy) in all intervention arms compare to control Olyset Net arm
- No difference between LN-PBO and LN-PBO & IRS arms (OR:0.80, 95%CI: 0.49-1.28, p:0.336) at 9 months

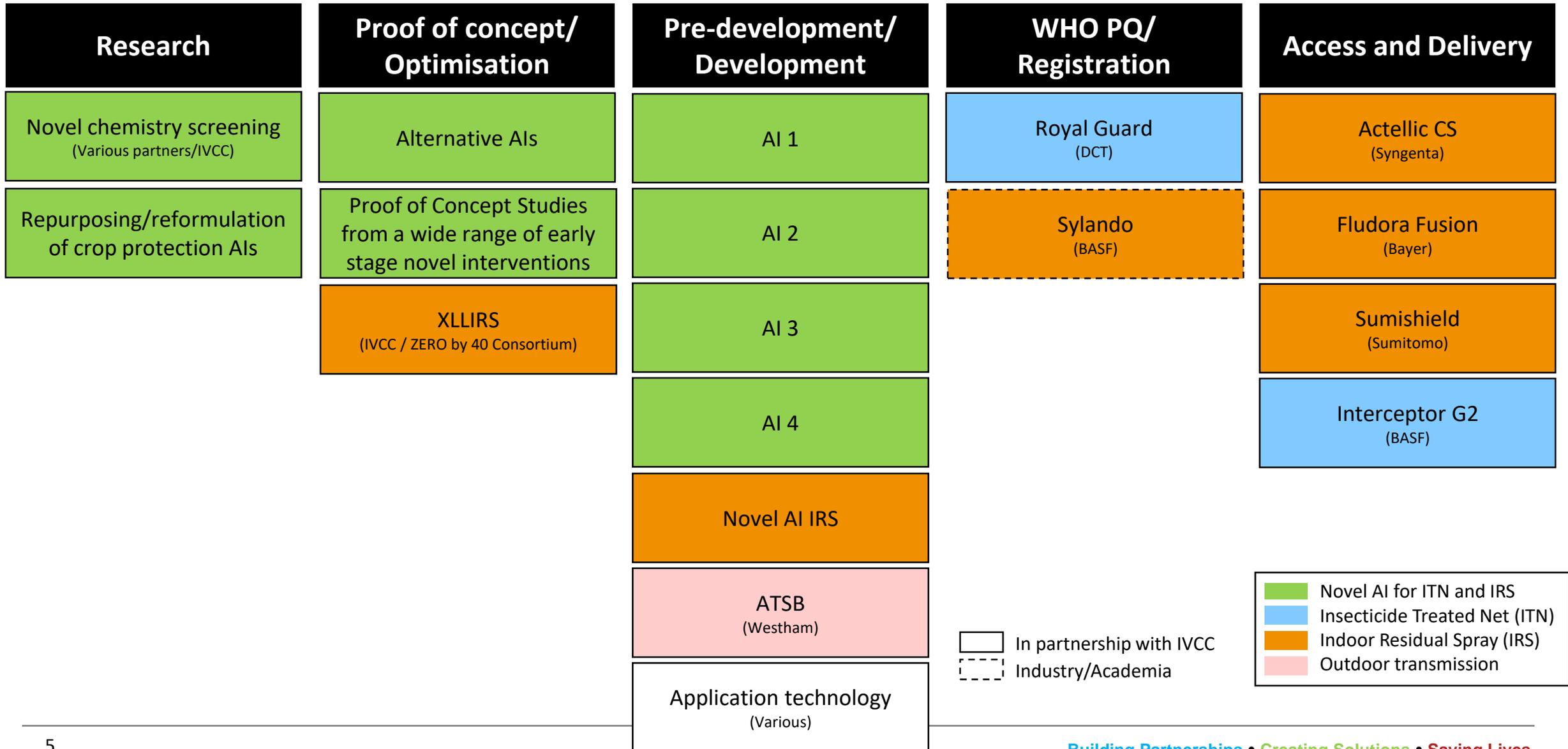
Protopopoff and Rowland LSHTM

30-50% reduction in prevalence

Product Development Partnership for New Active Ingredients



Formulation of AI into product will engage many others





The New Nets Project

New Nets Project Funders



Supported By



The Alliance for Malaria Prevention



New Nets Project Overview



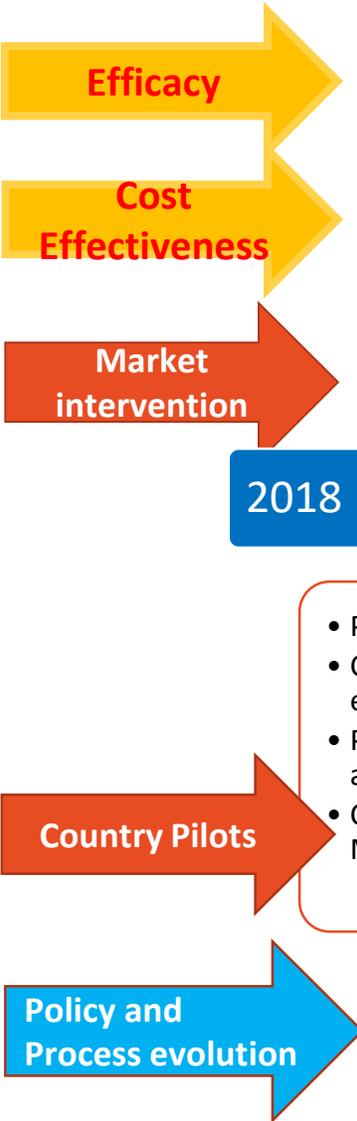
Interceptor G2 and Royal Guard LLIN Cluster Randomised Efficacy Trials

Operational Cost Effectiveness Data from Pilots

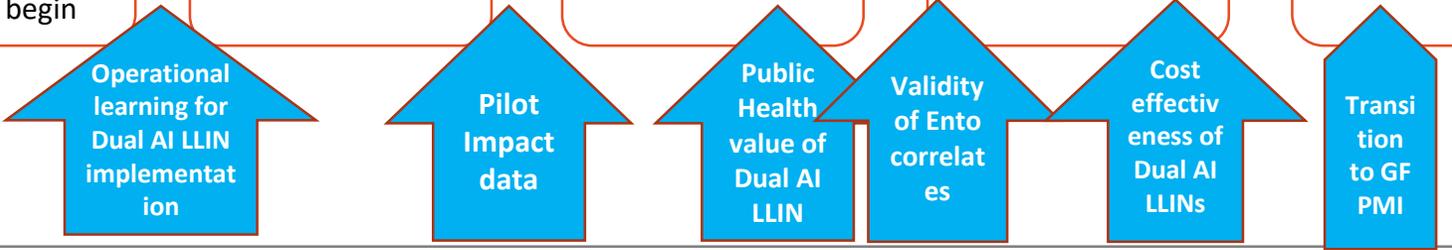
Co-payments for Dual AI LLINs in Pilots



New Nets Project Duration 4 Years



- 2018:
 - Project Startup
 - Country engagement
 - Pre-pilot assessment
 - COGs and Market research
- 2019:
 - 4 Effectiveness Pilots:
 - Burkina Faso
 - Mali
 - Rwanda
 - Mozambique
 - RCTs in Tanzania and Benin begin
- 2020:
 - 1 Effectiveness Pilot
 - 1 Operational Pilot
- 2021:
 - 2 Operational Pilots
- 2022:
 - Repeat 2019 Pilots
- 2023:
 - Post project



The NNP is an initiative established by Unitaid and the Global Fund in partnership with PMI and BMGF, working with other key stakeholders to catalyse the market introduction of next generation ITNs, those with two active ingredients aka dual AI ITNs

NNP countries

■ Effectiveness pilots

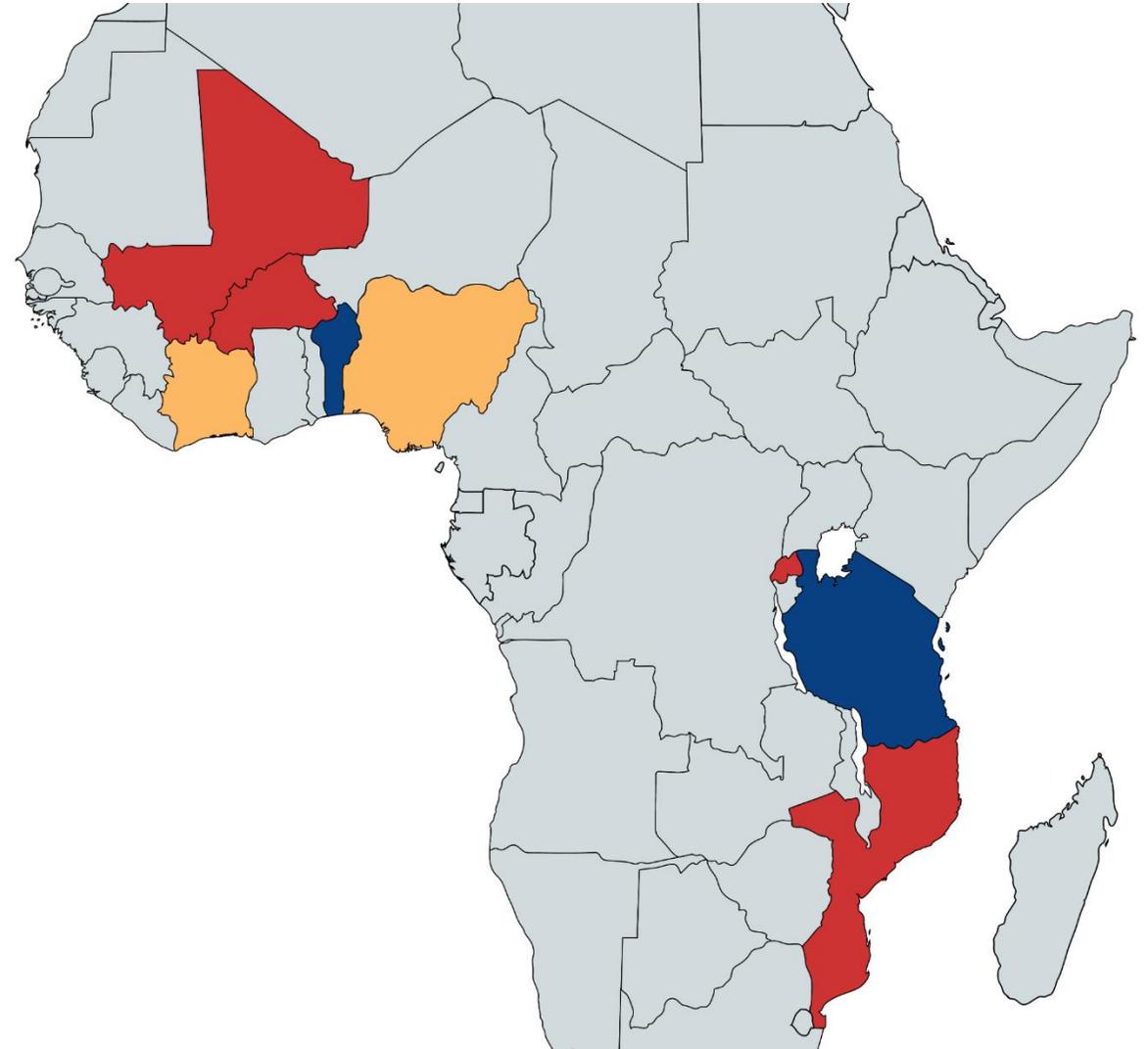
- Burkina Faso
- Mali
- Mozambique
- Rwanda

■ Pilots pending MOUs

- Nigeria
- Cote d'Ivoire

■ RCTs

- Benin
- *Tanzania**



New Nets Project Team Roles



IVCC Lead and Coordinator

- Negotiations with industry partners,
- Co-payment system and contracts to reduce price.
- COGs understanding and ability to get industry to cooperate on COGs.
- Links to the vector control product development pipeline.
- Links to Ag Chem CEO forum and the ask from industry.



PATH

- Cost effectiveness determination from pilot implementations

The Alliance for
Malaria Prevention

AMP

- Technical assistance to pilot implementations



PSI

- Compilation of cross-country lessons learned from pilot studies, funding for process evaluations

LSHTM

- Cluster Randomised trials of Dual AI LLINs and Entomological Correlates in trials

Tulane

- Cost effectiveness trials and data collection design

Imperial College

- Modelling of trials design and implementation impact

LSTM

- Entomological correlates of epidemiological Impact



Effectiveness Study objectives

In each pilot district (new net and standard LLIN comparator), enhanced surveillance activities will monitor the impact of mass distribution on 3 components, feeding into a broader analysis on cost-effectiveness



Epidemiological component – measure impact of new nets and standard ITNs, and if feasible PBO ITNs, through observational studies comparing trends in:

- Malaria incidence rates passively reported to the national health system (passive case detection (PCD)).
- Malaria infection prevalence, measured through Rapid Diagnostic Tests (RDTs), from annual cross-sectional surveys during peak transmission periods.



Entomological component – evaluate the impact of new nets and standard ITNs, and if feasible PBO ITNs, on vector population density, behavior, infection and resistance status

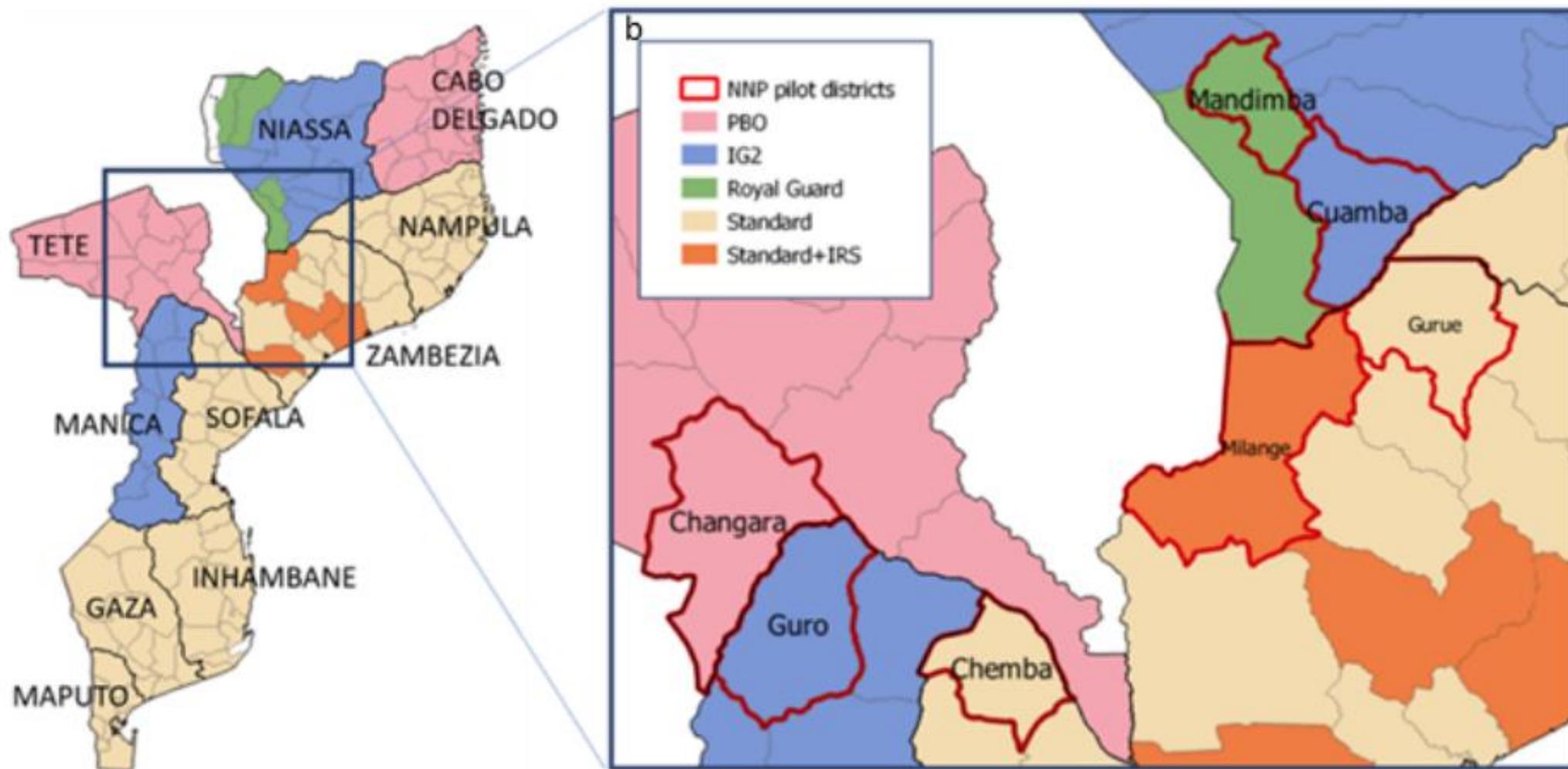


Anthropological component – map social determinants of impact for new nets and determine transmission risk through gathering evidence on ITN uptake and usage; collecting data on patterns, both indoors and outdoors, becomes an essential component of the evaluation of the ITN pilots for both modeling and contextual analysis of impact



Costing and cost-effectiveness component – estimate the cost and cost-effectiveness of new nets through data on product price, delivery and deployment costs, and effectiveness based on incidence rates

Current pilot plan: Mozambique



Note that project team is working to standardize map formats/colors

Attractive Targeted Sugar Baits (ATSB)

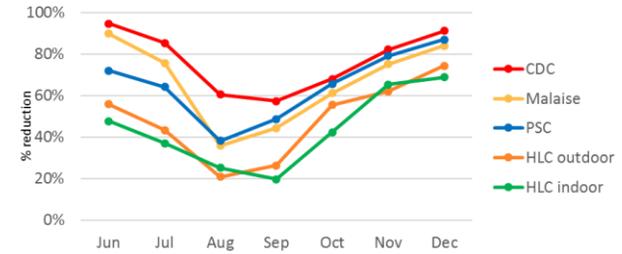


Reduce mosquito population in the peri-domestic area
(ongoing ento trials)

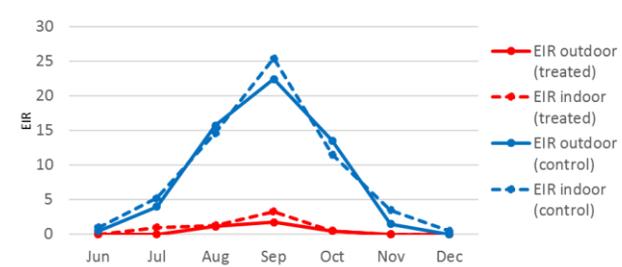
Will prevent malaria transmission
(to be demonstrated through epi trials)



Female anophelines population reduction



EIRs



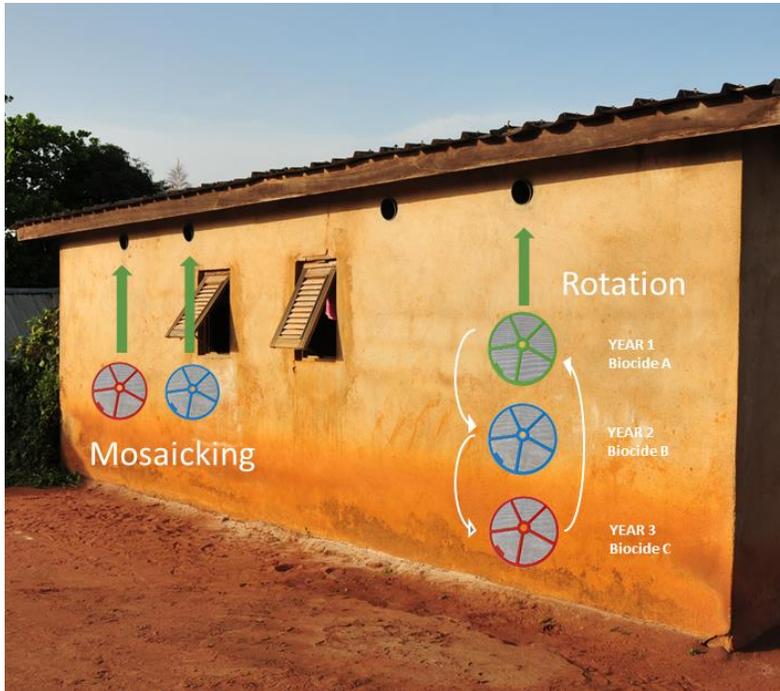
Expected launch date: 2024-2025

In2Care[®] EaveTubes[™]

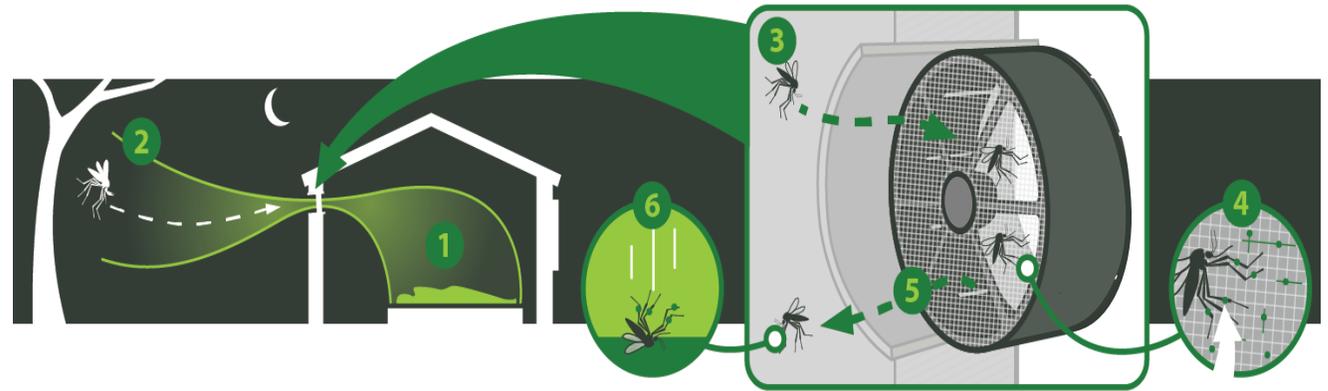
a novel, resistance-breaking, malaria control tool

How they work

1. Human odour
2. Attracts mosquitoes to Eaves
3. Blocked by EaveTubes
4. Pick up lethal dose insecticide
5. Leave the House
6. Die due to insecticide



are easy-to-install ventilation tubes and removable mesh inserts that are installed in the wall under the roof of houses.



Next steps

- 2019: PQ process started
- 2019: Operational manual large scale campaigns finalized
- 2020: Setup large scale production
- 2020: National registration in Tanzania and Ivory Coast
- 2021: National registration in 4 additional African countries

<https://youtu.be/DGyI9i4fpyQ>

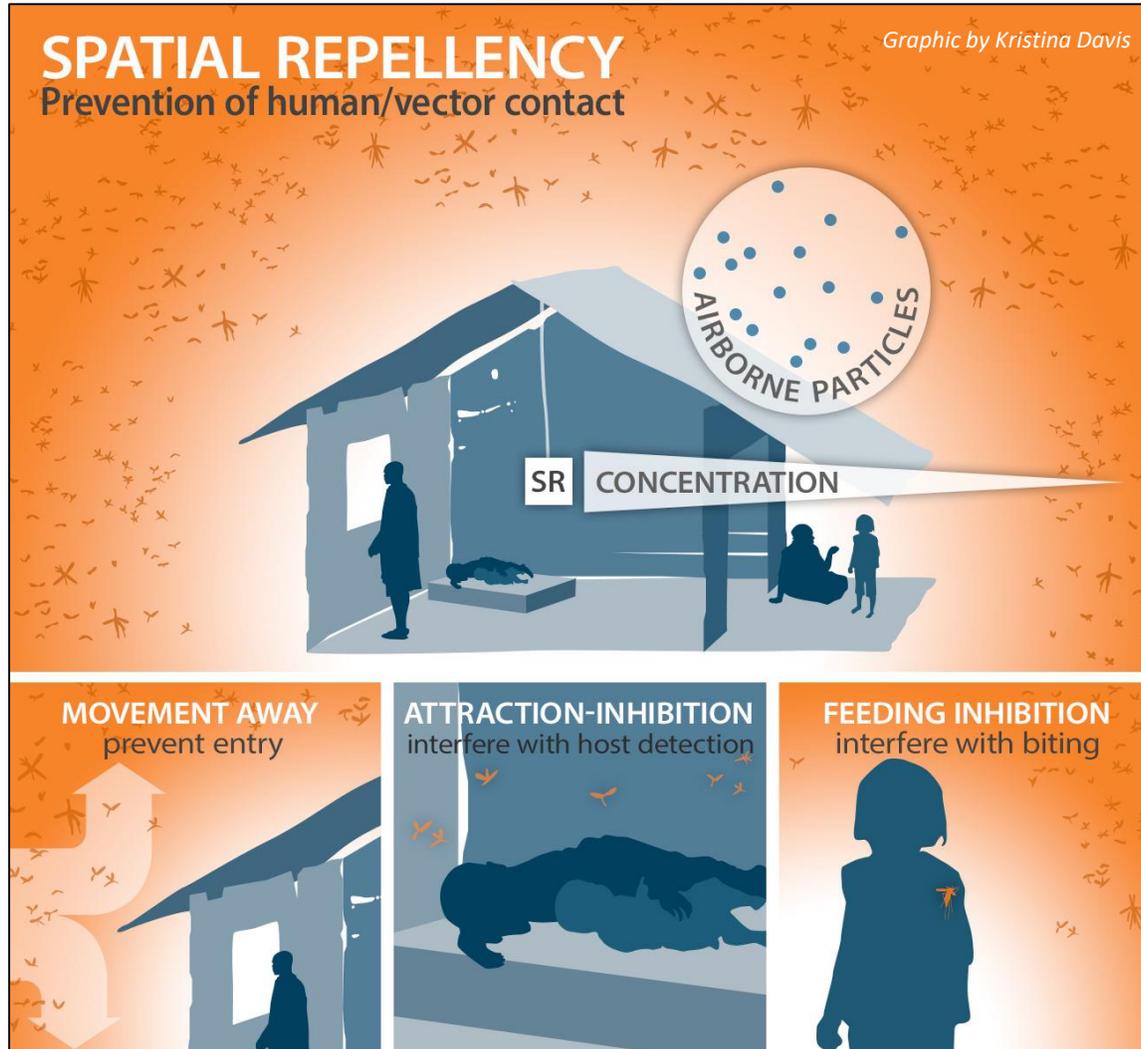
Ivermectin is a *complementary* strategy against:

- Outdoor biting
- Outdoor resting
- Day / Night Biting
- Early exit
- Feeding upon livestock

Trial Name	Lead Researcher	Country	Dose	Drug Combination	First results
MASSIVE	Umberto D'Alessandro	The Gambia	3 x 300	DHA-P MDA	2019
RIMDAMAL II	Brian Foy	Burkina Faso	3 x 300	SMC	2020
TBC	Kobylinski & Sattabongkot	Thailand	1 x 400	Ivermectin alone	2020
TBC	Anna Last	Guinea-Bissau	3 x 300	DHA-P MDA	2021
BOHEMIA	Rabinovich & Chaccour	Tanzania, Mozambique	1 x 400	Ivermectin alone + ivermectin to livestock	2021

- **BOHEMIA** aims at creating an *enabling environment* for a WHO Policy recommendation by 2023
- Evidence generation in two independent trials
- Parallel work with manufacturers to help ensure supply of quality-assured product by 2023
- Parallel work with stakeholders to facilitate policy adoption





Continuous release

Added Value:

Addresses daytime, early-evening and indoor/outdoor vector biting

Varied modes of action

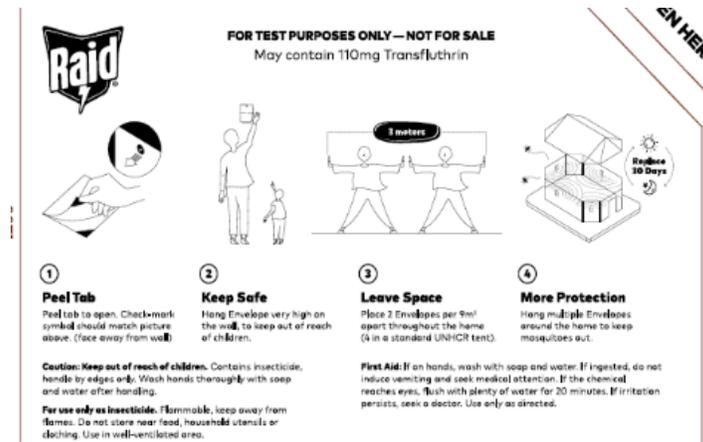
Innovation:

New actives, alternate target sites, exploitation of post-exposure effects

Spatial Repellent products for Public Health: SC Johnson & Son, Inc.



- Global dossier complete by Dec 2019 to support registration across a broad range of malaria-endemic countries
- In process with VCAG evaluation + PQT-VC



2014-2019

- Sealed film containing a volatile insecticide that emanates once opened, for a **2-week** duration of protection indoors
- Product evaluated in clinical trials in Indonesia and Peru

2019-future

- Improved version of our 2-week product that provides **1-month** of protection indoors
- Will be evaluated in upcoming clinical trials in Kenya, Mali, and Sri Lanka
- Country registrations for this product starting in 2020

Next generation

- New spatial repellent product in SC Johnson development pipeline to extend duration of protection to an **entire transmission season**

Barriers to adoption

	Workstream	Non Pyrethroid IRS	Dual AI LLINs	New AI IRS / LLINs	ATSB
DESIGN	Use Case / Entomology	Green	Green	Green	Yellow
	Target Product Profile	Green	Green	Green	Green
	Technology /IP Development	Green	Green	Green	Green
DEVELOPMENT	User compliance/ acceptability Implementability	Green	Yellow	Green	Green
	Regulatory / Safety / Environmental impact Qualification	Yellow	Green	Green	Yellow
	Manufacturability Delivery	Green	Green	Green	Green
LAUNCH	Epidemiology	Yellow	Yellow	Yellow	Green
	Economics / Funding stream / Demand Forecasting	Green	Red	Red	Red
	Policy / Strategy / Resistance management	Green	Yellow	Yellow	Yellow

- Proximate barrier to adoption of new products in the pipeline is the time needed for epidemiological evidence.
- Most severe barrier is the availability of funding for new products and new intervention classes
- Secondary barrier is policy Strategy and insecticide resistance management implementation

-
- **There is a rich potential pipeline of new products**
 - **The pipeline may dry up if product development barriers are too high.**
 - **Some of the much discussed development plans are higher risk than is acknowledged**
 - **Market interventions will be required to bring the products through development**

2019 LLINs Suppliers and Partners Meeting

UNICEF Supply Division
26 September 2019

unicef 
for every child

Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

2019-2021 LLINs Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation



UNICEF Supply Division

UNICEF's **Supply & Logistics** headquarters located in Copenhagen, Denmark

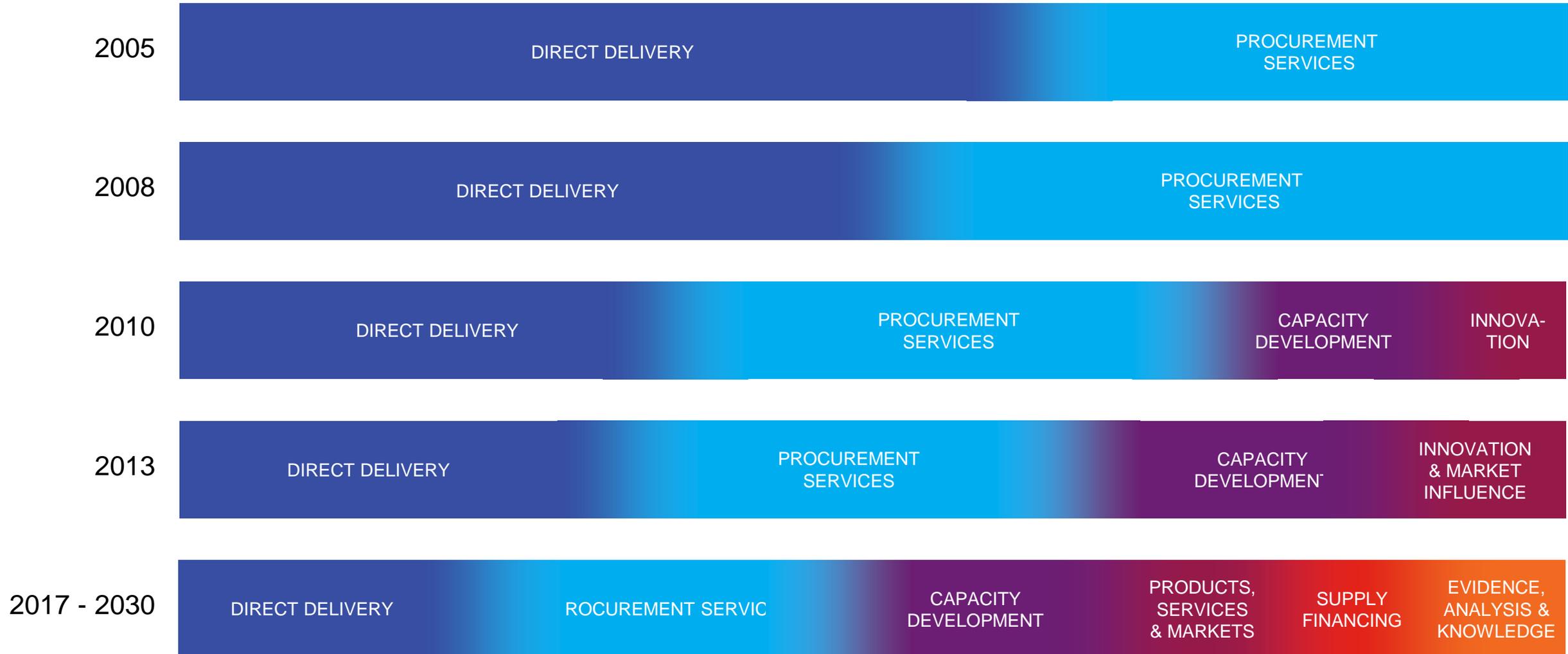
It is also home to the **largest humanitarian warehouse**

Other UNICEF warehouse hubs are located in **Dubai, Panama** and **Shanghai**

UNICEF's Supply Community of **1036 supply and logistics staff** serve children in **97 countries**

- Supports results for children with an **effective, efficient supply operation**
- Helps meet UNICEF's Core Commitments for Children in emergencies by providing **rapid response to emergency supply and logistics** needs
- Contributes to **influencing markets** to ensure sustainable access to essentials supplies for children
- Serves as a **centre of expertise** and knowledge on essential supplies for children and supply chains and **build capacities of national governments**
- Provides **procurement services** to governments and development partners on strategic-essential supplies
- Establishes **policies for supply chain** activities
- Uses product **innovation** to increase results and decrease costs

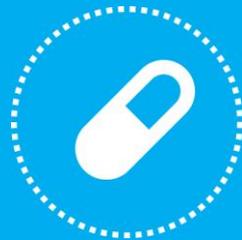
UNICEF Supply Function – high level vision



UNICEF procurement value by major commodity groups (2018)



Vaccines
\$1.453 billion



Pharmaceuticals
\$124.9 million



Water & Sanitation
\$117.2 million



Nutrition
\$184.0 million



Education
\$57.4 million



**Cold Chain
Equipment**
\$77.8 million



Medical supplies
\$106.0 million

\$3.480 billion

of supplies + services for 150
countries and areas

\$1.556 billion

in procurement on behalf of 107
self-financing governments and
partners

\$2.379 billion

supplies

\$1.101 billion

services

78% of UNICEF procurement is in
collaboration with other UN agencies
and partners

Key modality for market communication with public

Market notes & Manufacturer specific pricing

71 market notes published during 2014-16 covering 31 essential commodities/groups

Aims

- Inform demand (e.g. from COs, partners)
- Provide market signals (to suppliers, developers)

Content

- Product standards and specifications
- Market trends (procurement, pricing, products)
- Market deficiencies to be addressed

Manufacturers specific prices by product posted for vaccines, RUTF, LLIN, devices

UNICEF guiding procurement principles (1 of 2)

Each UN organization
has a
different mandate

but

all UN organizations
share the
**same procurement
principles**

- Fairness, integrity and transparency through competition
(clear & appropriate regulations/rules applied to all suppliers, fair process, equal treatment of suppliers, transparent system)
- Economy and effectiveness
(meet requirement in terms of quantity, quality, timeliness at the right place. Economy=minimize cost, Effectiveness=meet end-user interest)
- Best value for money
(Consider the optimum combination of factors in meeting the end user needs; BVM does not mean lowest cost but best ROI)
- Promotion of objectives of UNICEF
(fulfilling the mandate, goals and objectives)

UNICEF guiding procurement principles (2 of 2)

UN Supplier Code of Conduct

Children's Rights and Business Principles

No Child Labor, No Landmines

UNICEF's Policy on Conduct
Promoting the Protection and
Safeguarding of Children

UN Supplier Code of Conduct

Zero-tolerance for all forms of
fraud and corruption.

Zero tolerance to all forms of
sexual harassment and
exploitation

Information disclosure policy

Zero tolerance policy on gifts
and hospitality from suppliers

All UN and UNICEF registered suppliers sign on to the UN Code of Conduct.

- Based on the UN charter, the principles of the Global Compact and ILO standards;
 - ✓ *The UN expects that these principles apply to suppliers and their employees, parent, subsidiary or affiliate entities, and subcontractors; that they are seen as minimum standards that suppliers strive to meet and exceed them.*
- The code addresses:
 - **Labour conditions:** Freedom of Association, no force or compulsory, no child labour, discrimination, standards for working conditions.
 - **Human Rights:** No Harassment, Harsh or Inhumane Treatment, no manufacture or sale of mines.
 - **Environment:** Compliance with regulations, manage chemical and hazardous materials; waste and air emissions, Minimize Waste, Maximize Recycling.
 - **Ethical conduct:** No corruption, conflict of interest declaration, no gift and hospitality, post employment restrictions.

Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

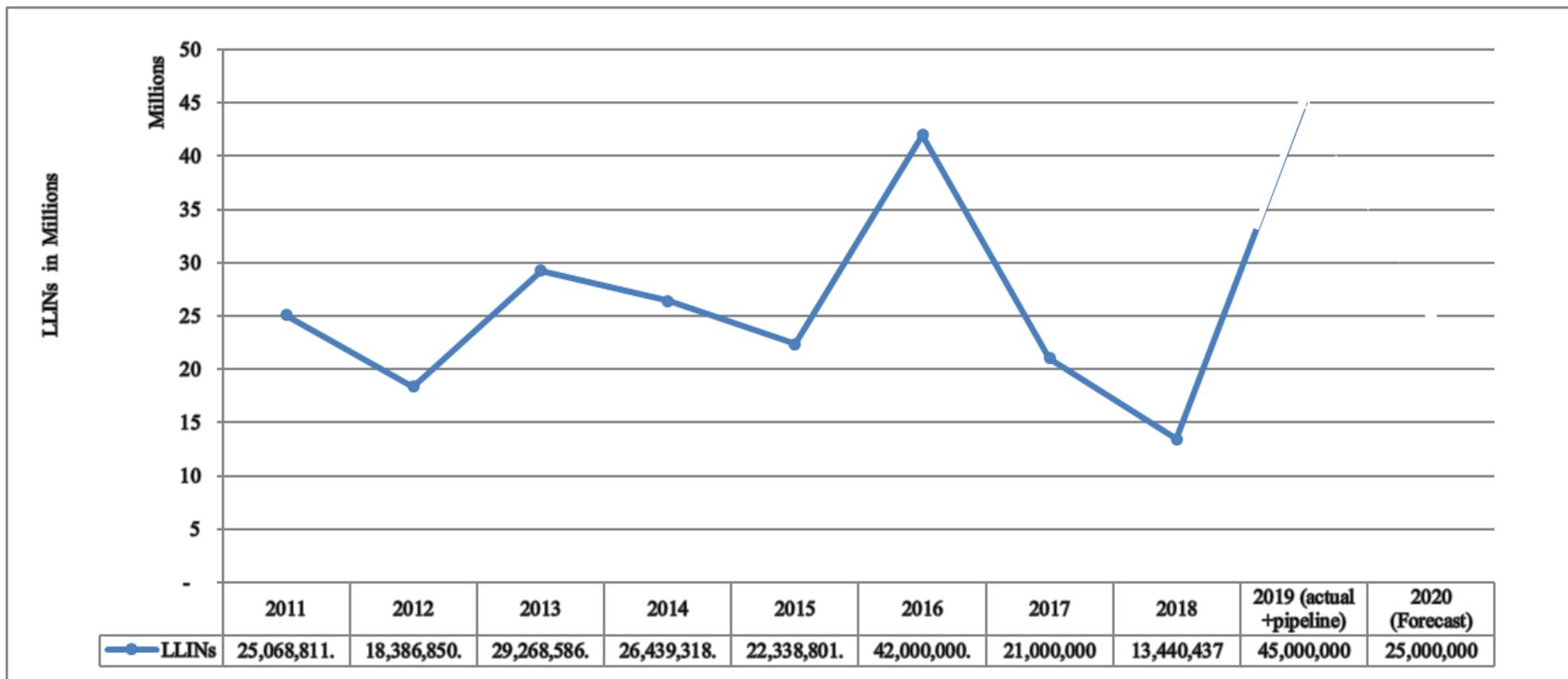
2019-2021 LLINs Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation

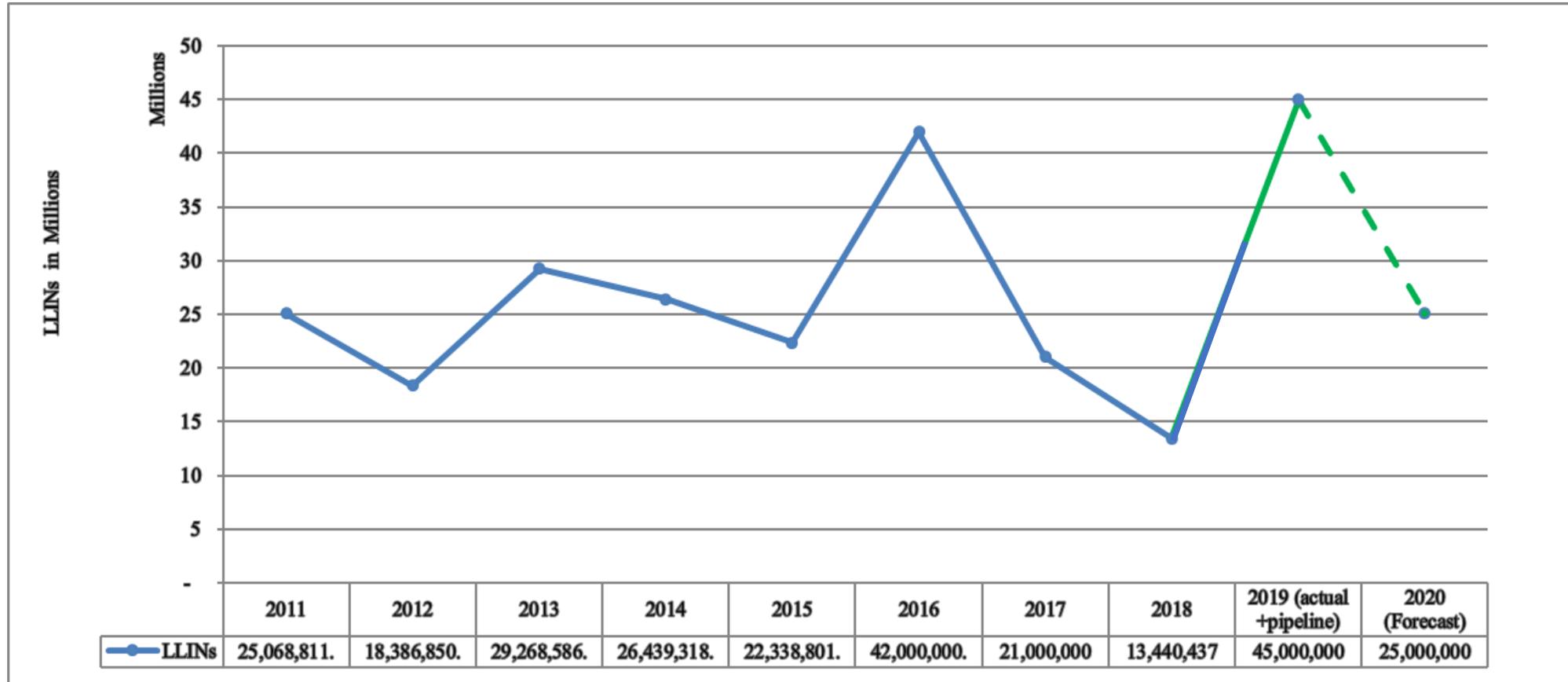


UNICEF's procurement up to Q3 2019 reached 32 million LLINs for 26 countries and is expected to reach 45 million by the end of 2019 according to the available forecast.



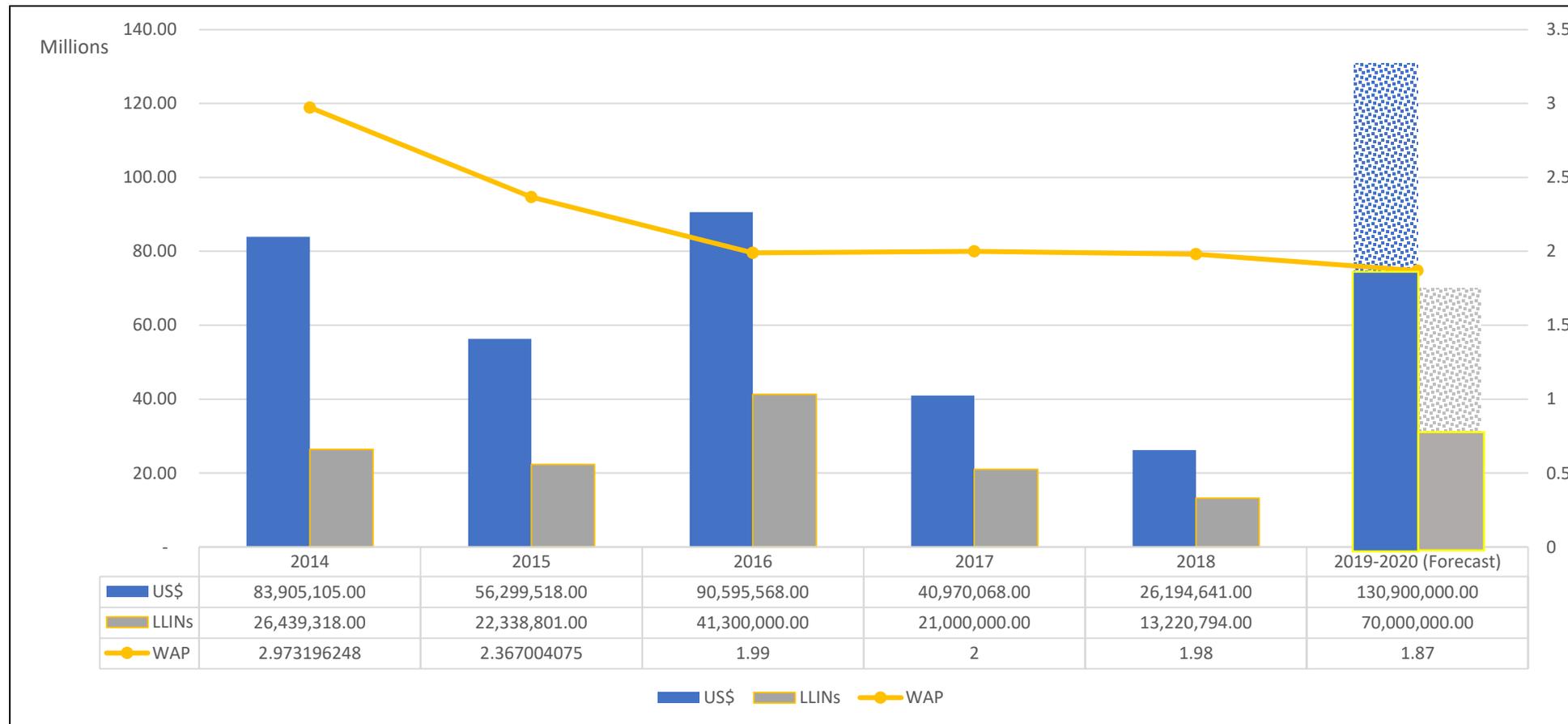
—●— Actual
—■— pipeline
- - - forecast

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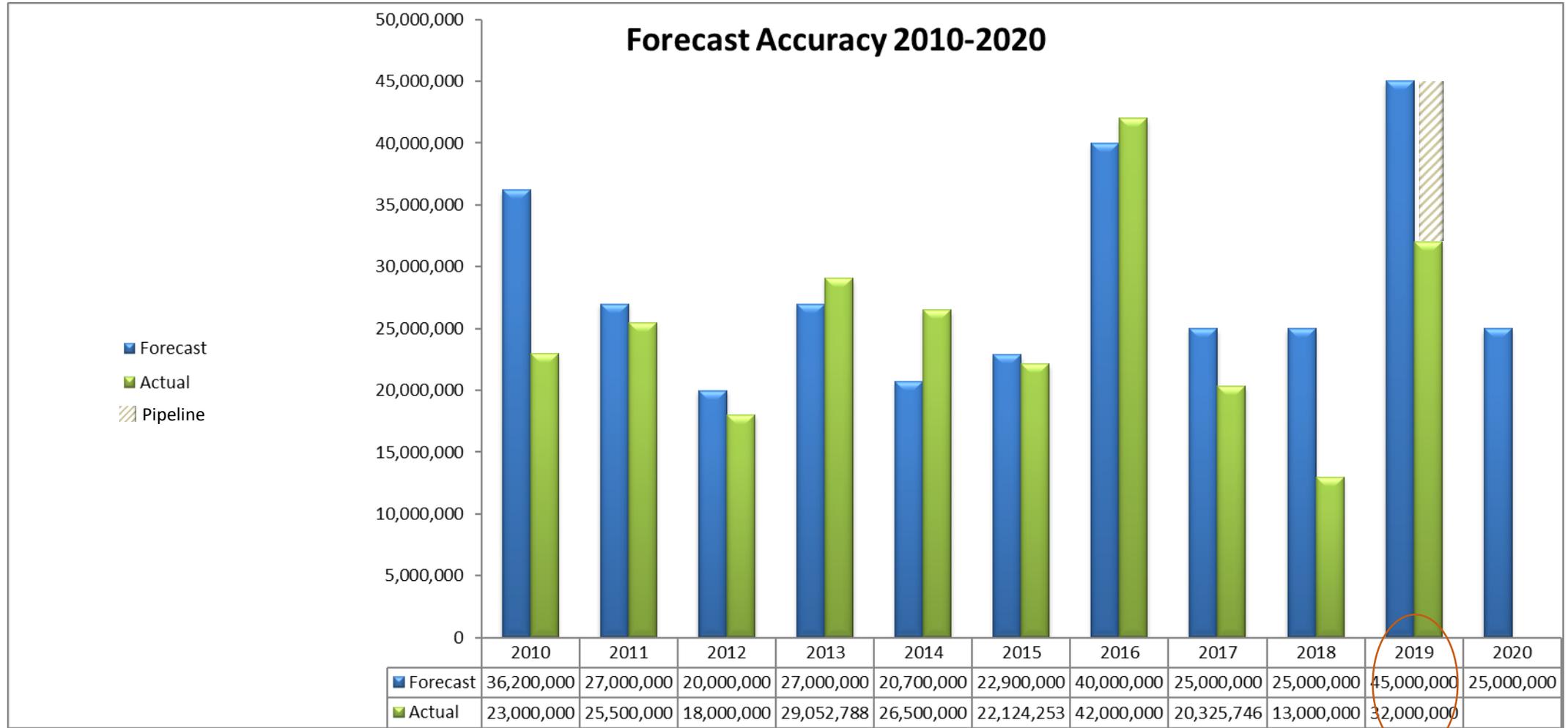
—●— Actual
—■— pipeline
- - - forecast

Clear decrease in the weighted average prices for all LLINs procured irrespective of the size, colour or denier.



In the last five years we have witnessed a higher demand for commonly manufactured products, which also results in lower weighted average price. Joint industry meeting and joint forecast presentation to industry have also contributed to this achievement.

UNICEF LLINs Forecast Accuracy 2010-2020



Increase in UNICEF forecast for 2019

Presentation Outline

About UNICEF Supply Division

Health Technology Centre

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

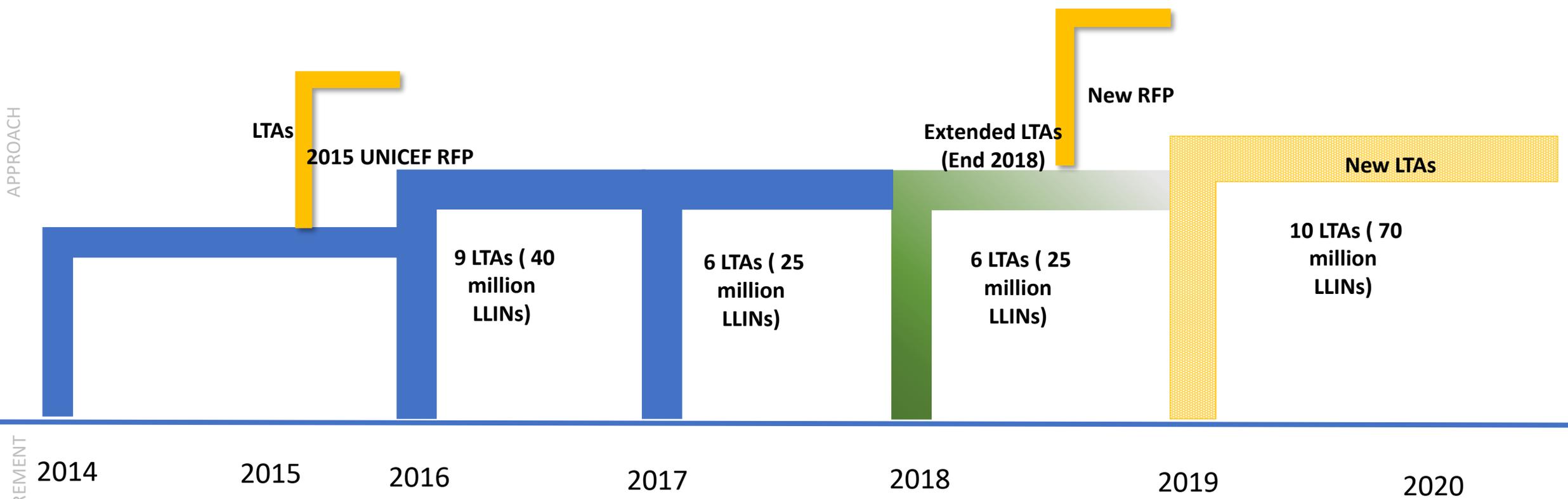
UNICEF Suppliers Performance Evaluation



UNICEF LLINs Procurement Strategy objectives for 2019-2021



2014-2020 Procurement Approach for the LLINs Procurement





Updates

- **2018 LLINs Suppliers Meeting was held in Supply Division on 27th August , 2018**
- **UNICEF Request for Proposal was issued on 27th Sept , 2018**
- **Industry Webinar was held on 5th October 2018**
- **Tender closed on 18 October 2018**
- **Contract awards 18 December 2018**
- **LTAs commenced on 1st January 2019**

Key Changes / highlights in UNICEF 2019-2021 Tender

- The adaption of the WHO PQ as a mandatory criterion instead of WHOPES phase 2 evaluation status > to ensure individual products are supported by existing specification and evaluation reports
- **2 years** Validity of proposals (allocations of quantities were done for 2 years) - possible extension for additional 12 months
- The tender included **price adjustment mechanism** (optional) >> as a result of the consultation with industry)
- Change in standard sizes : Rectangular (L)190x(W)180x(H)150cm, Rectangular (L)180x(W)160x(H)150cm ,Rectangular (L)190x(W)180x(H)180cm, Colors: White, Blue, Green
- The tender included an option to Include an offer for any LLIN product currently in the WHO PQ pipeline >>Conditional awards for products currently in the WHO PQ pipeline

Sustainability Focus in UNICEF 2019-2021 Tender

- Maintain using the expanded tender evaluation criteria to consider supply chain elements, i.e. optimized container loading, which would impact on not only on freight and container costs but also on carbon footprints associated with freight (economic and environmental pillar) >>**container loading capacity and landed cost as evaluation criteria in the tender document**
- Eco-friendly packaging: e.g. bio/Oxo degradable bag are **considered as UNICEF standard primary packaging with an option of Bulk packaging (without individual bags)**
- Explore opportunities for **local procurement in the countries** where WHO PQed LLINs are being produced or finalized (economic and social pillar)
- As the WHO PQ process does not consider issues around sustainability and sustainable procurement, UNICEF SD are likely to still conduct site visit to determine **suppliers Social Responsibility and Environmental impact**

Progress towards the Procurement strategy objectives

1: Ensure reliable, uninterrupted supply of LLINs to countries;

- The new tender allowed access to all PQ LLINs with updated commercial information prices, production capacities, container stuffing .
- 10 LTAs with more than 12 different production facilities (FCA points) were established for more than 70 million LLINs
- The awarded suppliers have a total annual production capacity of more than 300 million LLINs with 170 millions offered to UNICEF
- Stock levels will be monitored during the implementation of the LTAs >>few suppliers offering a free-of-charge stockpiling solution to UNICEF

2: Secure access to affordably priced LLINs in situations of increasing and uncertain demand;

- Overall WAP was reduced by 5%
- LTAs are valid for 2 years **including Price adjustment mechanism**
- All forecasted countries will have access to supply as per the requirement

3: Secure access to quality LLINs;

- The new tender allowed the adaption of the WHO PQ as a mandatory criterion instead of WHOPES phase 2 evaluation status, to ensure individual products are supported by existing specification and evaluation reports
- The tender linked the validity of any subsequent LTAs/award to the validity of the product PQ status
- The PQ will include inspection of manufacturing sites and assessment of relevant information
- PDI -Inspection guidelines under review
- PDIs Will be monitored during the implementation of the LTAs

4: Secure access to newly innovative LLINs products;

- PBO LLIN item was added to UNICEF supply catalogue- (4 new PBO nets options)

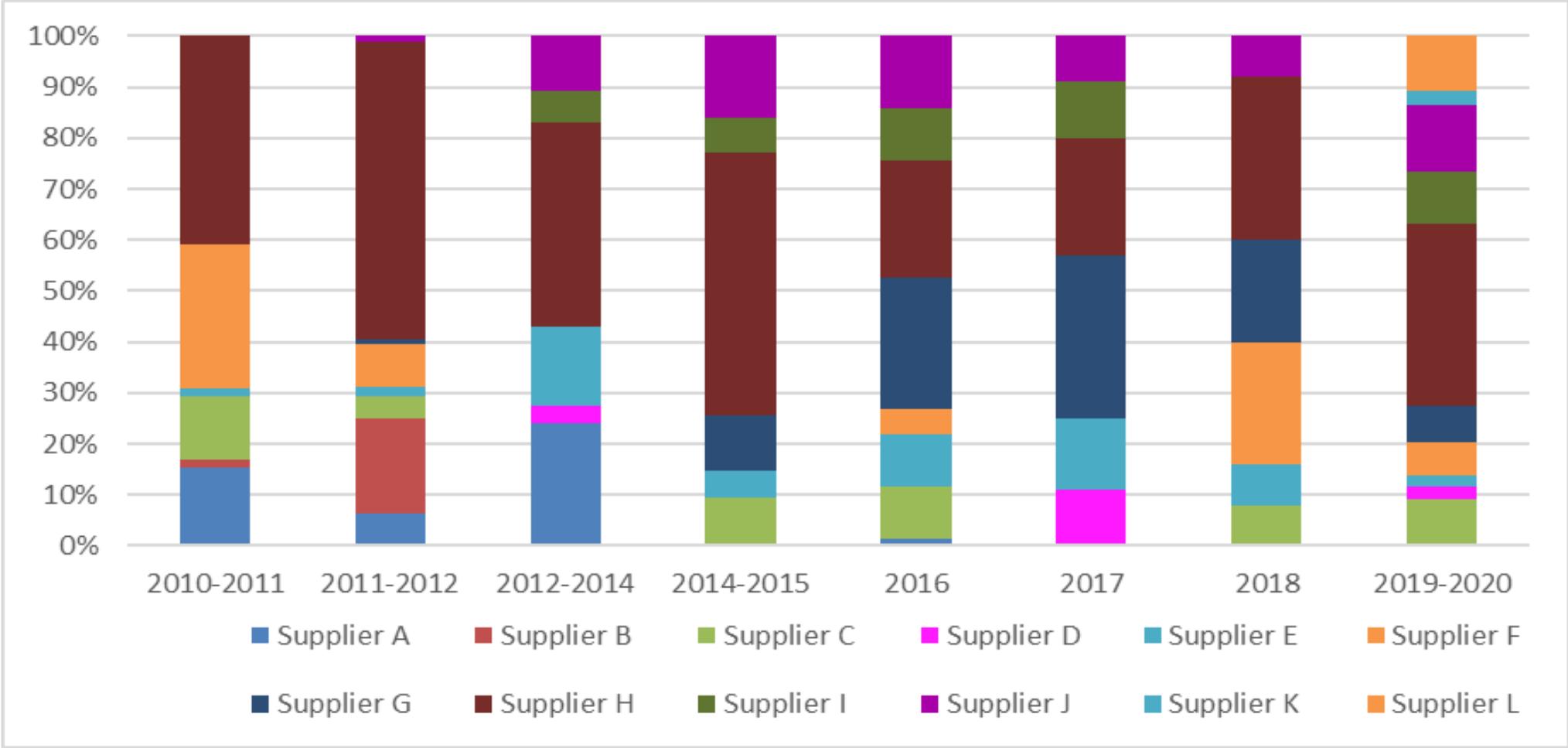
5: Continue to reduce the overall cost of LLINs supplied to programs through the continued application of supply chain cost considerations to UNICEF's LLIN procurement;

- Landed cost analysis was part of the evaluation of offers and factored in the allocation of quantities to the recommended suppliers
- Bidders were requested to provide their stuffing capacity for 40ft and 20ft container and that was the basis of calculation of the landed cost
- landed cost analysis will continue to be implemented during the LTAs period 2019-2020

6: Improve LLINs deliveries by engaging Industry to address programmatic and supply challenges and reduce environmental sustainability risk associated with LLINs shipments and packaging;

- Stuffing capacity provided by suppliers was improved compared to the previous tender cycle, however, actual savings will be monitored throughout the LTA
- Landed cost calculation was included as explicit tender / quantity allocation criteria
- Biodegradable bags offered as standard and included in tender adjudication and landed cost calculation
- Awards included manufactures with local facilities in Africa

Supplier percentage of LLIN awards 2010 – 2020



UNICEF LLINs WAP Data 2010-2020

The price range between the lowest and the highest unit price is less compared to the last 5 cycles of LTAs

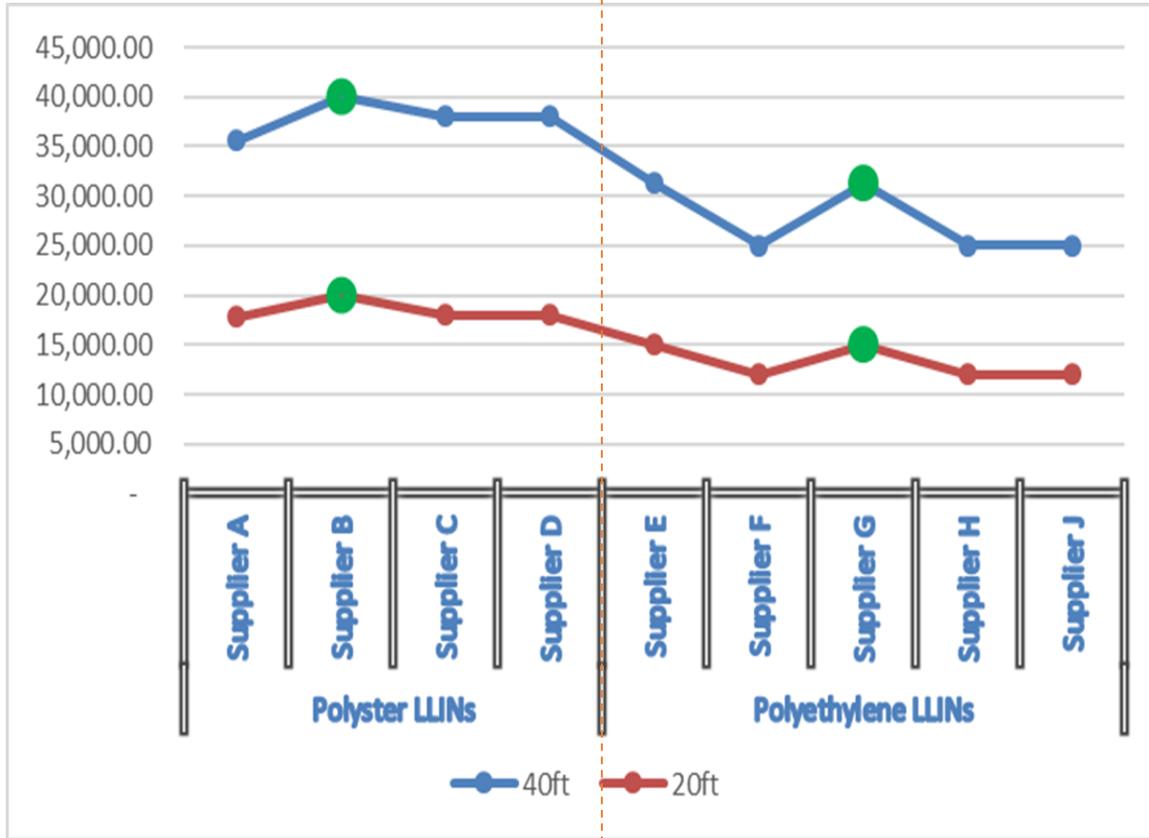
The estimated WAP for the 2019/2020 LTA Period for the standard size (190X180x150) white will be USD 1.85

The estimated WAP is also 5% less than that estimated after UNICEF's last tender awards for 2016/2017 which was USD 1.94

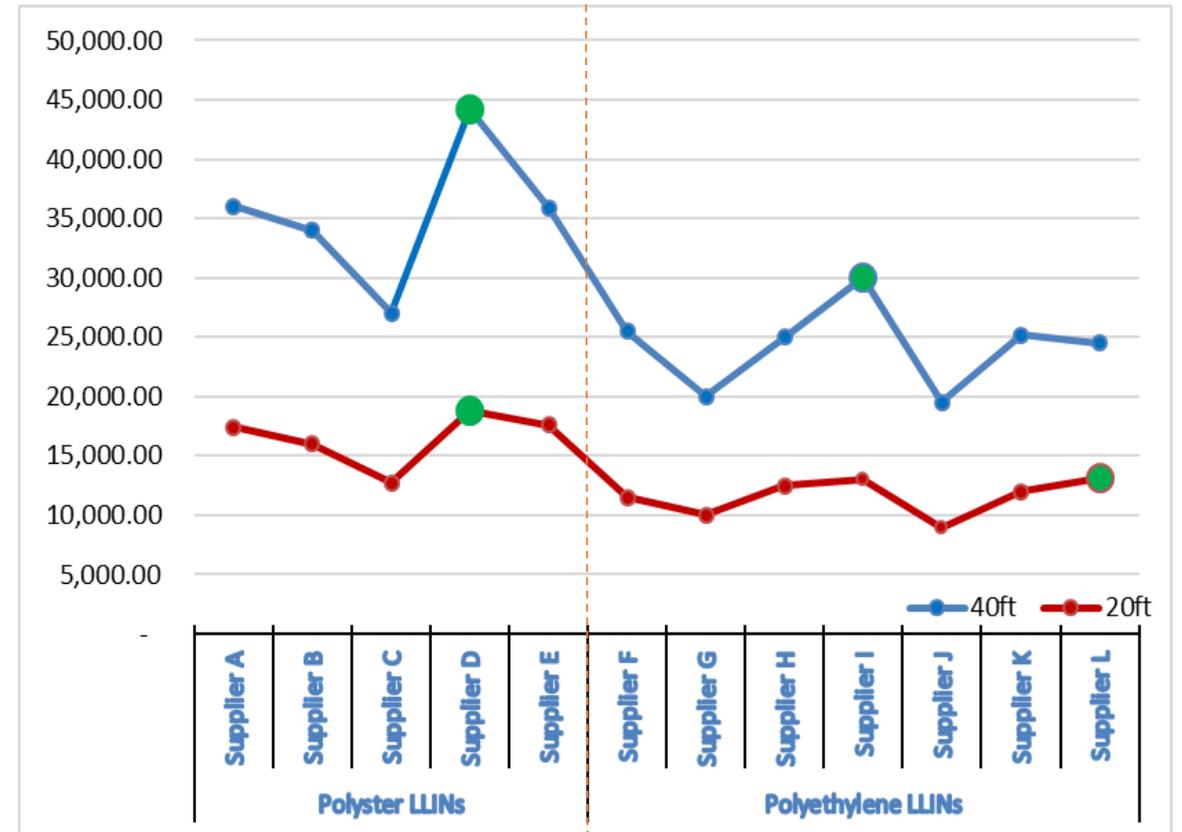


Container Stuffing Capacity per Supplier

2018



2019



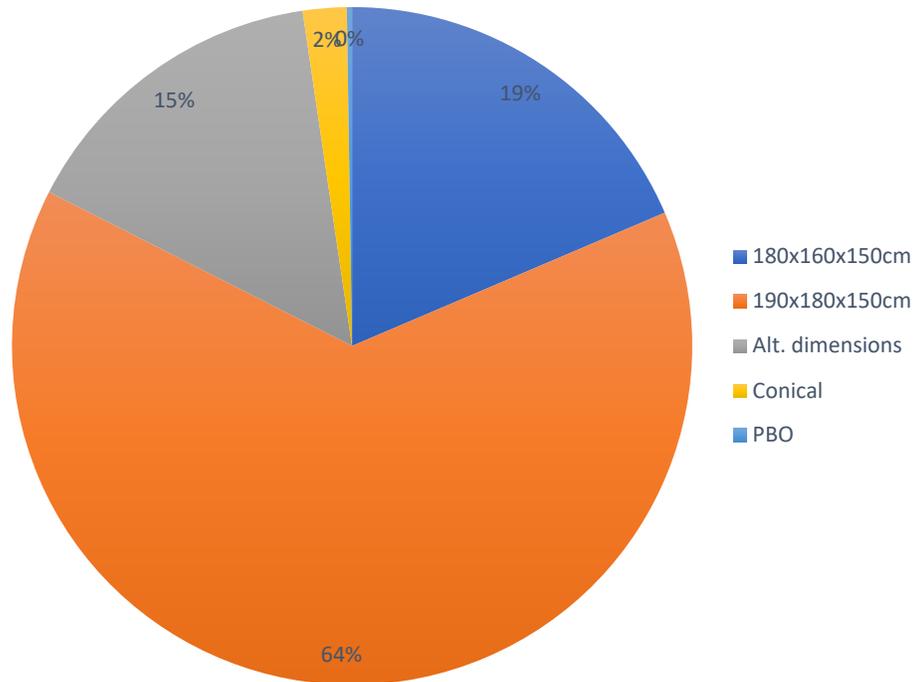
Increase in polyester nets stuffing capacity and slight improvement in polyethylene stuffing capacity

UNICEF LLINs LTAs utilizations 2014-2020

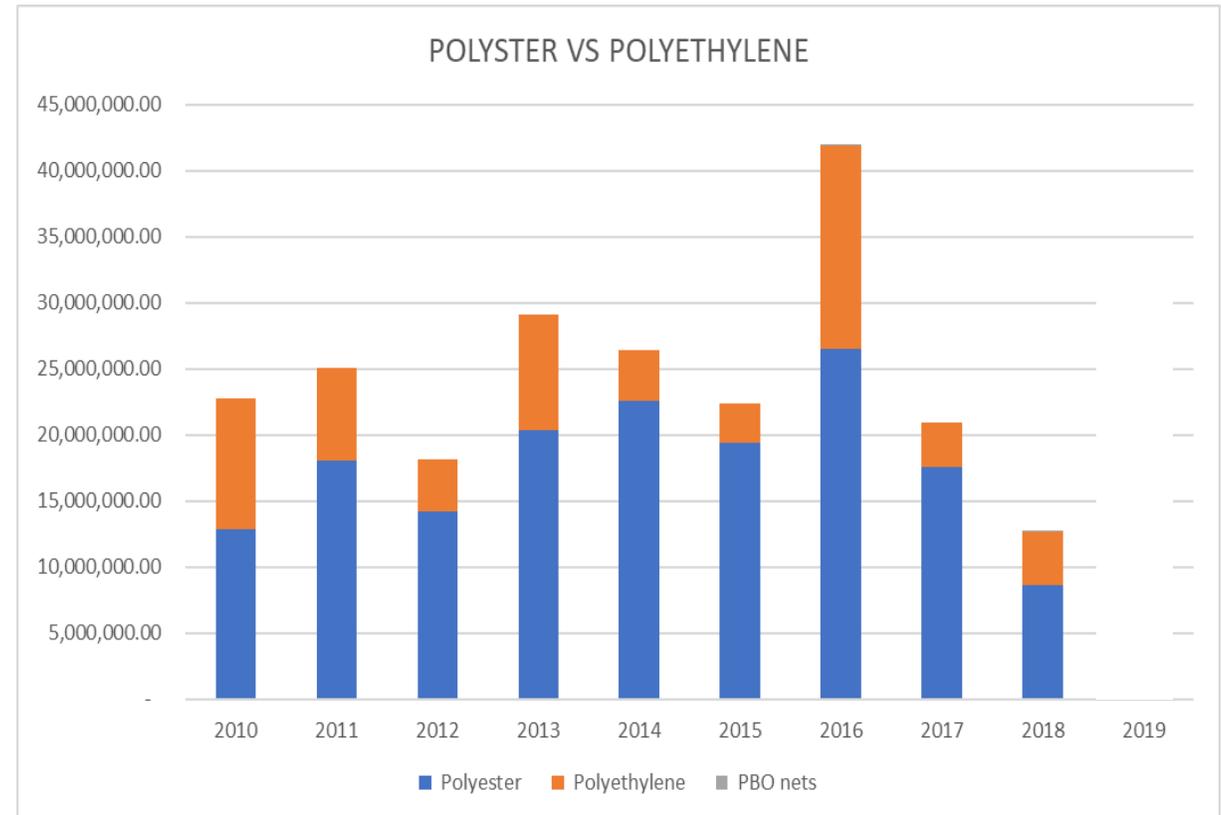


2019 LLINs Procurement trends (Sizes, net type)

Distribution of sizes 2010-2019



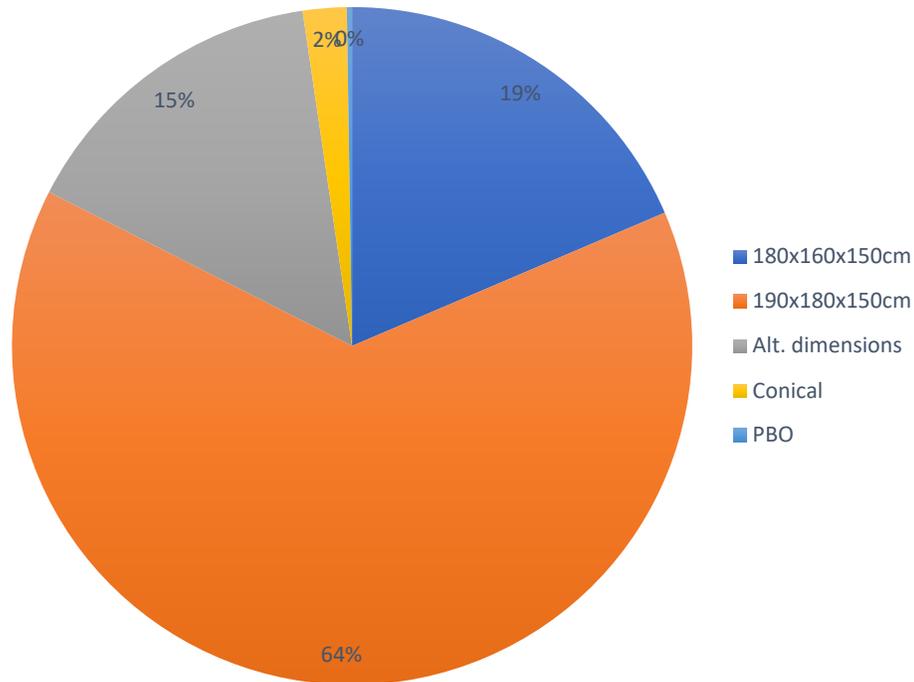
The procurement of conical nets has been reduced due to its higher price than the other standard sizes and the longer lead times for manufacturing.



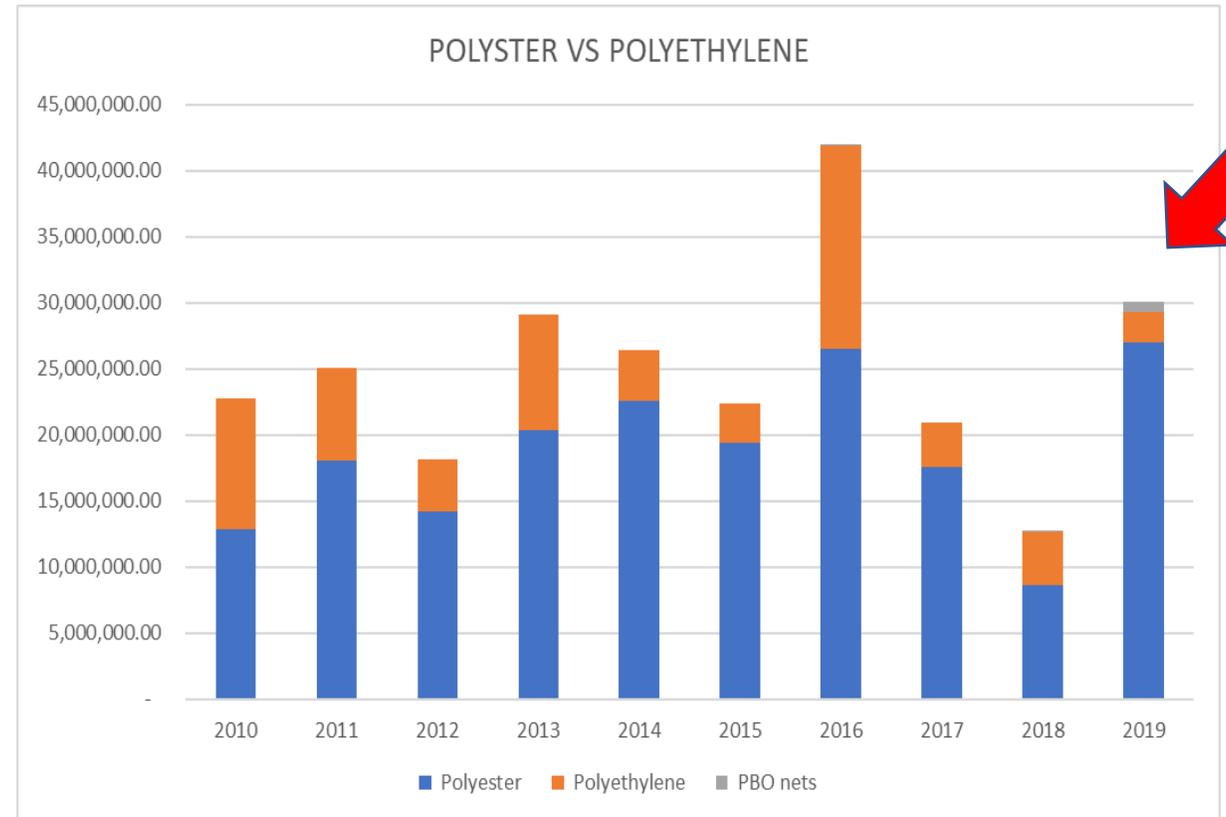
Continued trend of preference for polyester vs polyethylene nets .. especially during mass campaigns

2019 LLINs Procurement trends (Sizes, net type)

Distribution of sizes 2010-2019



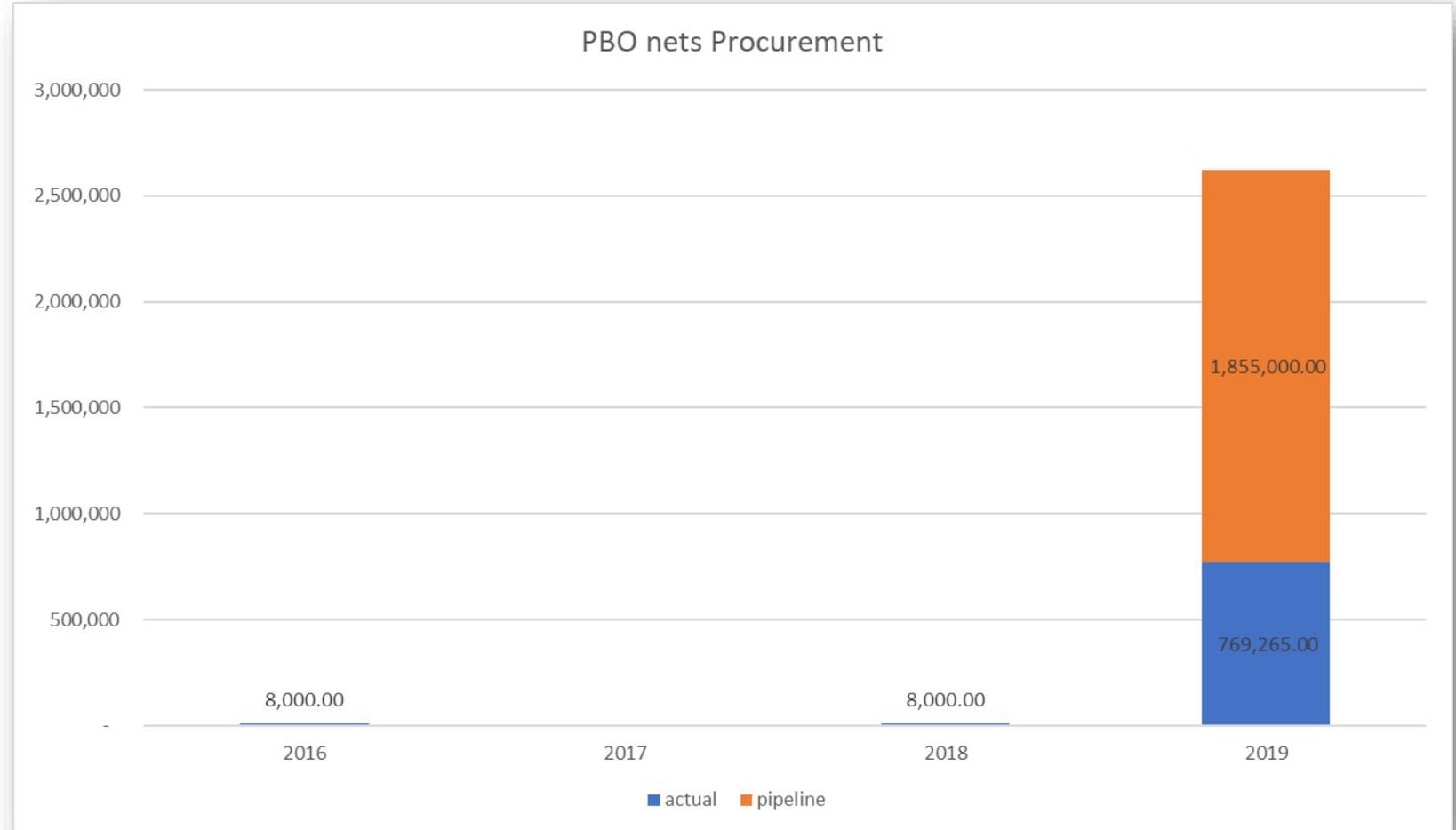
The procurement of conical nets has been reduced due to its higher price than the other standard sizes and the longer lead times for manufacturing.



Continued trend of preference for polyester vs polyethylene nets .. especially during mass campaigns

UNICEF Procurement of PBO nets

- 8000 PBO nets were procured in 2016 and in 2018
- We have procured more than 700K PBO nets in 2019 to 3 countries from 2 suppliers
- Additional 1.8 M LLINs are on our pipeline (for 2 countries)



Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

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UNICEF Suppliers Performance Evaluation



PO Quantity by Receiving Country and FCA Port

FCA ● Chennai, India ● Dar Es Salaam, Tanzani ● Ho Chi Minh, Vietnam ● Shanghai, China ● Shenzhen, China ● Tianjin, China



Progress of UNICEF 2019 LLINs campaigns



Sudan Campaign



9,6M LLINs



239 containers



18 shipments from 2 FCA ports



1 delivery point (12 Districts)



All 239 containers shipped and received at port of arrival.

Loaded and shipped from 2 locations within less than 4 months.

Burundi Campaign



6.3M LLINs



162 containers



13 shipments from 4 FCA ports



3 delivery points (20 districts)



10 container received at port of arrival, 152 still en route to port of arrival.

All 152 containers loaded and shipped from 4 locations within 3.5 months.

Chad Campaign



8.2M LLINs



205 containers



18 shipments from 4 FCA ports



3 delivery points (13 districts)



129 containers en route to port of arrival, 76 containers still to be loaded.

All 205 containers scheduled to be loaded and shipped from four locations within less than 2 months.

Challenges

Emergency Orders

- Fast response on emergency requirements
- Availability for smaller quantities
- In-country registration requirements

Campaigns

- Availability of large quantities at time of PO placement
- Proper markings on shipment and documents for easy identification
- In country registration requirements

Transportation

- Availability of larger amounts of containers
- Close co-ordination of loading to avoid delays
- Congestion at port of arrival

Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

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UNICEF Suppliers Performance Evaluation



UNICEF Suppliers performance evaluation

PO Delivery date

The date when the Freight forwarder receives the goods at port with the full set of documents -as per the PO INCOTERMS.

Goods readiness date

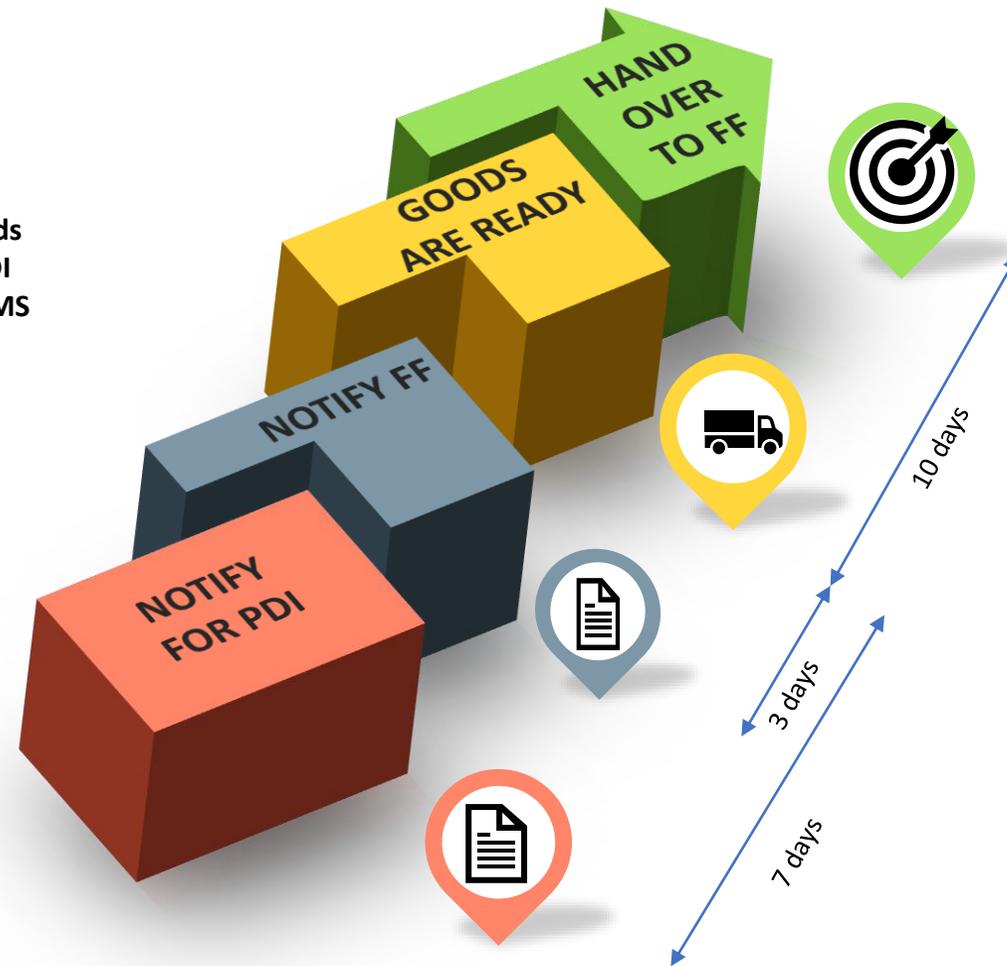
The date when the supplier will make the goods and related documents available including PDI and ready for pick up as per the PO INCOTERMS

Notification of Goods readiness date

Complete the NGR form of the PO 3 days before the goods are ready, send to FF copy SD

Notification for PDI/QAC

Send notification to SD -7 days before the goods readiness date



Freight forwarders receives the goods & full doc

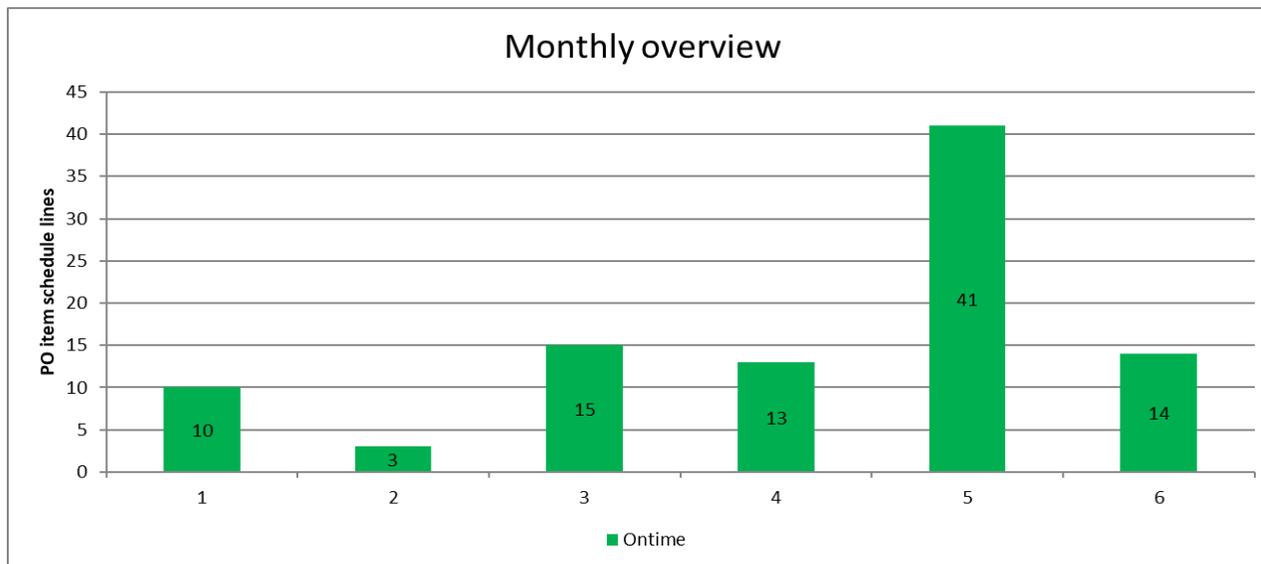
PO delivery date accepted by the supplier

Purchase order no : 45135811	
Issue date	: 18 September 2014
Delivery date	: 13 October 2014
Delivery terms	: INCOTERMS 2010
	: FCA Dublin Airport, Ireland
Payment currency	: EUR
Payment terms	: within 30 days Due net

Evaluating and monitoring supplier performance against their contractual obligations

KPI12 –% Timeliness of Supplier Deliveries (PO item schedule lines) Jan-June 2019

96
shipments
on time



- Evaluating and monitoring supplier performance against their contractual obligations
- KPIs per supplier are closely monitored by SD
- UNICEF will check with the LTA holder(s) the availability for a given LLINs quantity prior to issuing any Purchase Orders – which should be aligned with the production capacity / Lead times mentioned in the LTA



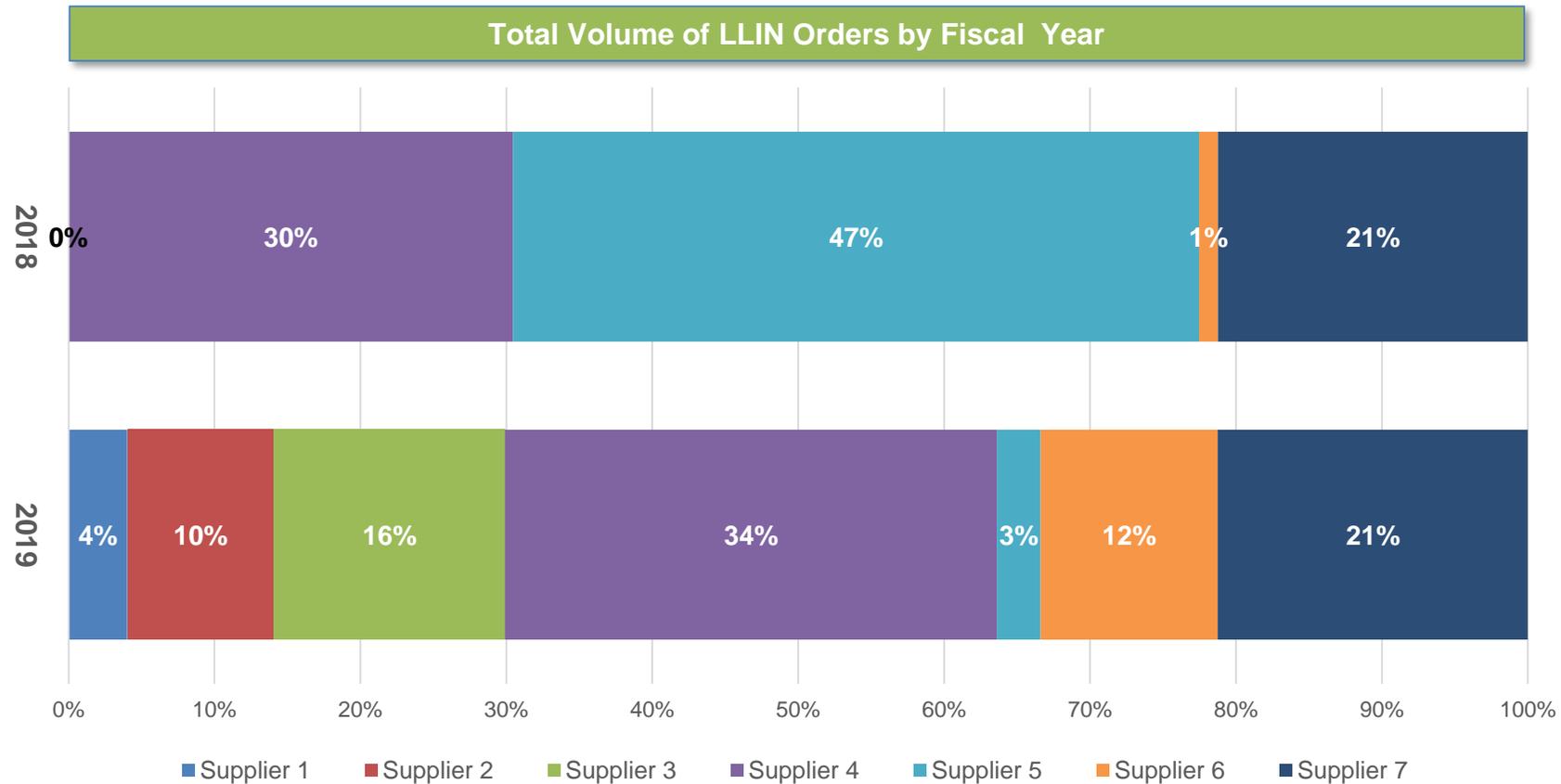
Thank you

PMI LLIN Sourcing and Procurement Update

September 26, 2019

PMI's current goal is to help countries reach and maintain universal coverage of long-lasting ITNs for all individuals living in malaria endemic areas, with a specific target that at least 90% of households with a pregnant woman and/or children under five years of age own at least one ITN.

Changes to Market Landscape and Procurement Processes Result in Shifting Market Share and Increased Market Health



LLIN Standardization

- Rationalization of LLINs sized offered (8 specifications):
 - Rectangular, Polyester, 190x180x150, white
 - Rectangular, Polyester, 190x180x170, white
 - Rectangular, Polyester, 180x160x170, white
 - Rectangular, Polyester, 180x160x150, white
 - Rectangular, Polyethylene, 190x180x170, white
 - Rectangular, Polyethylene, 190x180x150, white
 - Rectangular, Polyethylene, 180x160x170, white
 - Rectangular, Polyethylene, 180x160x150, white
- Eliminated redundant sizes that add complexity
 - E.g. 190x180x170 vs. 180x190x170 (L x W x H)
- Ceased the procurement of hooks and strings packaged with LLINs
- Limited artwork to a single, standard PMI packaging logo
- Maintain 100 denier minimum standard for polyester nets

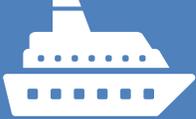
Four essential dimensions evaluated to assess “healthy market,” specific output metrics tailored to individual markets

	Key questions and output metrics	Opportunities
Global capacity	<p>Is there sufficient supply to meet demand?</p> <ul style="list-style-type: none"> – Supply and demand gap – Existence of demand forecast – Forecast accuracy – Lead times, stock out rate 	<p>Standard nets: More than sufficient global capacity, however not all eligible per PMI standards.</p> <p>New nets: Information about country demand and potential for new manufactures to enter depends on efficacy studies required to qualify suppliers .</p>
Affordability & funding	<p>Is pricing affordable?</p> <ul style="list-style-type: none"> – Price relative to substitute and peer markets – % Supply base utilized – Funding and demand gap – Projected funding 	<p>Standard nets: Opportunity to reduce COGS and bring down overall costs</p> <p>New nets: Lack of demand visibility and unknown adoption timelines inhibit forecast accuracy. Minimum volume guarantee and/or other subsidies could bring ITNs into a more affordable range.</p>
Supply risk	<p>Is there sustainable, secure supply of these products?</p> <ul style="list-style-type: none"> – Number and diversity of suppliers – Margins / price relative to cost – Product registration coverage – Scalability of capacity 	<p>Standard nets: Evaluation criteria is weighted using a best value approach with emphasis is placed on minimizing supplier concentration.</p> <p>New nets: Shifting demand should produce incentive for suppliers to innovate new effective nets to combat resistance. It is important that global market deals with first mover suppliers do not eliminate incentive for new entrants.</p>
Product quality & appropriateness	<p>Are there quality products that meet user needs?</p> <ul style="list-style-type: none"> – Effective products with regulatory approvals – Quality of products – Appropriateness based on target customer needs – Incentives for innovating improved products 	<p>Standard nets: Potential to become ineffective due to increasing pyrethroid resistance.</p> <p>New nets: Additional data required to ensure appropriateness based on efficacy compared to alternatives. Emphasis will be placed on providing the opportunity and incentive for suppliers to pursue production of new nets.</p>

Strategic Procurement Objectives

- Promote **competition** to the maximum extent practical
 - Competition among IDIQ holders for share of total PSM procurement
- Deliver critical health commodities **on time**
 - Supplier performance monitoring, staggered GADs, potential for make to stock
- Operate an **efficient** and effective supply chain
 - Reduced procurement lead time through reduced tendering burden, potential for improved planning resulting in cost savings across supply chain
- Retain **flexibility** in order to be agile and responsive to changing needs and priorities
 - Option to compete orders and re-solicit pricing or proposals
- Pursue near and long-term **best value** in accordance with program objectives
 - Best value determination per evaluation criteria

“Best Value” Determined across multiple Criteria in Support of Near and Long-Term Programmatic, Market, and Supply chain objectives

					
Total Landed Cost	Supplier Performance	Registration Coverage	Product Portfolio	Quality	Market Health Considerations
<p>Suppliers that offer competitive pricing minimize cost burden on recipient countries, enabling increased coverage and available funding for other life saving medical supplies. Additional benefit is derived when supplier(s) are able to make goods available closer to the destination, thereby minimizing the burden of the freight cost.</p>	<p>Inclusive of:</p> <ul style="list-style-type: none"> • On-time delivery (GAD adherence) • Avoidance of incidents impacting on-time in full delivery • Quality control (nets that are in-line with product specifications) 	<p>Many countries impose varying levels of registration requirements. Suppliers that invest in broad registration coverage provide greater value by increasing the ability to import the required product(s)</p>	<p>Certain products may have infrequent or uncertain demand. But Suppliers' investment in developing and maintaining such products within their portfolios increase the project's ability to respond when the needs arise.</p>	<p>Strict minimum eligibility standards maintained for all nets procured for recipient countries to ensure that a manufacturer can produce product(s) capable of achieving the desired result for the end user.</p>	<p>PMI aims to limit supply risk while ensuring sufficient capacity exists to meet current and future global demand, as well as drive value through competitive market dynamics by procuring from multiple suppliers</p>

Allocation and Order Assignment Processes are Designed to Reward Suppliers Offering Best Value Without Compromising Project Goals

Market Share Allocation



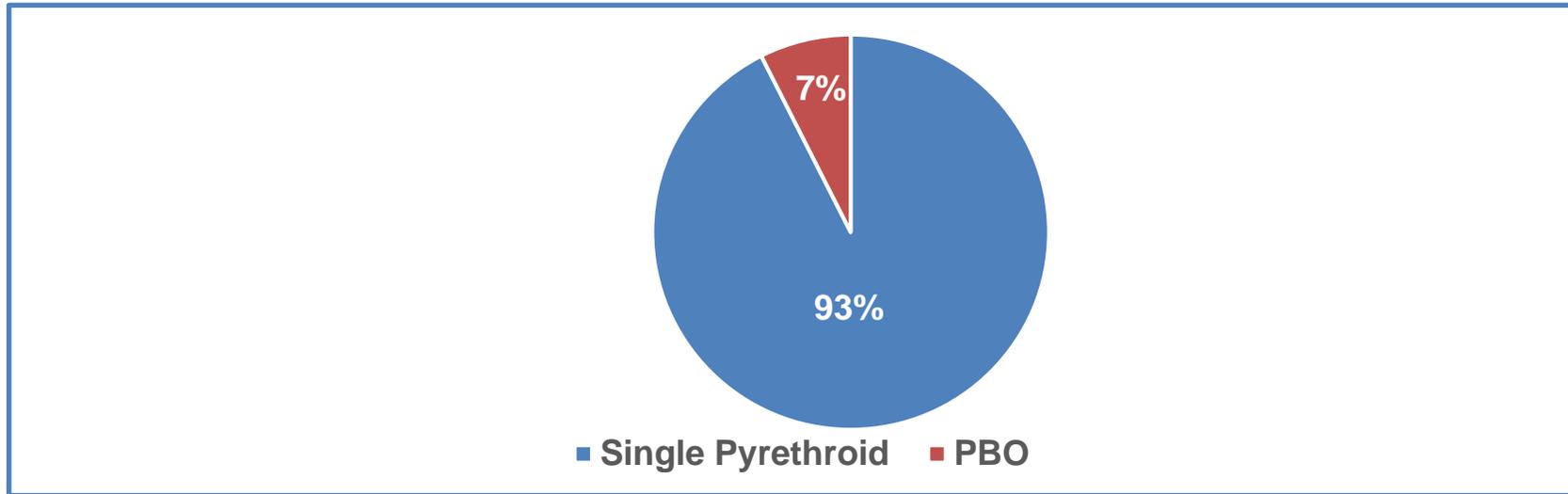
Order Assignment



Process	Communication
<p>Awarded suppliers are evaluated against each other to determine allocation (market share) targets</p> <ul style="list-style-type: none"> • Evaluation objective is to score suppliers in terms of best value to PMI and thereby determine appropriate market share • Depending on demand/breadth of supply base, not all suppliers that were awarded LTAs will receive an allocation 	<ul style="list-style-type: none"> • Supplier-specific volume forecasts are provided at the product level for the coming fiscal year • Suppliers are informed of strengths/weaknesses of offering that primarily influenced its allocation
<ul style="list-style-type: none"> • Following receipt of firm orders from recipient countries, each order is assigned either individually or in bulk, depending on factors such as urgency, funding, etc. • Individual order assignments take into consideration a variety of constraining factors, such as country registration and shelf life requirements, production capacity, market share targets, etc. 	<ul style="list-style-type: none"> • Suppliers are informed of assigned orders, subject to confirmation of ability to meet GAD(s), registration status, etc. <ul style="list-style-type: none"> • Period between order assignment and GAD can range from 1-18 months • If confirmed, PO will be issued upon availability of funding

Demand for PBO Nets Slowly Materializing

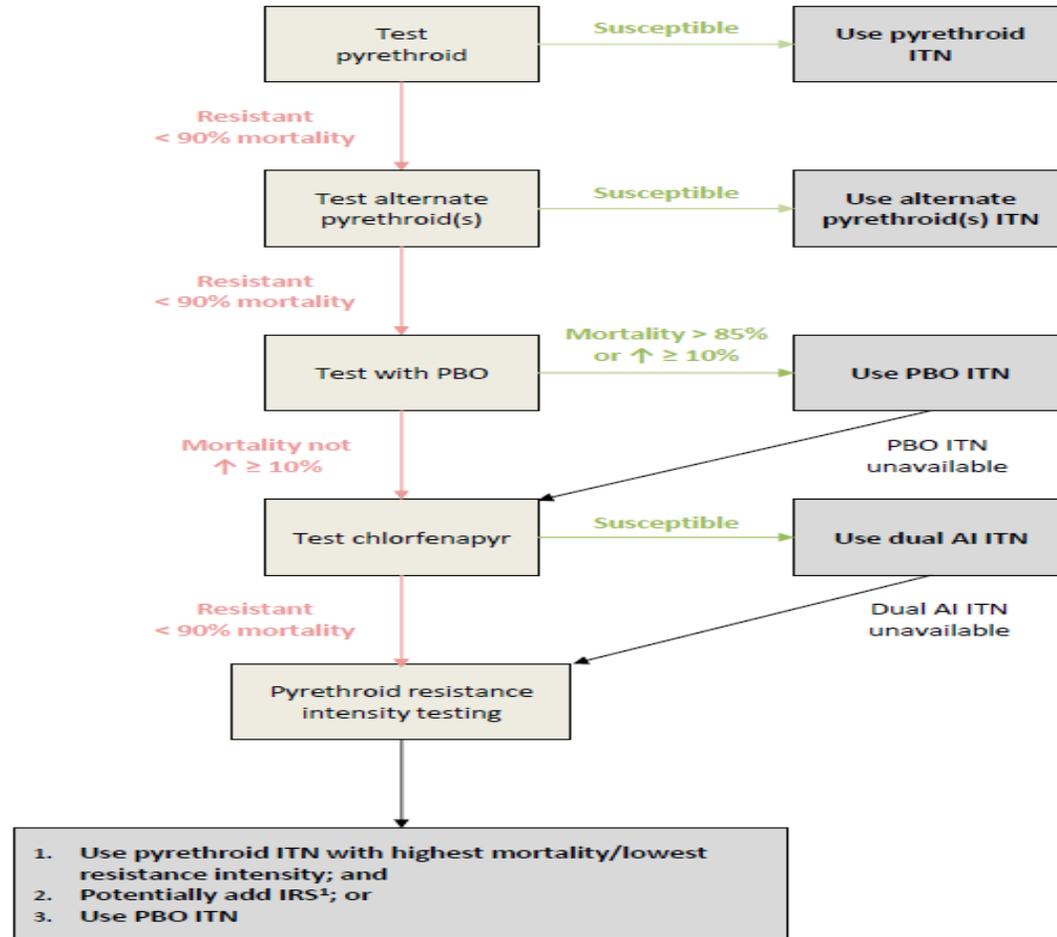
Type of Net Procured October 2017 – June 2019



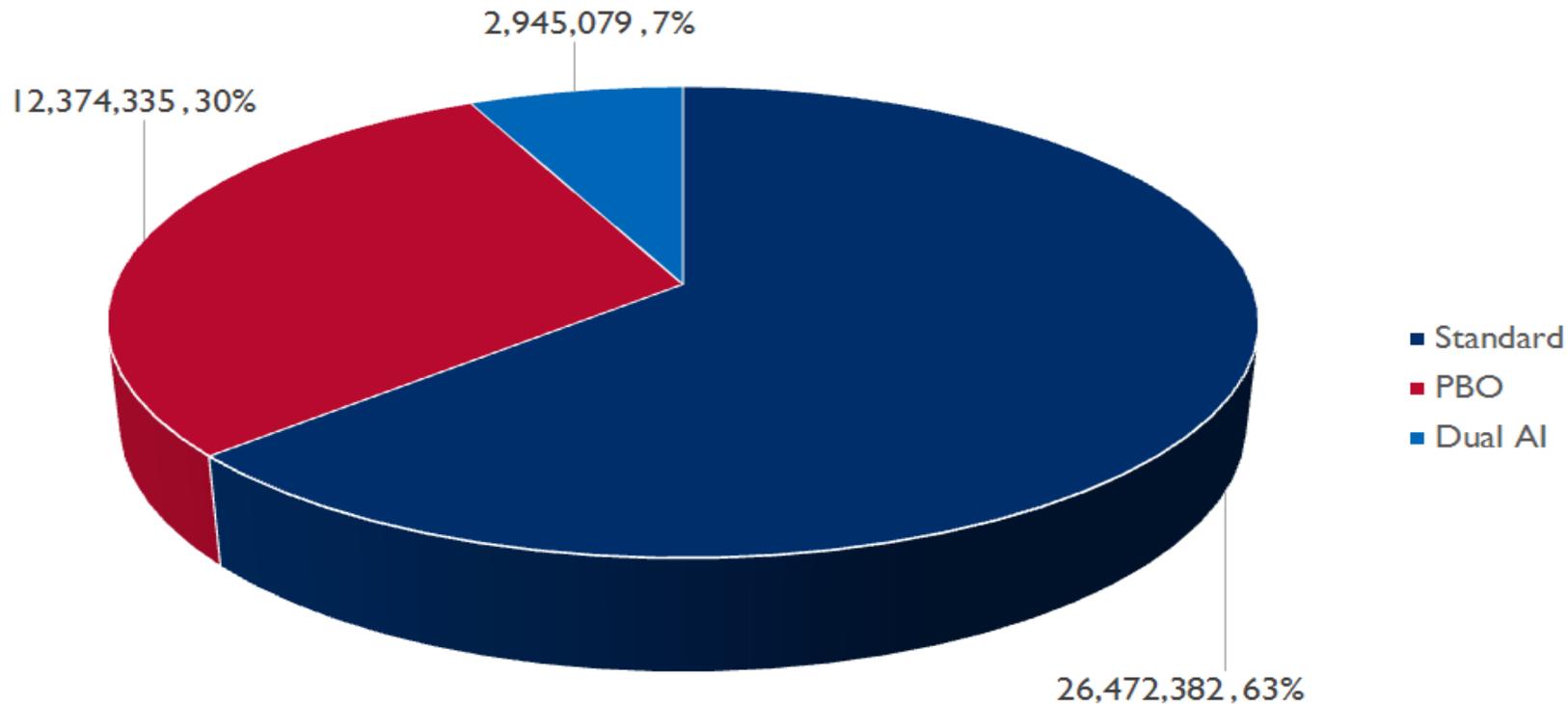
More than 100 million nets PMI procured in FY2018 through Q2 of FY2019: 93% were single pyrethroid.

Given expected demand increase for the PBO nets, additional PBO net suppliers being evaluated by PMI for QA approval and addition to the PSM list of eligible suppliers.

PMI Decision Tree for Selection of ITNs Based on Insecticide Resistance Monitoring Data



Demand for PBO and Dual AI Net is Projected to Increase Substantially¹ in FY20



1. For presentation purposes only.
Not a confirmed commitment of PMI

Thank You



USAID
FROM THE AMERICAN PEOPLE

PRESIDENT'S MALARIA INITIATIVE



**Long-lasting Insecticidal Nets
Supplier & Partner Consultative Meeting**

Global Fund LLIN Strategy

26 September 2019

Singapore

Global Fund Team

Disclaimer

The Global Fund Procurement Strategy on LLINs is currently under development and will be finalized in the forthcoming weeks.

This document presents the Global Fund's current intention which is subject to change.

The data and information herein are provided for illustrative purposes and derived from a limited and preliminary analysis of the Global Fund.

The present document shall not be considered as the Global Fund's representation or commitment of any kind.

Agenda

- **The Global Fund: Introduction, Market Shaping Strategy & Strategic Sourcing**
- LLIN Market Observations
- LLIN Procurement Strategy: 2020 - 2021
- Global Fund 2019 LLIN Tender Approach and Timelines

Key contacts on the LLIN Procurement Strategy



Philippe François
Head, Sourcing & Supply Chain Dept.



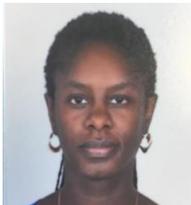
Lin (Roger) Li
Senior Manager,
Strategic Sourcing



Azizkhon Jafarov
Manager, Global Sourcing,
Health Technologies



Alain Prat
Team Leader, Quality Assurance,
Health Product Management,
Sourcing & Supply Chain Dept.



Clarisse Morris
Specialist, Global Sourcing, Health
Technologies, Vector Control



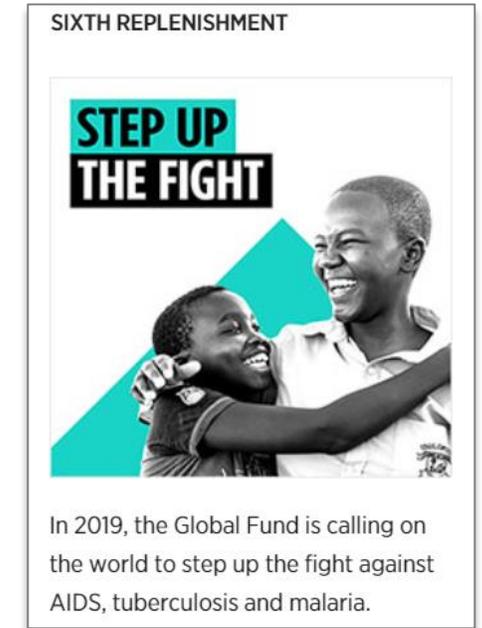
Tulin Kontente Adiyaman
Legal Counsel



Artem Lazurenko
Integrity Due Diligence Specialist

The Global Fund

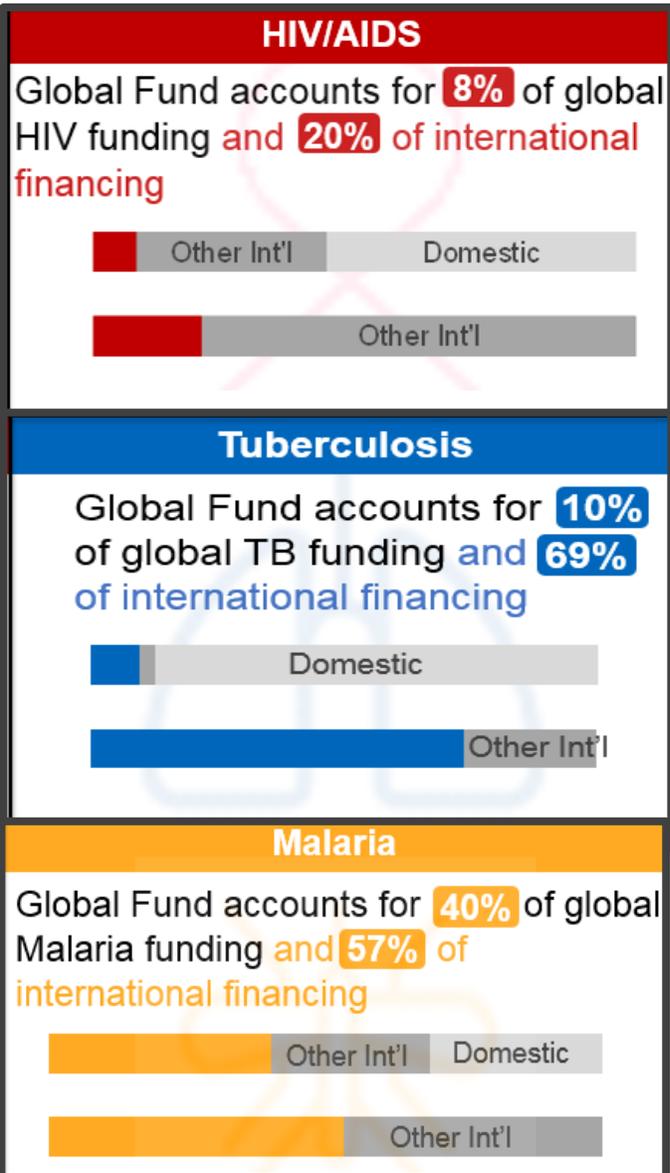
A 21st-century partnership organization to accelerate the end of HIV, tuberculosis and malaria as epidemics



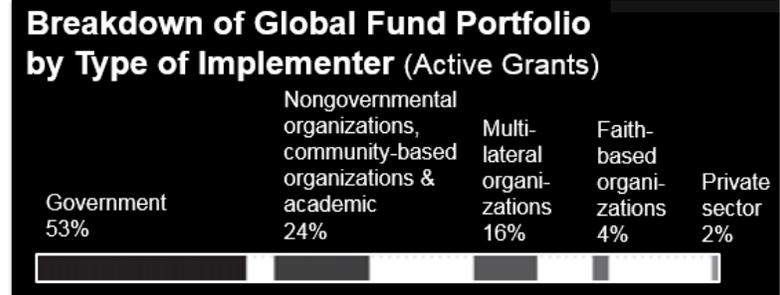
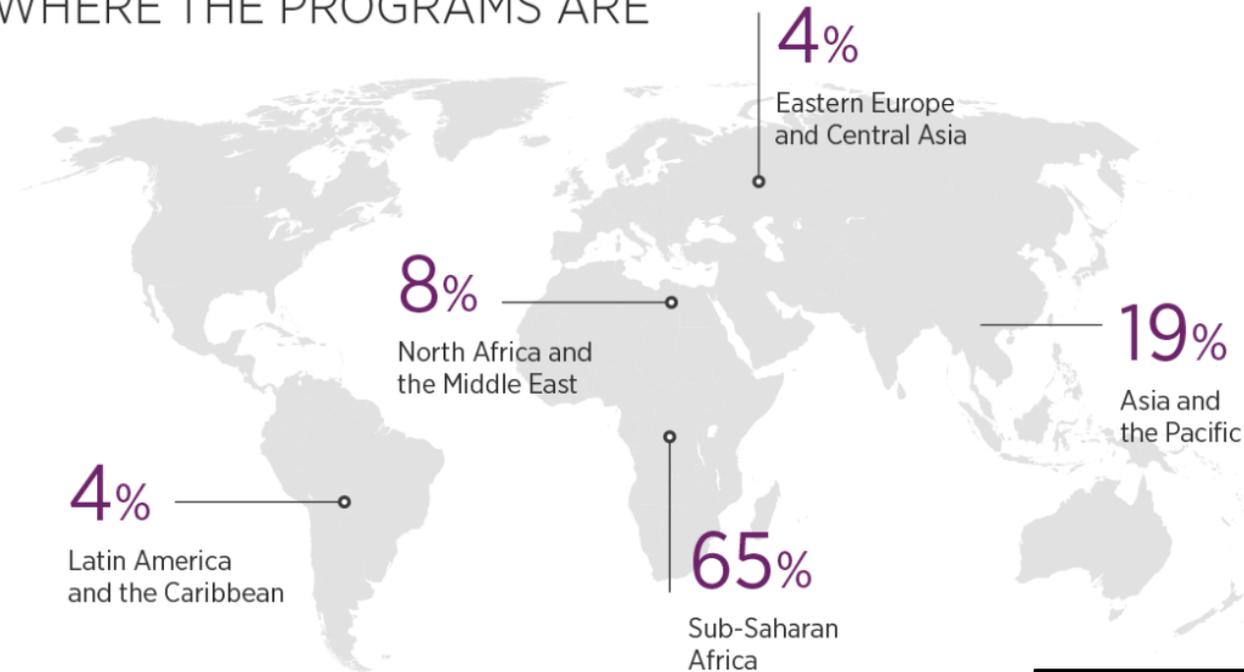
Founded in 2002, the Global Fund is the **leading contributor of resources in the fight against AIDS, tuberculosis and malaria**. It **mobilizes and invests nearly US\$4 billion a year** to support countries and communities most in need. It has an active portfolio of **over 430 active grants in over 100 countries**, implemented by local experts.

The Global Fund is calling on the world to step up the fight against HIV, TB and malaria. In October 2019, President Macron will host the Global Fund's Sixth Replenishment Conference in Lyon. This Replenishment seeks to raise at least **US\$14 billion** to help save 16 million lives, **avert 234 million infections** and help the world get back on track to **end these diseases**. Of the at least US\$14 billion, the Global Fund is calling on the private sector to mobilize at least US\$1 billion to step up the fight.

The USD 4 billion per year spent by the Global Fund is critical in the fight



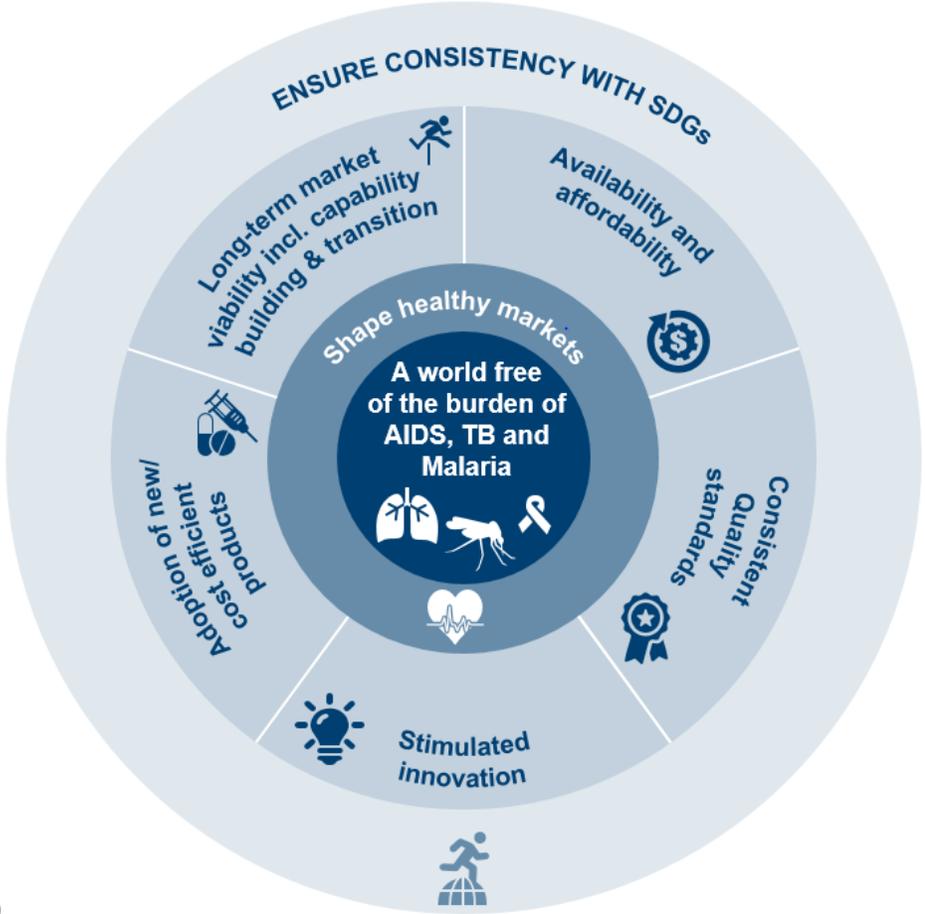
WHERE THE PROGRAMS ARE



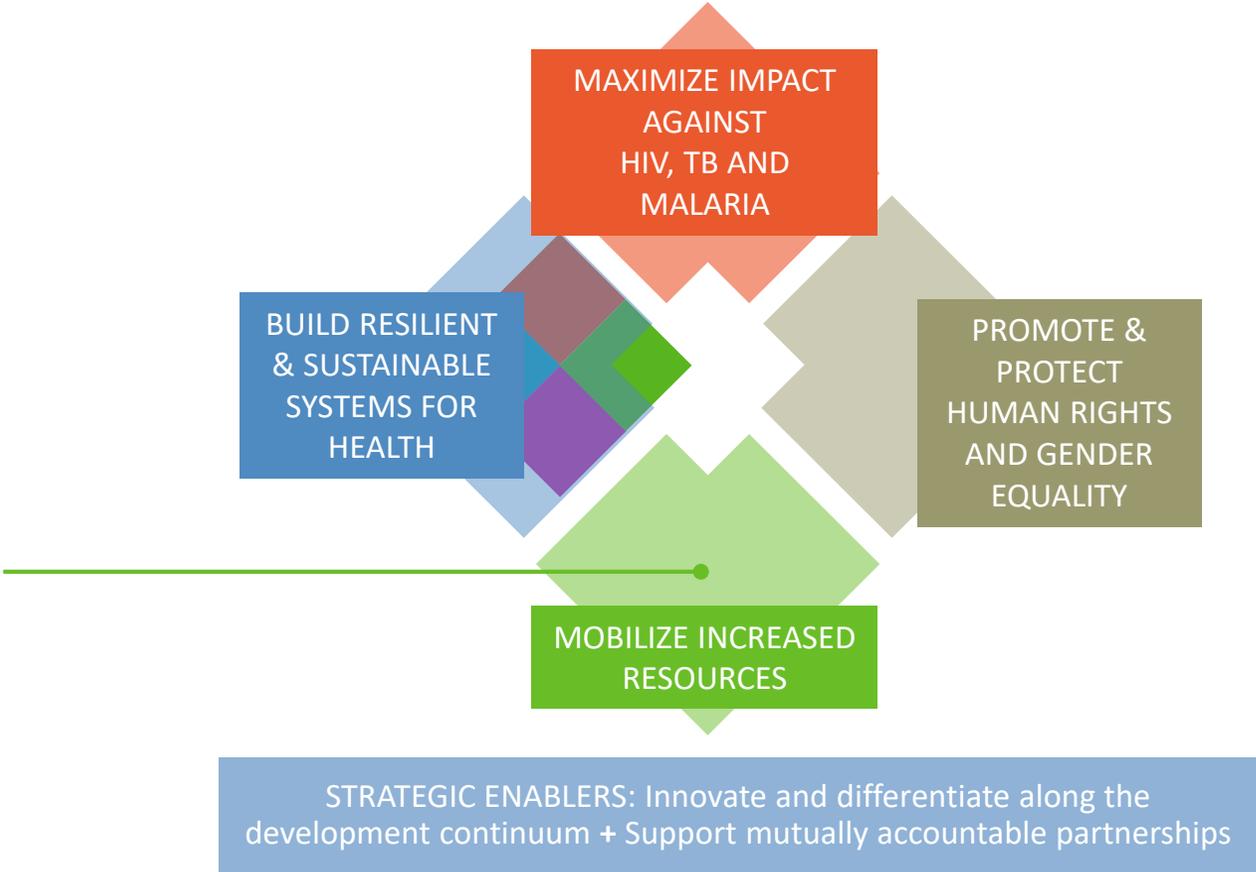
Funding sources [2016 data for HIV/Malaria, 2018 for TB]: OECD DAC-CRS; UNAIDS FactSheet World AIDS Day 2017, UNAIDS; Global Tuberculosis Report 2018, WHO; World Malaria Report 2017, WHO *GF share of international financing*: Global Fund 2017 Results Report. Figures are global and are not solely for countries where Global Fund resources are disbursed.

The Global Fund's Market Shaping Strategy extends beyond its direct spend to help ensure healthy markets and value for money

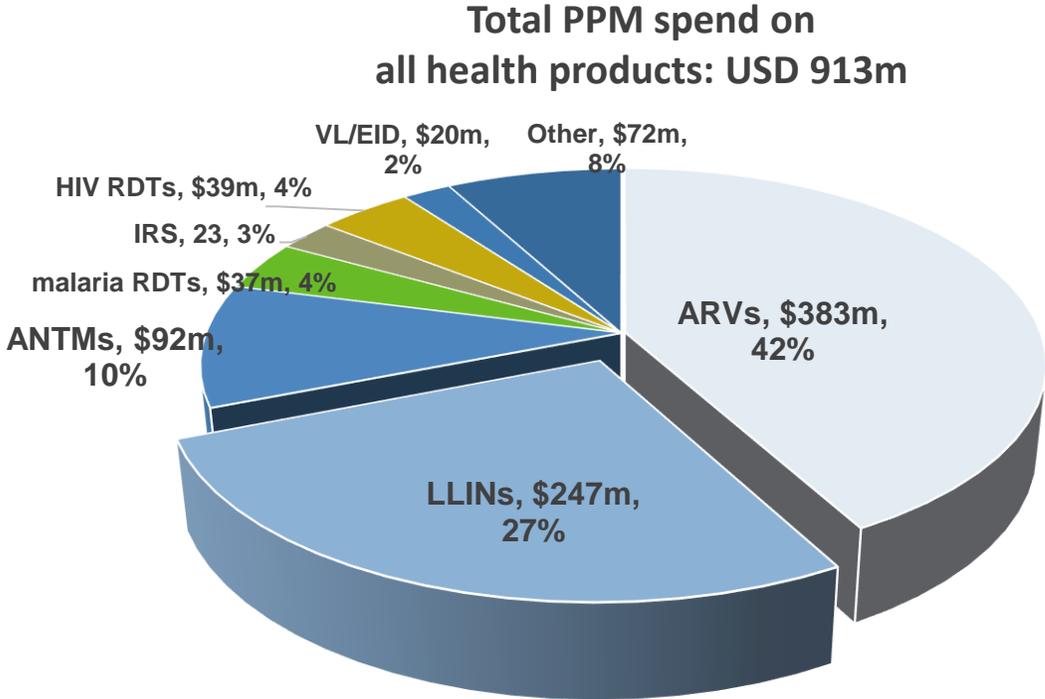
Mission of the Global Fund's Market Shaping Strategy:
Leverage our position to facilitate healthier global markets for health products – today and in the future



Global Fund Strategy 2017-2022



44% of the Pooled Procurement Mechanism (PPM) health product spend is for malaria-related products and 27% is spent on LLINs



Malaria product volumes

Prevention		LLINs	108m nets
		IRS	1m liters
Diagnostics		Malaria RDTs	120m tests
Treatment		ANTM medicines	110m treatments

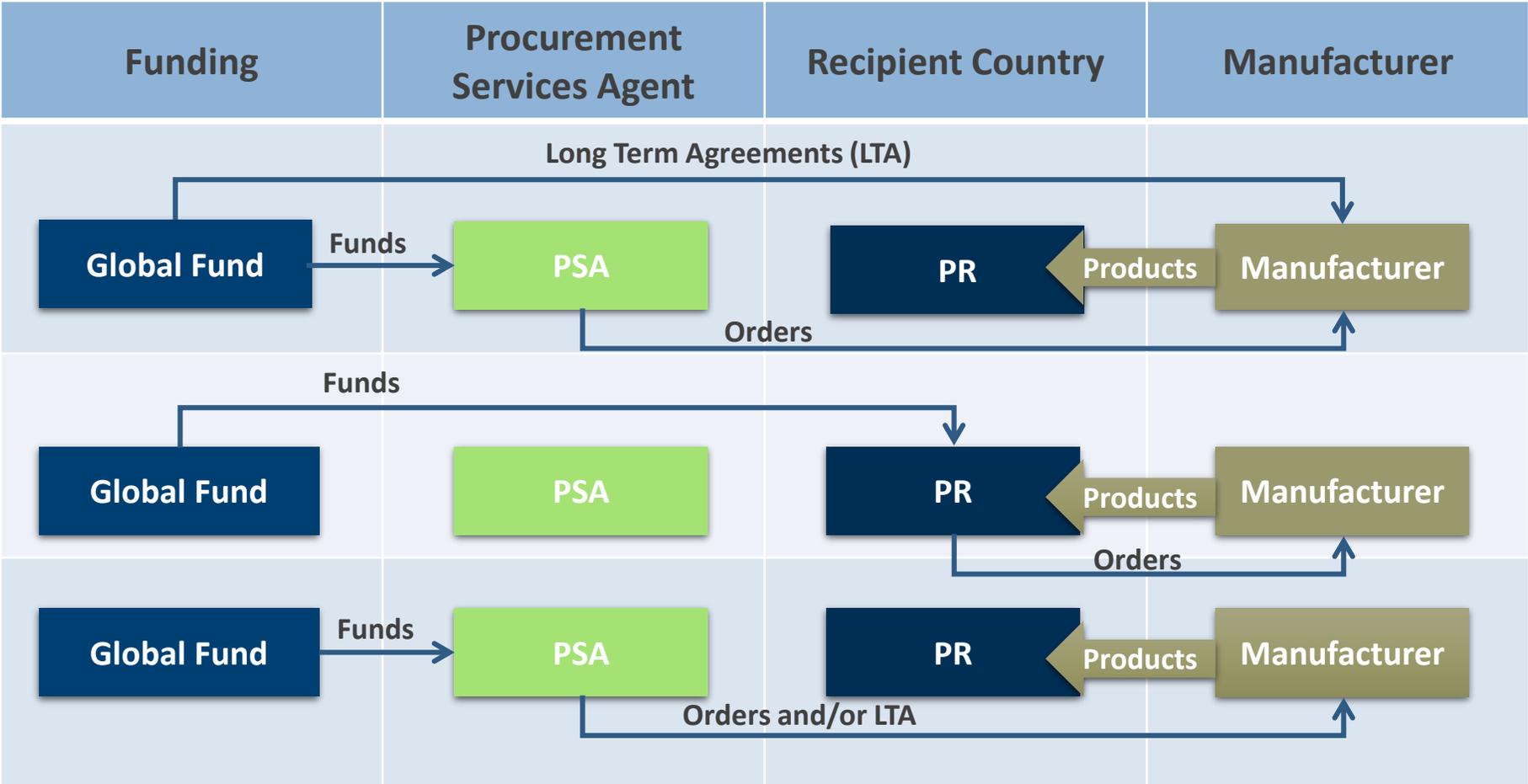
Acronyms:

- ARVs: Antiretroviral medicines
- ANTMs: Antimalarial medicines
- IRS: Indoor Residual Spraying
- LLINs: Long-Lasting Insecticidal Nets
- RDTs: Rapid Diagnostic Tests
- VL/EID: Viral Load/Early infant diagnosis
- Other: General lab equipment & supplies, essential medicines, condoms, and other diagnostics

The Pooled Procurement Mechanism is the largest of the Global Fund’s procurement channels, representing just over half of the Global Fund health product spend, depending on the category

~55% of Global Fund health product spend

Pooled Procurement Mechanism (PPM)



Partners, donors and other stakeholders expect the Global Fund to deliver a responsible procurement approach that supports the Sustainable Development Goals



In 2015, countries gathered and committed to end poverty, protect the planet and ensure prosperity for all. Increasingly, partners and donors are keen to see how they can leverage their investments to deliver on shared objectives of the SDGs.

Responsible procurement features in the Global Fund’s market shaping work

DIMENSIONS



Economy

Description

- Provide additional economic benefits to in-country community
- Empower community by sharing knowledge



Ecology

- Mitigate effect on environment along the end-to-end supply chain
- Use knowledge and skills to contribute to a constant rise in eco-efficiency



Society

- Promote fundamental human rights, e.g.,
 - Advocate for decent labor conditions
 - Promote children rights
- Promote workers’ health and safety



Business practices

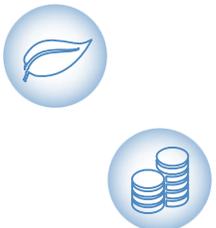
- Promote best business practices among suppliers and other buyers



Principles for building holistic standards

- Build on existing guidelines
- Provide practical guidance
- Include phased approach
- Focus on procurement
- Align with GF objectives

The Global Fund addresses each dimension of the responsible procurement framework through a case-by-case approach

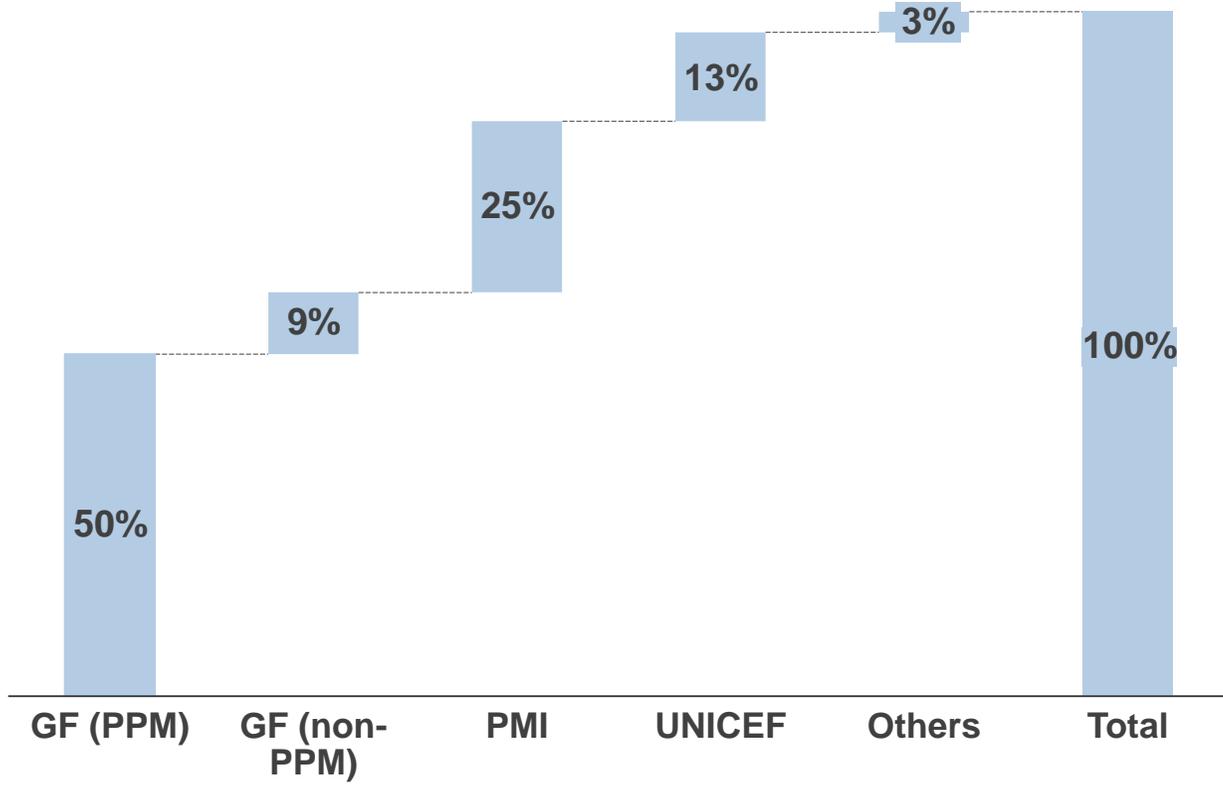
Dimensions addressed	Case examples	Issues	Solutions
	 <p>LLIN</p>	<ul style="list-style-type: none"> ▪ LLIN manufacturing countries have weak regulators' focus on textile ▪ Plastics and insecticides used for LLINs present high chemical risks for environment ▪ Historical reputational issues related to corruption, environment and disposal 	<ul style="list-style-type: none"> ▪ GF mandated social and environmental assessment by a 3rd party for 7 LLIN production sites in 3 countries. GF provided action plans for each assessed site to implement environmental and labor regulations ▪ GF encouraged Principal Recipients to order bulk packaging of LLINs for campaigns, reducing plastic waste by an estimated 940 tons in 2018
	 <p>Artemisinin</p>	<ul style="list-style-type: none"> ▪ Agricultural artemisinin prices are volatile due to: <ul style="list-style-type: none"> ▪ Overproduction capacity because of low technical barrier to entry ▪ Lack of harmonized quality standards ▪ Agricultural artemisinin price volatility causes supply interruptions to ACT suppliers 	<ul style="list-style-type: none"> ▪ GF mitigated price volatility and environmental risks by visiting agricultural artemisinin producers and reviewing Environmental, Health and Safety (EHS) practices: <ul style="list-style-type: none"> ▪ GF conducted agricultural artemisinin manufacturer qualification through 3rd party ▪ GF incentivized best practices by manufacturers through 3 year volume allocations
	 <p>ARV</p>	<ul style="list-style-type: none"> ▪ Prior reliance on spot tenders contributed to an important reliance on delivery by air ▪ Poor performing suppliers lobby when losing volumes ▪ Outer/secondary paper cartons traditionally included for multi-month ARV packs increase transportation weight and waste 	<ul style="list-style-type: none"> ▪ GF implements performance-based allocations to suppliers, with more than 80% of ARV volume shipped by sea ▪ GF encouraged Principal Recipients to switch to carton-less packaging of multi-month ARVs, reducing freight volume, costs, paper and waste

We have been working with other buyers and partners to deliver market shaping value

Leveraging impact

- 1 Gain visibility on procurement practice and planning
- 2 Coordinate tender cycle and timeline
- 3 Align principles of performance-based procurement approach
- 4 Join/pool Procurement practice

Indicative % of the global LLIN market



 Moving forward, we are seeking for strengthening collaboration to further leverage volume and deliver Market Shaping Value collectively.

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Global Fund's balanced supply system, embedded in its strategic sourcing work, has brought impressive results and helped shape the LLIN market

- A**
 - ❖ Provided **100m nets** per year **at the lowest possible affordable and sustainable price**
 - ❖ Achieved an average **price reduction of 5%** over the past 3 years

- B**
 - ❖ Supplied **90% of LLINs timely and in full** in 2016-2019

- C**
 - ❖ Created **a resilient supplier base** with production **in 6 different countries**
 - ❖ Promoted **responsible and sustainable business practices**:
50% of nets were supplied without bags resulting in **940 tons** of plastic waste avoided

- D**
 - ❖ Met the **Global Fund's and national quality** requirements
 - ❖ **Mitigated implementation risks** including supply continuity risks

- E**
 - ❖ Published **reference prices**
 - ❖ **Provided access** to PPM long term agreements to **other partners**
 - ❖ Incentivized a **broad national registration footprint**

In simplified terms the LLIN production process involves 3 steps

1. Active ingredients (AI) - Insecticide

- Most manufacturers **source AIs** rather than produce them in-house

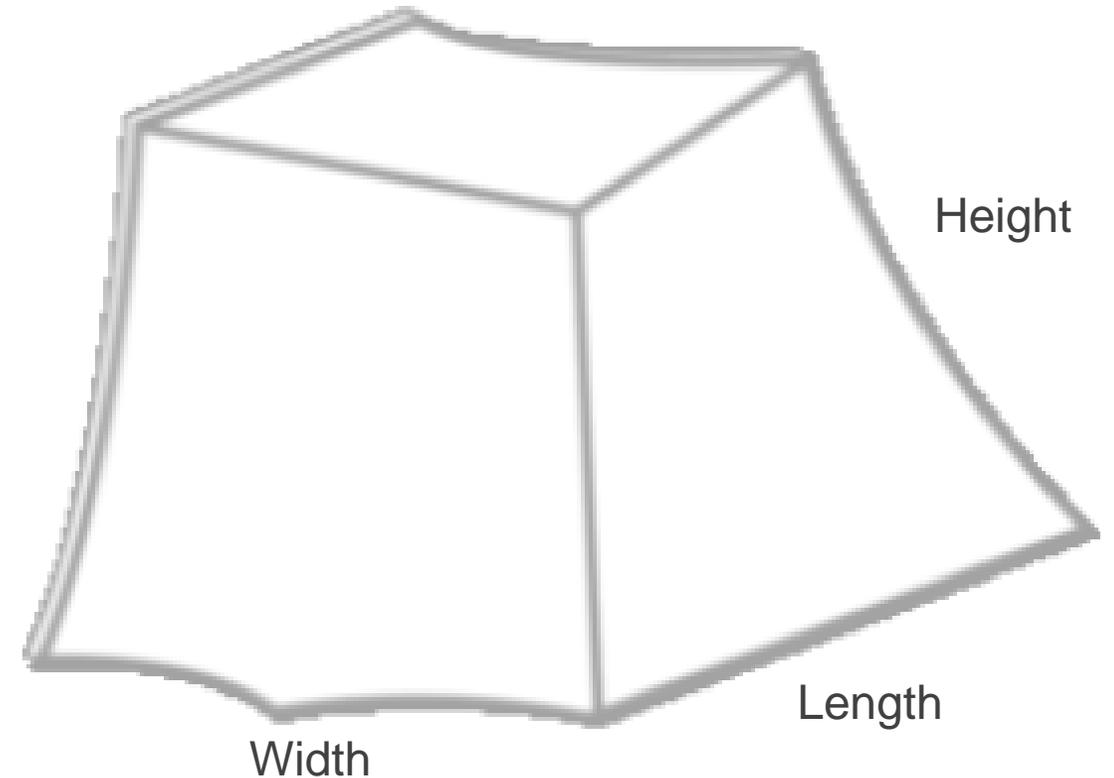
2. Formulation - key supplier know-how

- Coat the **polyester** (PES) fibers with insecticide; or
- Incorporate insecticide into the High Density **polyethylene** (HDPE) fibers

3. Manufacturing nets – Textile

- In-house process, outsourced or a mix of both

Example: 180x190x160cm (LxWxH)



There is a wide variety of **production arrangements** across the end-to end production process creating concerns about **supply continuity, transparency, consistent quality management, anti-competitive practices** and **business commitment**

1 Active Ingredient

- Manufactured in-house vs. sourced from a 3rd party

2 Masterbatch/formulation

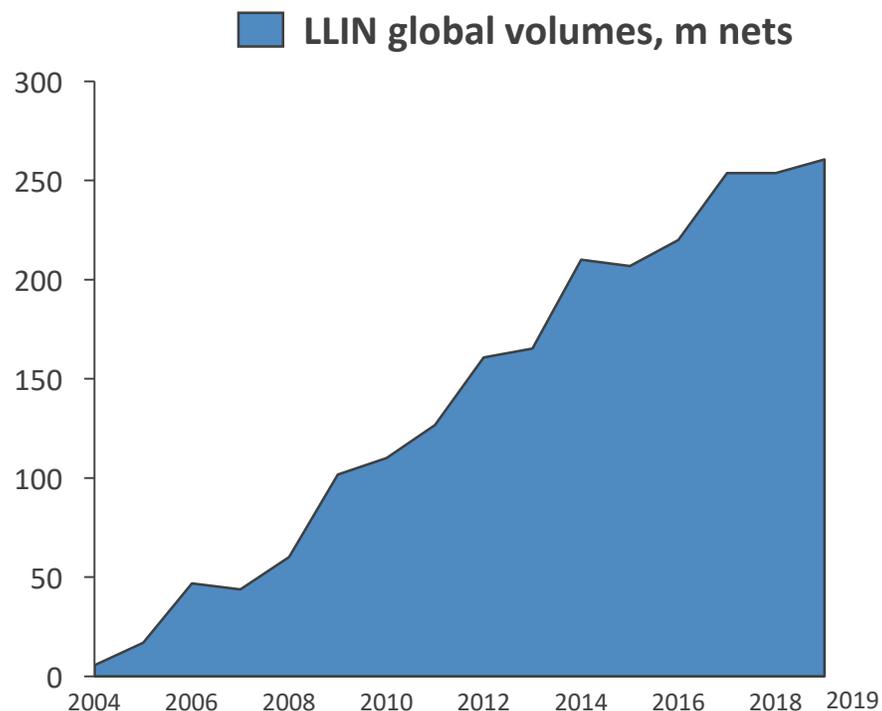
3 Incorporating masterbatch into fiber/coating fabrics

4 Knitting (making fabrics)

5 Cutting, stitching, sewing and packing

- a) **Manufactured in-house** (ownership of fixed assets, technology-know-how, and production)
 - b) **Co-owned and/or outsourced manufacturing:** sub-contracted with some investment (e.g. in machinery)
 - c) **Entirely outsourced manufacturing** process – sub-contracted
- We observe overlapping arrangements – same contractor engages with a number of suppliers with different type of arrangements*

Additional market observations



- **LLIN volumes have increased significantly** over the past 15 years.
- **Barriers to market entry are low** leading to an increasing number of suppliers of pyrethroid nets. **Excess capacity** has resulted in **fierce competition**.
- **LLIN regulatory** process is still **relatively new**, **LLIN quality concerns** are not fully addressed.
- **WHO PBO guidelines** are **challenging to implement** and product specifications vary significantly. In addition **demand for PBO nets is increasing**, while only **few PBO** nets are **prequalified**.
- **Prequalified dual AI nets** are not **eligible** for mainstream Global Fund procurement.
- **Peaks in LLIN demand** are a continuing challenge.
- In response to the Global Fund's previous procurement strategy, **production capacity in Africa** has increased over the past 3-6 years.
- **Inappropriate business practices** (disingenuous lobbying, predatory pricing, unreported non-compliance with MFN clause, anti-competitive behavior)

Agenda

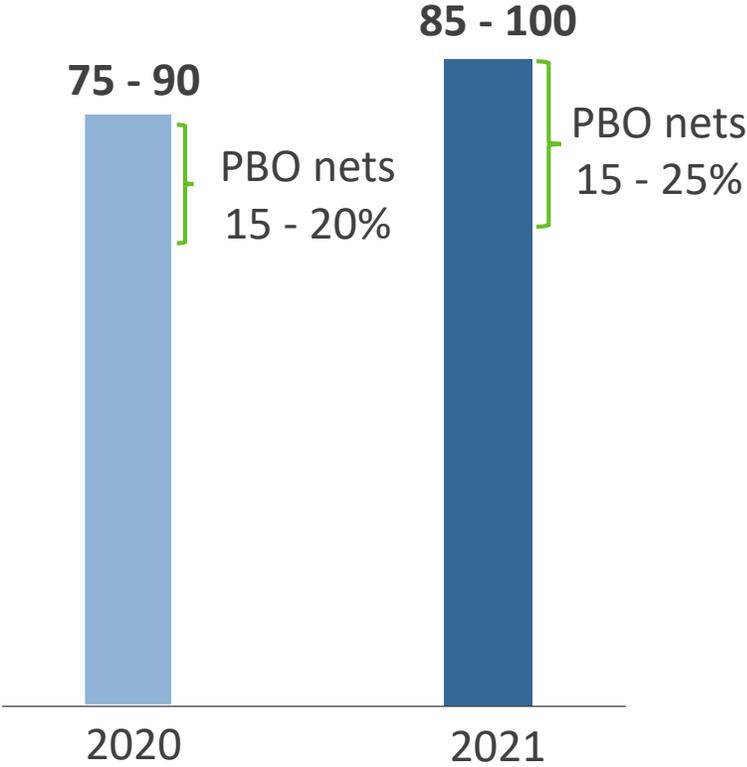
- The Global Fund: Introduction, Market Shaping Strategy & Strategic Sourcing
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Product scope and indicative product volumes* LLIN Bridging Procurement Strategy (2020 – 2021)

Tender Product Scope

Product set	Indicative volume split across product sets
1. Pyrethroid nets	<ul style="list-style-type: none"> 75 - 85%
2. PBO nets	<ul style="list-style-type: none"> 15 - 25% There is interest in increasing the demand for PBO nets
3. Dual AI nets	<ul style="list-style-type: none"> Demand is currently managed through catalytic funding Explore synergies for mainstream procurement

LLIN Demand projection (millions)



Strategic objectives

Leverage volume and joint effort to maximize market shaping value delivery with an emphasis on 5 dimensions, and provide data to support future regulatory and policy implementation.

1. **Quality** assured products
2. Greater **affordability** and improved **delivery** performance
3. **Supply continuity** and long-term **supply base sustainability**
4. Foster **innovation**, facilitate adoption and accelerate scale-up of new products
5. Promote **responsible procurement**

A Bridging Strategy

Evolving the LLIN Procurement Strategy in a shifting product and policy landscape



4 Key Features of the Strategy

- 1** Recognize supplier investment to ensure supply continuity, and prompt sustainable business practices
- 2** Joint effort to support WHO PQ process implementation with a focus on QMS strengthening
- 3** Gradually address Environment, Health and Safety (EHS) concerns through the Responsible Procurement Framework
- 4** Strategic projects: future ambitions on plastic recycling, reuse, and environmentally friendly materials

1

Provide a volume commitment to recognize supplier investment to ensure supply continuity and to prompt sustainable business practices

Indicative

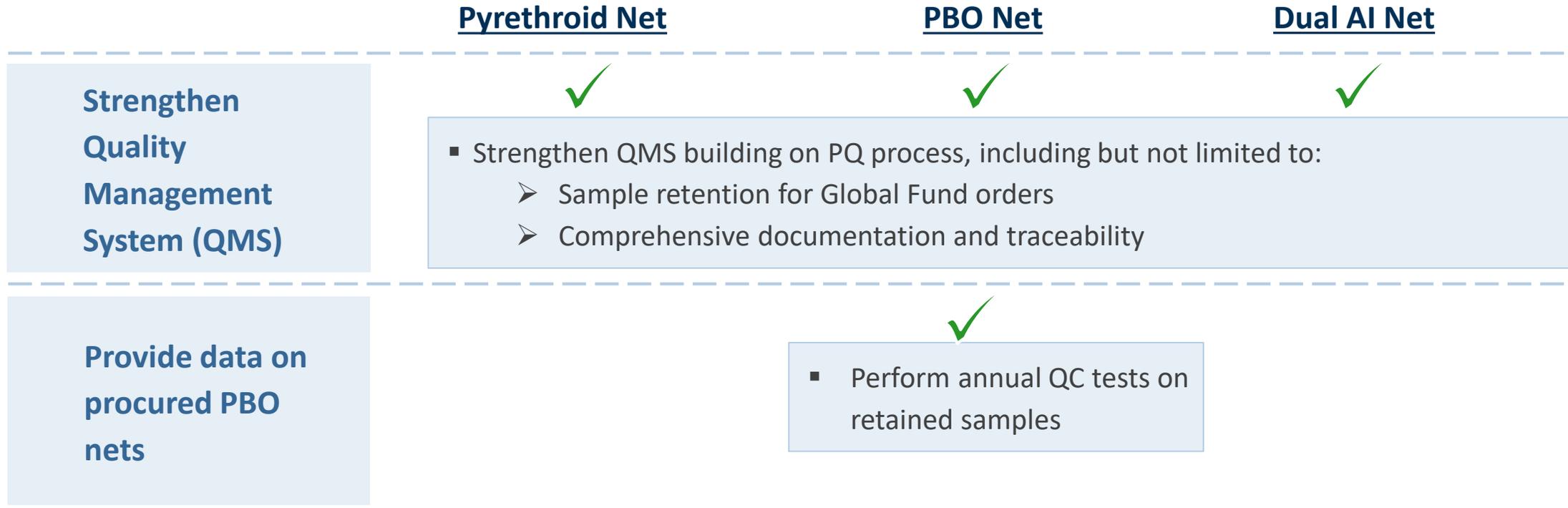
Degree of ownership/investment in these 5 steps	Commitment as % of supplier allocation
1. AI production	15%
2. Masterbatch/formulation technology	15%
3. Incorporating/coating	15%
4. Knitting (making fabrics)	15%
5. Cutting, stitching, sewing and packing	15%
Total:	75%

Suppliers will need to provide evidence for each claimed level of ownership/investment.

During contract implementation:

- Suppliers are required to provide evidence against Global Fund requirements as illustrated above. Subject to evaluation and review, the Global Fund may commit **up to 75% of annual supplier allocation** according to the level of the ownership.

2 Joint effort to support WHO PQ process implementation with a focus on QMS strengthening



During contract implementation:

- Failure to demonstrate QMS strengthening may lead to significant reduction of annual allocation and commitment
- A non-conforming product may lead to termination of the allocation and commitment or other commercial implications, as appropriate

3

Gradually address Environment, Health and Safety (EHS) concerns through the Responsible Procurement Framework

Pyrethroid Net

PBO Net

Dual AI Net

Enhancing
Environment,
Health and
Safety (EHS)



We will require a gradual improvement of the Environmental Management Systems (EMS) and Occupational Health & Safety Management Systems (OH&S) from corporate standards to national standards and towards international standards

During contract implementation:

- Failure to demonstrate progress of EMS and OH&S strengthening may lead to significant reduction of annual allocation and commitment.

4

Strategic projects to address concerns around LLIN plastic in terms of recycling, reuse and introducing environmentally friendly materials

The projects will be assessed along the following dimensions:

Effort/Investment	Is there additional significant effort or investment required to execute the project?
Feasibility	Are these strategic projects feasible to be implemented within the course of the implementation period? Are there any dependencies on other stakeholders (Global Fund, WHO, countries, etc.)?
Ability	Is the supplier able to implement these strategic projects within the course of the implementation period?
Potential value/impact	What is the total potential value/impact that can be yielded by these projects within the course of the implementation period?

During contract implementation, remaining cautious about the cost implications and country ability to implement

- Up to 10% of annual Global Fund volume may be reserved for strategic project implementation

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Principles of our approach

Tender Eligibility

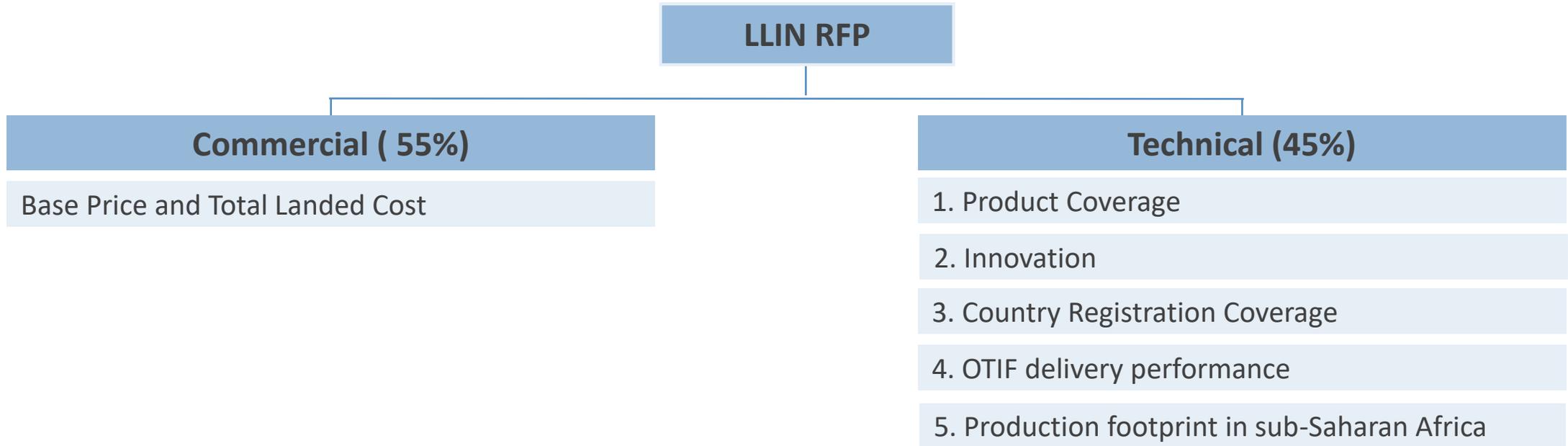
Global Fund Quality Assurance requirements for LLINs

The tender also incorporates legal requirements and an Integrity and Due Diligence Process to **assess threats and risks to values, objectives and reputation of the Global Fund.**

Performance Principles

1. **Volume allocations and commitments** will be managed throughout contract implementation via a **performance-based approach**
2. **On Time In Full (OTIF)** delivery against promised lead times is also part of the performance-based approach
3. **Sustainable supply and good business practices** will be key focus areas during contract implementation
4. The Global Fund values **responsible procurement** and will factor this during implementation

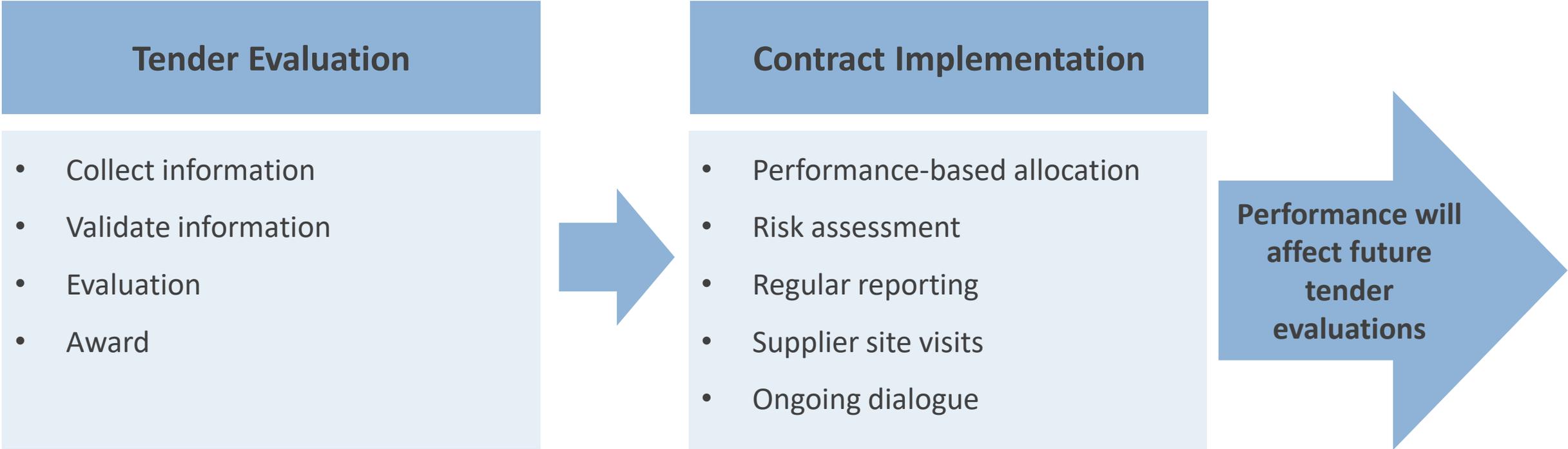
Tender Evaluation Structure



- **The full scope of evaluation criteria** will be **reapplied at annual performance reviews** for subsequent allocation periods
- There will be a **process** to consider **new entrants and/or new products** that become **eligible** for procurement **after tender closure (subject to review)**
- **Volume discount will not be part of tender evaluation**, but will be considered in implementation

Evaluation ratios commercial (55%) vs. technical (45%) have remained the same as in the previous tender in 2015

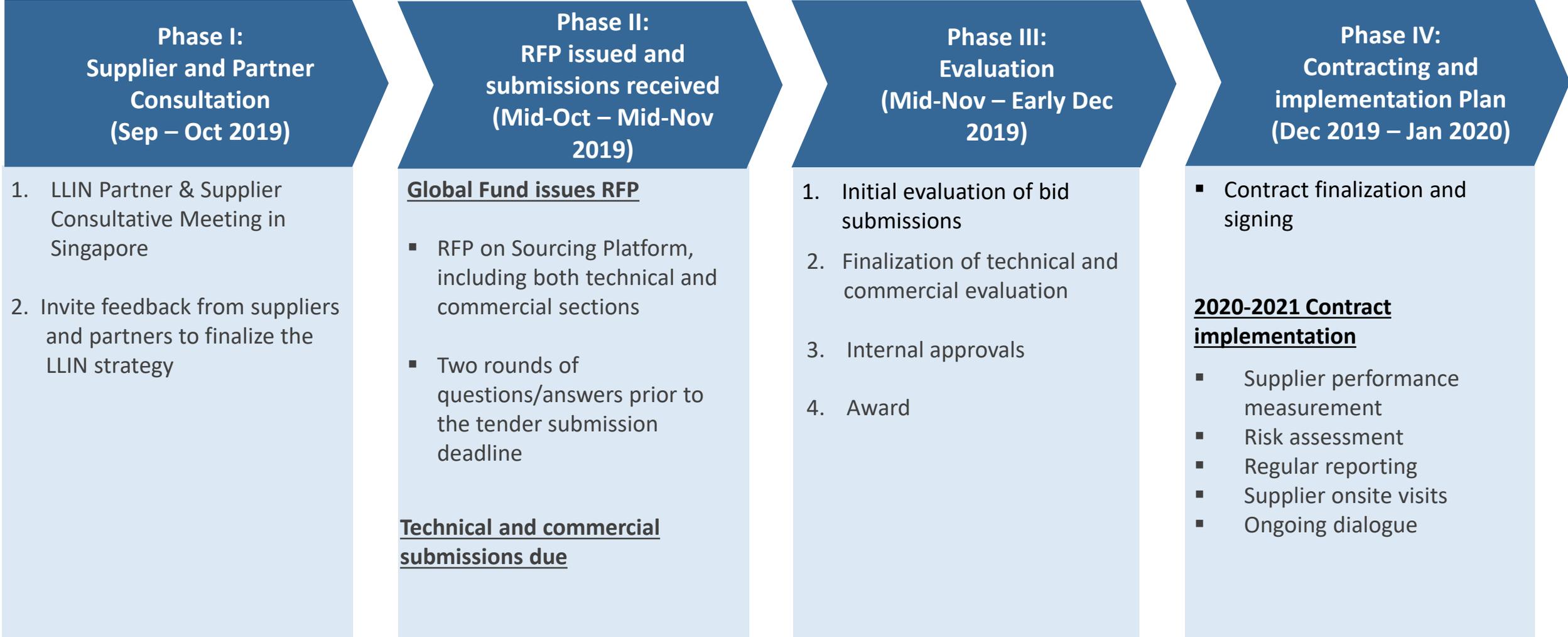
During contract implementation our focus will be on generating value through supplier relationship management



Key measures – Most Favored Nation (MFN) Clause

- MFN clause in contract supports our efforts to ensure best value for Global Fund
- We will proactively manage the principles and implementation of the MFN clause
- Suppliers are required to notify the Global Fund of all their tender price submissions within 7 days
- These notifications will not automatically trigger the MFN clause. Rather the Global Fund will review the submissions and accompanying justifications and decide accordingly.

2019 LLIN tender approach and timelines (indicative)



Request for Proposal Preparation

1. RFP Documentation will be available through the Sourcing Platform and posted on the Global Fund website for downloading
2. There may be a number of documents:
 - Main RFP document
 - Schedules
 - Certificate of Conformance
 - Confidentiality agreement
 - Integrity Due Diligence questionnaire
 - Draft Framework Agreement
3. To submit a complete response to RFP, bidders will need to comply with all requirements as specified
4. We will request a significant amount of information. We will clearly advise which information will be evaluated and which info is for implementation purposes only

Objectives for individual supplier meetings on 27 September

- ✓ Ensure the procurement strategy and approach are understood
- ✓ Listen to your views, and advise on any gaps and/or concerns
- ✓ **We are listening through 4 October 2019 on any further clarifications on the overall strategy**

Thank you!

