Global Fund, UNICEF and PMI LLIN Supplier and Partner Meeting

Dubai, 25-26 October 2017
Welcome remarks by Patrik Latin
Chief Procurement Officer
The Global Fund
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.30 – 9.00</td>
<td>Welcome coffee</td>
<td></td>
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<tr>
<td>09.00 – 09.15</td>
<td>Welcome remarks</td>
<td>Patrik Latin (Global Fund)</td>
</tr>
<tr>
<td>09.15 – 10.00</td>
<td>LLIN Procurement Update and the way forward: Global Fund</td>
<td>Mariatou Tala Jallow (Global Fund)</td>
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<td></td>
<td></td>
<td>Aziz Jafarov (Global Fund)</td>
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<tr>
<td>10.00 – 10.45</td>
<td>Procurement Update: UNICEF</td>
<td>Abdallah Makhlof (UNICEF)</td>
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<td></td>
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<td>Lama Suleiman (UNICEF)</td>
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<tr>
<td>10.45 – 11.15</td>
<td>Coffee</td>
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<tr>
<td>11.15 - 12.00</td>
<td>Procurement Update President’s Malaria Initiative (PMI)</td>
<td>Lisa Hare (President’s Malaria Initiative)</td>
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<tr>
<td>12.00 - 12.45</td>
<td>Quality Assurance</td>
<td>Alain Prat (Global Fund)</td>
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<tr>
<td></td>
<td>- Challenges, Achievements and the way forward</td>
<td>Stuart Turner (UNICEF)</td>
</tr>
<tr>
<td>12.45 – 13.00</td>
<td>Durability Update</td>
<td>Lisa Hare (President’s Malaria Initiative)</td>
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<tr>
<td>13.00 – 14.00</td>
<td>Lunch</td>
<td>Hatta Room</td>
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</tbody>
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## Agenda Day 1 (afternoon)

### TECHNICAL UPDATES

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.00 – 15.30</td>
<td><strong>WHO Vector Control Prequalification Program:</strong>&lt;br&gt;- Process, Priorities and Updates&lt;br&gt;- Manufacturing Inspection Guidelines&lt;br&gt;- WHOPES Update</td>
<td>Marion Law (WHO PQ Vector Control)&lt;br&gt;Dominic Schuler (WHO PQ Vector Control)</td>
</tr>
<tr>
<td>15.30 – 16.00</td>
<td><strong>Innovation to Impact Update</strong></td>
<td>Angus Spiers (Innovation to Impact)</td>
</tr>
<tr>
<td>16.00 – 16.30</td>
<td>Coffee</td>
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</tr>
<tr>
<td>16.30 – 17.00</td>
<td><strong>Adopting new generation LLINs</strong>&lt;br&gt;- Update on the Global Fund Catalytic Funding Mechanism</td>
<td>Scott Filler (Global Fund)&lt;br&gt;Alexandra Cameron (UNITAID)</td>
</tr>
<tr>
<td>17.00 – 17.20</td>
<td><strong>New vector control products pipeline</strong></td>
<td>Tom McLean (IVCC)</td>
</tr>
<tr>
<td>17.20-17.30</td>
<td><strong>Day 1 Closing</strong></td>
<td>Patrik Latin (Global Fund)</td>
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</tbody>
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## Agenda Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Activities</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.30 - 09.00</td>
<td>Coffee</td>
<td><strong>Discussion: What is next for our LLIN procurement strategies?</strong></td>
</tr>
<tr>
<td>09.00 – 11.00</td>
<td>Three break-out sessions /consultations:</td>
<td>Facilitators:</td>
</tr>
<tr>
<td></td>
<td>- How to incorporate technical developments into LLIN procurement strategies?</td>
<td>Group 1 (Dubai Ballroom): Angus Spiers</td>
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<td></td>
<td></td>
<td>Group 2 (Training Room): Scott Filler</td>
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<tr>
<td></td>
<td></td>
<td>Group 3 (Dhaid Room): Alexandra Cameron</td>
</tr>
<tr>
<td>11.00 – 11.30</td>
<td>Coffee</td>
<td></td>
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<tr>
<td>11.30 – 13.00</td>
<td>Break-out sessions feedback</td>
<td><strong>Dubai Ballroom</strong></td>
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<td></td>
<td>Wrap up</td>
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</tr>
<tr>
<td>13.00 – 14.00</td>
<td>Lunch</td>
<td>Hatta Room</td>
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**INDIVIDUAL MEETINGS**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.00 – 17.30</td>
<td>Global Fund and UNICEF meetings with suppliers</td>
</tr>
</tbody>
</table>
THE GLOBAL FUND
SOURCING STRATEGY & SUPPLY
Procurement Update & Way Forward
Mariatou Tala Jallow
Azizkhon Jafarov
Lin (Roger) Li
Clarisse Morris
Content Overview

• Global Fund Market Shaping Strategy Update

• Highlights on the LLIN Sourcing Strategies

• Market perspective and next LLIN Sourcing Strategy
The Market Shaping Strategy (MSS) is a key component of The Global Fund’s mission.

**Mission of MSS:** Leverage our position to facilitate healthier global markets for health products – today and in the future.

A world free of the burden of AIDS, TB and Malaria.

Source: Team analysis
Healthy markets have 6 characteristics

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Innovation</strong></td>
<td>There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers</td>
</tr>
<tr>
<td><strong>Availability</strong></td>
<td>New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in low- and middle-income countries. Adequate and sustainable supply exists to meet global needs</td>
</tr>
<tr>
<td><strong>Demand and adoption</strong></td>
<td>Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products (within their local context)</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>Medicines and technologies are available at an internationally-recognized standard of quality, and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product</td>
</tr>
<tr>
<td><strong>Affordability</strong></td>
<td>Medicines and technologies are offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers</td>
</tr>
<tr>
<td><strong>Delivery</strong></td>
<td>Supply chain systems (including quantification, procurement, storage, and distribution) function effectively to ensure that products reach end users in a reliable and timely way</td>
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Source: Market Shaping Strategy, Annex 1 to GF/B4/17 - Revision 1
The market shaping strategy has come a long way

1. Birth of market shaping strategy
   - PPM is created to leverage GF volumes

2. Market shaping strategy 2.0 2011-2016
   - GF strategy 2012-2016

3. PPM reaches $1bn/year
   - Plan for reform: value for money

4. First Annual Strategic Review
   - Second Phase of MSS implementation

5. 4th Annual Strategic Review
   - Reinforcement and development of market shaping objectives and toolkit

Adoption of objective and guiding principle of market shaping

New market shaping strategy, incl. specific instructions for ARVs

Call to more proactively shape markets

Recognition of GF’s abilities to influence market and call to extend toolkit

Reinforcement and development of market shaping objectives and toolkit

1 Market Dynamics Ad-hoc Committee
Source: Team analysis
The journey to evolve sourcing needs to take place against the backdrop of existing strategies and initiatives

- Market Shaping Strategy 2016-21
- Supply Chain Implementation Plan
- GF strategy 2017-22
- Others, incl. responsible procurement
- Implementation of wambo.org

Implementing the second phase of the MSS

Source: Team analysis
Partner and donor organizations have raised concerns about Responsible Procurement which GF has addressed through several initiatives.

- GF introduces the supplier code of conduct
- GF addresses LLIN ecological concerns through its anti-malaria strategy
- GF starts risk assessment per product category
- GF appoints its first ethics officer
- GF signed the Joint Intergency Statement for sustainable procurement
- DFID raised concerns about LLINs misuse
- GF sign contribution agreement with Norway on eco-footprint
- GF joined the SPHS¹ task team on sustainable procurement

¹ SPHS: Sustainable Procurement in the Health Sector
SOURCE: WHO
GF plans to define a tailored, holistic **Responsible Procurement** approach across 4 elements

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Economy</strong></td>
<td>▪ Provide additional economic benefits to in-country community</td>
</tr>
<tr>
<td></td>
<td>▪ Empower community by sharing knowledge</td>
</tr>
<tr>
<td><strong>Ecology</strong></td>
<td>▪ Mitigate effect on environment along the end-to-end supply chain</td>
</tr>
<tr>
<td></td>
<td>▪ Use knowledge and skills to contribute to a constant rise in eco-efficiency</td>
</tr>
<tr>
<td><strong>Society</strong></td>
<td>▪ Promote fundamental human rights, e.g.,</td>
</tr>
<tr>
<td></td>
<td>– Advocate for decent labor conditions</td>
</tr>
<tr>
<td></td>
<td>– Promote children rights</td>
</tr>
<tr>
<td></td>
<td>▪ Promote workers’ health and safety</td>
</tr>
<tr>
<td><strong>Business practices</strong></td>
<td>▪ Promote best business practices among suppliers and other buyers</td>
</tr>
</tbody>
</table>

**Principles to build holistic standards**

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

**SOURCE:** Adapted from corporate responsibility’s framework by Crane et al, 2014
wambo.org connects PRs to the best available sourcing options

**Products from multiple sources**

wambo.org ambitions to promote best in class LTAs and sourcing options, internally through the Global Fund or through partners, and make them available to its users.

- **Global Fund LTAs**
  - LLINs
  - ACTs and other anti-malarials
  - ARVs
  - Viral Load / EID

- **Outsourced LTAs**
  - Condoms & Lubricants (UNFPA)
  - Vehicles & Generators (UNOPS) **soon!**

- **Outsourced catalogues**
  - RDTs
  - Other diagnostics
  - Non-core pharmaceuticals
  - Laboratory supplies
  - Medical equipment

**POs transit through PSAs* (and equivalent)**

wambo.org issues Purchase Orders (POs) on behalf of its users to PSAs (and equivalent) who cascade them to the relevant manufacturers and logistics providers.

**e-RFQs direct to manufacturers soon!**

*PSA: Procurement Services Agent
All PPM transactions are now flowing through wambo.org

Launch of product categories

wambo.org has launched all of the product categories available to PRs through PPM at a careful pace and is now looking to expand to non-health through the UNOPS MoU and TB through the GDF MoU.

On-boarding of Global Fund PRs

wambo.org is available to nearly 700 users from 90 PR organisations in 56 countries. The Global Fund ran 8 regional workshops in 2016 to train and on-board these users: wambo.org is configured to the needs of each individual PR’s approval governance.

By the end of June 2017, all PRs historically ordering through the manual process had been on-boarded to wambo.org: all transactions are now electronic.

Spend on wambo.org by Category*

Since its launch in January 2016, over 300 POs have been processed through wambo.org for a total value of over $715 million.

*excludes impact of logistics costs, data January 2016 – September 2017
The Global Fund is taking wambo.org to the next stage and piloting the use of domestic funds

**Background**

In May 2017, the Board approved a pilot for the procurement through wambo.org of 10 purchase transactions using domestic funds. Findings will inform the extension of wambo.org into Phase 2 beyond the Global Fund.

**Pilot scope**

- Only **government** PRs that are currently PRs (no NGO, only countries w/ active grants)
- Can purchase **any product available** on wambo.org
- **Upfront payment**
- Limit of 10 transactions
- Key caveats
  - Subject to manufacturers agreeing to extend price
  - May or may not go beyond pilot phase
Highlights on LLIN Procurement Strategy

Mariatou Tala Jallow
Aziz Jafarov
LLIN sourcing has been evolved along 2 strategic rounds

First round LLIN Sourcing Strategy
2014-2015

- Maximize investments on LLINs within a dynamic and sustainable market environment
- Address price volatility and standardization

Second round LLIN Sourcing Strategy
2016-2017

- Maintain availability and affordability
- Strive for continuous improvement
- Support investment in innovation
- Maintain flexibility and prepare for change
In order to maximize investments on LLINs within a dynamic and sustainable market environment, the first round pursued 6 targets:

- Develop **new supply chain model**, incl. direct supplier management, risk reduction, updated pooled procurement and improved delivery.
- Create **new processes**, incl. forecasting to **improve net availability** in line with country programs.
- Move towards **standardization of specifications** to simplify procurement and production.
- Unlock value for GF in LLIN through **improved sourcing and greater understanding** of the market.
- Engage with other agencies and suppliers to **drive innovation and collaboration**.
- Encourage **local production** to WHO standards without de-stabilizing the market (where appropriate).
The first LLIN Strategy round in 2014-2015 already delivered significant impact

✅ Started **new way of doing business**

✅ **Diversified supplier base** by selecting 9 suppliers to procure 167 million nets

✅ Enabled more **stable/predictable pricing**

✅ Improved demand **visibility and delivery performance**

✅ Initiated **support for local manufacture**

✅ Enabled **product standardization**
Building on the first round achievements, the 2016-2017 LLIN Sourcing Strategy set ambitious targets to shape LLIN markets.

- **Maintain availability and affordability**
  - Ensure *sufficient capacity is maintained* across the 3 year replacement cycle
  - Optimize *plant utilization* where feasible
  - Encourage *manufacture close to the customer*
  - Support *ROI on supplier-owned assets*

- **Support investment in innovation**
  - Recognize the *differences between origination and equivalence*
  - Support *ROI in new products*
  - Participate in and support initiatives on *durability and resistance*

- **Strive for continuous improvement**
  - Adopt a *landed cost approach*
  - Improve *data management*

- **Maintain flexibility and prepare for change**
  - Prepare for product differentiation
  - Develop mechanisms to *support change*
  - Encourage *QMS adoption* prior to WHOPES PQ

These targets were reflected in the tender structure.
As part of the Framework Agreements all Suppliers agreed to comply with the Integrity Pact and Business Conduct Standards.

- Textile industry risks
- Chemical industry risks
- Past history of corruption
- Weak law and regulatory enforcement on human and labour rights
- Vulnerable, low skilled workforce
- Likelihood of subcontracting

LLIN procurement exposes GF to several risks.

Panel suppliers participate in site audits and surveys to mitigate these risks.
10 Panel suppliers were selected out of 12 bidders

Framework Agreements have been signed with all panel suppliers for 2 years

All but one of supplier allocations were met in 2016

2017 Allocation levels are on track for most suppliers

<table>
<thead>
<tr>
<th>Supplier</th>
<th>2016 Orders placed (mln)</th>
<th>2017 Orders placed and in process up now</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier 1</td>
<td>12.8</td>
<td>9.5</td>
</tr>
<tr>
<td>Supplier 2</td>
<td>5.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Supplier 3</td>
<td>6</td>
<td>5.0</td>
</tr>
<tr>
<td>Supplier 4</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Supplier 5</td>
<td>14.9</td>
<td>10.5</td>
</tr>
<tr>
<td>Supplier 6</td>
<td>7.2</td>
<td>6.4</td>
</tr>
<tr>
<td>Supplier 7</td>
<td>18.8</td>
<td>10.6</td>
</tr>
<tr>
<td>Supplier 8</td>
<td>15.2</td>
<td>9.9</td>
</tr>
<tr>
<td>Supplier 9</td>
<td>10.4</td>
<td>10.1</td>
</tr>
<tr>
<td>Supplier 10</td>
<td>6.3</td>
<td>5.2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>97.9</td>
<td>70.7</td>
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</tbody>
</table>
Achievement: Improved supplier performance management

Framework Agreements contain specific performance indicators

- Purchase order confirmation time
- On time in full (OTIF) goods readiness for transportation

Supplier performance is monitored continuously and evaluated twice a year

✓ Performance affect allocated volumes per supplier
✓ Challenges and issues are discussed and resolved constructively

RESULTS

OTIF reached 98% in 2016!
Achievement: Standardized LLIN Color 2016 - 2017

Major preference for white and light blue

One Country 7.3M nets
One Country 1.2M nets
Achievement: Standardized LLIN Sizes

- 2016 – 2017: **161 million** nets were procured or are in process (as of 31/7/2017)
- **Three sizes represent 50%** of nets ordered
- **Six sizes represent 80%** of nets procured

![Image of LLIN nets]

- 190x180x180 (19\%)
- 190x180x160 (6\%)
- 180x160x150 (12\%)
- 180x160x170 (13\%)
- 190x180x150 (16\%)
- 180x160x180 (17\%)
- Other sizes (50%)
LLIN Market – Global Fund Perspective and Next steps
PPM LLIN Volumes/Market from 2014 to date

<table>
<thead>
<tr>
<th>Year</th>
<th>LLIN Quantity in millions</th>
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<tbody>
<tr>
<td>2014</td>
<td>98</td>
</tr>
<tr>
<td>2015</td>
<td>83</td>
</tr>
<tr>
<td>2016</td>
<td>98</td>
</tr>
<tr>
<td>2017</td>
<td>82</td>
</tr>
<tr>
<td>2018 projection</td>
<td>110</td>
</tr>
</tbody>
</table>
Demand and Supply

Deliveries to PPM PRs, million units

Problem

- 10 out of 12 eligible LLIN manufacturers are selected as panel manufacturers in GF 2014 tender for 2015-2016 implementation
- Average deliveries to PRs are at 7.25 mn nets per month, which is just 1/4 of committed capacity
- Some of panel manufacturers offer very aggressive prices to other buyers to maintain minimum production load and skilled works

Solution

- GF competitive tender has adapted to the balanced supply system approach to evaluate the supply base. Both “originator” and “me-too” manufacturers are kept as panel manufacturers
- GF allocation was structured in the way to be able to respond to both low and high demand periods

Opportunities and Challenges

- Idle capacity can be utilized further to return value
- As LLIN are a labor intensive operation, sustainability issues become an emerging concern
- How many panel LLIN manufacturers we need to achieve our mission is at question

1 Data source: Regular Manufacturer performance review meeting
2 In 2017, 1 more LLIN manufacturer is pre-qualified with “me too” products
Technical developments

• **13 WHO-recommended pyrethroid nets** currently available (excl. PBO nets)

• In addition, several suppliers are **developing additional pyrethroid only** nets e.g. different denier or a different net material than their standard products

• The 5 WHOPES-recommended synergistic nets contain **varying levels of PBO**, which complicates product selection

• One **new generation net received WHOPES recommendation** so far, but WHO guidance on its use is still pending
Many achievements, but there remain challenges to be addressed

Although we achieved a lot…

- **Impact**
  - Standardized package of accessories (net specifications), incl. colour coding the nets to support initiatives on durability monitoring
  - **Stable prices** with observed decrease
  - Flexibility for new products is built into the Framework Agreements

- **Supply**
  - Quarterly allocation updates for suppliers
  - Selected 10 panel Suppliers
  - Manufacture closer to customer (lower landed cost and shorter lead time)
  - Improved supplier performance management
  - Increase On Time In Full deliveries to 98% in 2016

- **Product and price**
  - Procured 169 mn nets (2016-2017) with estimated value of $350 mn by mid 2017

... there remain challenges to be tackled

- **Impact**
  - Trade-off between evolving of new-generation nets and availability/affordability

- **Supply**
  - Significant manufacturing over-capacity
  - Align changes in the LLIN pre-qualification process and roles
  - One WHOPES-recommended new generation net, but WHO guidance is still pending

- **Product and price**
  - Product differentiation guidance (e.g. PBO nets) is challenging to implement
  - Limited number of new generation nets in the development pipeline
Next steps

- Extension of the 2016/17 Framework Agreements - 2018
  - 2017 Supplier performance evaluation - Jan/Feb 2018
  - 2018 allocation - Jan/Feb 2018
- Launch LLIN Sourcing Strategy and global tender – 2018
  - Continue consultations
  - Continue supplier visits
  - Define Sourcing Strategy
THANK YOU
UNICEF – how we work

• Works across 190 countries and territories

• Works with governments based on country specific agreements to address country specific needs and contexts

• Supports global efforts and works in partnerships with governments, other UN organizations

• Is entirely funded by voluntary contributions from the public and the private sector; it does not receive funding from the UN

• Has an annual budget of approximately USD 5 billion to achieve results for children

• Works in Programmes, Advocacy, Innovation, Technical Assistance

• Supplies are an important component of this budget and are a direct expression of children’s rights
Supply Division in the UNICEF structure
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 and Panama.

UNICEF’s Supply Community of 983 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.
241,976 kits packed and shipped:
- 143,068 shipped from Copenhagen
- 94,203 shipped from Shanghai
- 4,402 shipped from Dubai
- 303 shipped from Panama

$114.4 million value of throughput:
- $103.7m from Copenhagen
- $8.9m from Shanghai
- $1.4m from Dubai
- $433,709 from Panama

Technical Support
- Emergencies
- Local kit packing
- Warehouse assessment
- Warehouse inventory management
- Training

25% of the outgoing orders are for emergency response
UNICEF procurement value by major commodity groups in 2016

- **Vaccines**: $1.643 billion
- **Pharmaceuticals**: $160.6 million
- **Water & Sanitation**: $108.2 million
- **Nutrition**: $150.6 million
- **Medical supplies**: $138.7 million
- **Bed nets**: $90.7 million
- **Education**: $83.8 million

- **Supplies**: $2.637 billion
- **Services**: $882 million

81% of UNICEF procurement is in collaboration with other UN agencies ($2.858 billion)
UNICEF Procurement over 10 years

3 x growth in procurement over 10 years

Local and international procurement grown at same rate

Faster growth in recent OMP period

Increases can be explained by:

- Increasing aid flows over decade
- Growing ambitions of programmes (e.g. to reach more children with more vaccines, to reduce inequities)
- Proliferation of partnerships (Gavi, GFATM, GAIN, GPE…) with supply component
- Drive towards the MDGs
- Increasing number of emergencies and protracted crises during 2015
Total savings target for 2012–2016 was $810 million. This was exceeded by $846 million by end-2016.

Cumulative savings from 2012 to 2016:
- Total supply savings achieved from 2012 to 2016: $1.656 billion
- 2016: 
- 2015: 
- 2014: 
- 2013: 
- 2012: 

Total savings target for 2012–2016 was $810 million. This was exceeded by $846 million by end-2016.
<table>
<thead>
<tr>
<th>Commodity</th>
<th>Savings</th>
</tr>
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<tbody>
<tr>
<td>Rotavirus vaccine (RV)</td>
<td>$277 million</td>
</tr>
<tr>
<td>Inactivated polio vaccine (IPV)</td>
<td>$112.4 million</td>
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<tr>
<td>Pentavalent vaccine</td>
<td>$113.7 million</td>
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<tr>
<td>Pneumococcal vaccine (PCV)</td>
<td>$14.4 million</td>
</tr>
<tr>
<td>Auto-disable (AD) syringes</td>
<td>$2.1 million</td>
</tr>
<tr>
<td>Human papillomavirus vaccine (HPV)</td>
<td>$22 million</td>
</tr>
<tr>
<td>Bed nets (LLINs)</td>
<td>$25.4 million</td>
</tr>
<tr>
<td>Pentavalent vaccine</td>
<td>$1.7 million</td>
</tr>
<tr>
<td>Oral polio vaccine (OPV)</td>
<td>$757,000</td>
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<tr>
<td>Children’s winter Clothing</td>
<td>$5.4 million</td>
</tr>
<tr>
<td>Cold chain equipment</td>
<td>$4.3 million</td>
</tr>
<tr>
<td>Sleeping mats &amp; thermal blankets</td>
<td>$275,000</td>
</tr>
<tr>
<td>Antiretroviral medicines (ARVs)</td>
<td>$7.3 million</td>
</tr>
<tr>
<td>Amoxicillin dispersible tablets (DTs)</td>
<td>$1.3 million</td>
</tr>
</tbody>
</table>

**Procurement approaches used**

- UNICEF long-term arrangements (LTAs)
- Strategic procurement
- Special contracting
- Leveraging partnerships (e.g. coordinated forecasts and/or procurement, sharing LTAs)
- Price transparency
- Other (e.g. reduced material cost)
**Products & Markets: Harnessing the power of business**

**Influence global and local markets for existing and future products**

- Communicating unmet needs to market actors and sharing market analyses
- Accelerating R&D and scale-up
- Addressing market deficiencies (access, affordability, quality, sustainability, VfM)

Ultimately to **improve the lives of all children**

**Healthy markets** that are oriented to meet the current and future needs of children

**Product innovation** facilitate access to fit-for-purpose strategic essential commodities for children

**Collaboration** to drive product development and consolidate market engagement across buyers/donors to benefit children
Collaborations

Working together via formal and informal partnerships with long-standing and new actors

Collaborative category management leverages economies of scale across UN to achieve mutually beneficial market outcomes → Savings, VfM, contributions to the Grand Bargain

Coordination with R&D funders for complementarity to push and pull innovation

Private sector partners, innovators, suppliers to develop products to fill unmet needs, to compete in healthy markets curated by UNICEF
Health Technology Centre – UNICEF SD
### HTC Structure and Product Portfolio

<table>
<thead>
<tr>
<th>Malaria Prevention and Diagnostics</th>
</tr>
</thead>
</table>
| • Long Lasting Insecticidal Nets (LLINs), Malaria Vector Control interventions.  
• Rapid Diagnostics Tests (RDTs) for Malaria, HIV, Hepatitis, Syphilis, ... etc.  
• Point of care Diagnostics, e.g. HIV POC HIV EID VL Diagnostics.  
• Innovative diagnostics, e.g. ZIKV POC/RDT.  
• Clinical laboratory supplies. |

<table>
<thead>
<tr>
<th>Medical Devices</th>
</tr>
</thead>
</table>
| • Safe Injection Devices (AD, Re-Use Prevention, and Disposable syringes).  
• Waste Management Systems.  
• Hospital and Medical Equipment, Neonatal Intensive Care Unit Equipment.  
• Disability and Assistive Technologies.  
• Oxygen Systems, Acute Respiratory Diagnostic Aid (ARIDA) Devices.  
• Emergency Health Kits, Personal Protective Equipment (PPE). |

<table>
<thead>
<tr>
<th>Cold Chain</th>
</tr>
</thead>
</table>
| • Cold chain equipment: refrigerators, freezers, vaccine carriers and cold packs.  
• Solar Direct Drive (SDD) CCE.  
• Remote Temperature Monitoring.  
• Cold Rooms. |
Guiding Procurement principles

- **Promotion of objectives of UNICEF**
  (fulfilling the mandate, goals and objectives)

- **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)
2017 LLINs Suppliers and Partners Meeting

UNICEF LLINs Procurement Update
UNICEF historically invited all suppliers who have submitted their products for evaluation by WHOPES, but the minimum requirement for awarding a contract has always been an Interim recommendation by WHOPES.

UNICEF has carried out factory visits and set additional quality assurance criteria.

In many countries, LLIN product selection is determined by in-country product registration and country program preferences. Although in a number of countries all WHOPES recommended products are accepted,
UNICEF LLINs Procurement – Prices

Price range of LLINs and WAP

Prices shown above for standard size: (L)190x(L)180x(W)150cm White
LLINs Market Analysis

Production capacities are determined on the basis of standard, most commonly produced LLINs

LLINs suppliers Global production capacities
UNICEF Procurement 2011-2017

- Annual procurement is not linear.
- The inclusion of some large-scale roll-out projects and some countries only procuring LLINs on a two-three year cycle affect UNICEF’s LLIN procurement trend.
- Substantial differences may also occur on an annual basis between the number of LLINs delivered and LLINs procured on account of long-lead delivery times, including shipping and transit.
- UNICEF’s procurement in 2017 reached 15 million LLINs so far for 23 countries.
UNICEF Procurement 2011-2017

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- UNICEF’s procurement in 2017 reached 15 million LLINs so far for 23 countries
UNICEF Procurement 2012-2017 Q3

<table>
<thead>
<tr>
<th>Year</th>
<th>LLINs in Millions</th>
<th>US$</th>
<th>WAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012-2013</td>
<td>47,446,169</td>
<td>157,293,801</td>
<td>3.32</td>
</tr>
<tr>
<td>2014-2015</td>
<td>48,778,119</td>
<td>131,485,314</td>
<td>2.70</td>
</tr>
<tr>
<td>2016-2017(Q3)</td>
<td>56,300,000</td>
<td>120,700,000</td>
<td>2.14</td>
</tr>
</tbody>
</table>
UNICEF LTAs for 2016-2017

2016

- Following the Global fund and UNICEF joint suppliers meeting in Sept 2015, UNICEF RFP for the Procurement of LLINs for 2016-2017 was issued (for 40 million LLINs).
- 9 LTAs were established - valid until end of 2016 with a possibility of extension for another 12 months (end of 2017).
- The overall WAP was USD1.94 >> 30% less than the 2014-2015 WAP for the same size >> in 32 million saving for 2016.
- The overall WAP for the standard size (190X180x150) white was USD1.94 >> 30% less than the 2014-2015 WAP for the same size >> in 32 million saving for 2016;

2017

- 25 million LLINs were forecasted for 2017 (40% lower than the actual procurement of 2016).
- UNICEF concluded that the requirements could be adequately covered by less than the 9 suppliers awarded in 2016.
- In applying the criteria of lowest pricing and taking into consideration the suppliers production capacity and containers stuffing capacity for each, (6) LTAs with 90% of the 9 LTA holders' global production capacity of 2016 were extended until end of 2017.
UNICEF LTAs for 2016-2017

Status of current LTAs: Jan 16 - Oct 17

- Total Requirement
  - Original Target Qty: 40,000,000
  - Additions: 25,000,000
  - Utilized: 41,516,268

- Utilized
  - Additions: 15,000,000
  - Pipeline: 5,000,000
Important Considerations in LLINs Procurement ..
UNICEF LLINs Procurement – Value for Money

• UNICEF has always encouraged entry of new suppliers to ensure access and availability.

• UNICEF does not base its Value for Money concept solely on the lowest prices, but has extended it to include timeliness of availability, quality, acceptability of product by end users and the total logistics costs (including calculation of total landed cost per LLIN).
LLIN tender selection criteria went beyond core commodity price.

UNICEF incorporated landed cost in contracting of bednets including:
- Freight
- Shipper's Own Container (SoC) (avoid detention and demurrage charges)

UNICEF also incorporated other supply chain considerations in the tender:
- Production lead times
- Transit delivery lead times

Impact:
- Supplier with the least expensive commodity cost is not the lowest landed cost.
- Supplier with lowest price is not always the fastest.
- Can reduce freight costs and container use by half and reduce delivery times.

**Assumptions:** Based on an order of 1M LLINs delivered in bales in 40 ft. High Cube containers
UNICEF Suppliers performance evaluation

**PO delivery date**
- acknowledged / accepted by the supplier

**Notification of Goods Readiness form**
- 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.

**Goods Readiness date**
- 3 days

**Notification for PDI / QAC – copy FF**
- 7 days

**PO delivery date FCA Containerized port**
- 10 days

**Freight forwarders receives the goods & full doc**
- The date provided to SD by the freight forwarder reflecting the date when the Freight forwarder receives the goods at port with the full set of documents as per the PO INCOTERMS.

**Days : working days**
UNICEF Procurement approach for 2018-2019

Due to the current transition from WHOPES into WHO PQ, UNICEF decided NOT to issue a tender this year, extend 2016 LTAs until end 2018 and issue tender Q3 2018.

Looking ahead:

• Input provided on interim review of products
• Value based procurement criteria.
• Work with partners to further integrate the sustainability aspects beyond landed cost evaluation into the next tender(s) >> specifications for Biodegradable packaging;
• Durability Specifications to be integrated into procurement decisions?
Evolution of UNICEF Procurement Approach for LLINs
## The tentative timeline for the next tender cycle

<table>
<thead>
<tr>
<th>Activity</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q2</td>
<td>Q3</td>
</tr>
<tr>
<td>Discussion with partners on the new evaluation process for VC products and its impact on LLIN industry</td>
<td>Q3</td>
<td></td>
</tr>
<tr>
<td>Join Industry Consultation with the Global fund</td>
<td></td>
<td>Q3</td>
</tr>
<tr>
<td>Procurement strategy update</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement strategy review in-house</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tender issuance, Evaluation and LTA recommendations</td>
<td>Q4</td>
<td></td>
</tr>
</tbody>
</table>

According to the above tentative timeline, the new tender will most likely be issued during Q3 2018 (July - August)
Thank You
PMI’s LLIN Sourcing Strategy

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

October 25, 2017
Agenda

- PMI Background
  - Overview
  - LLIN SKU Rationalization
  - Contracting and Tendering Approach
  - Timeline and Next Steps
  - Discussion
U.S. President’s Malaria Initiative Background

PMI Strategy 2015-2020

• **Goal:** The U.S. Government’s goal is to work with PMI-supported countries and partners to further reduce malaria deaths and substantially decrease malaria morbidity, toward the long-term goal of elimination.

• **Objectives:**
  1. Reduce malaria mortality by one-third from 2015 levels in PMI-supported countries, achieving a greater than 80 percent reduction from PMI’s original 2000 baseline levels.
  2. Reduce malaria morbidity in PMI-supported countries by 40 percent from 2015 levels.
  3. Assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination.

• **Where:** 24 focus countries and a regional program in the Greater Mekong Subregion plus 2 non-focus countries.
  – Round 1 – FY 2006: Angola, Tanzania and Uganda
  – Round 2 – FY 2007: Malawi, Mozambique, Rwanda and Senegal
  – Round 5 – FY 2017: Burkina Faso, Cameroon, Cote d’Ivoire, Niger and Sierra Leone

• **Funding:** steadily increased from $30 million in FY 2006 to $750 million in FY 2017.

• **Who:** The National Malaria Control Programs in coordination with other national and international partners; and nonprofit organizations, faith-based organizations, community groups, academia, and the private sector.
PMI Current Procurement Process

1. Planning process via the Malaria Operational Plan
   a. Work with the National Malaria Control Program, donors and partners to get accurate need, quantification and timing of arrivals.
   b. Funding decided for net procurement and distribution pending approval of the PMI Interagency Group and final availability of funds. Approved MOPs posted on PMI.gov

2. Funding: Available one year after MOP is posted

3. The USAID Mission sends requests to the GHSC-PSM Project

4. GHSC-PSM verifies the order request and details with the country, once finalized a request for quotes is sent to vendors that successfully applied to the published EOI. GHSC-PSM choses the manufacturer based on which can best meet the country needs. It sends a purchase order once it receives PMI’s final approval and the vendor may officially start production. Pre-shipment QA is conducted for all orders.

5. Key needs: Meeting country specifications, pricing, ability to meet desired delivery date in country.

• Note: PMI has determined that the equivalency status based only on Phase 1 laboratory studies is insufficient to determine eligibility for PMI procurement
Agenda

- PMI Background
- **New Strategy Overview**
  - LLIN SKU Rationalization
  - Contracting and Tendering Approach
  - Timeline and Next Steps
  - Discussion
Overview

PMI, through its partner, GHSC-PSM, aims to put in place a long-term LLIN sourcing strategy that mitigates market risks, addresses challenges facing our supply chain and our suppliers, and reaps the potential benefits of SKU rationalization.
PMI procurement has become more standard yet additional options exist for optimal product rationalization given cost and lead time.

- In 2015 PMI provided conical nets to only Rwanda, Senegal, South Sudan, and Tanzania.
- In 2016, PMI is only providing conical nets to Rwanda.
- Share of polyethylene nets have been reduced over the last five years (generally go with alpha-permethrin insecticide).
- Only Malawi requests green; no country requested dark blue in 2015 onwards.
- Other countries have all ordered white nets in the past; light blue and blue are the standard alternative colors to white.

SOURCE: PMI ITN large dataset, December 2015. Note: these total numbers vary slightly from the PMI 10th annual report (e.g., total nets procured in 2012-2015 are 21M, 41M, 32M, and 42M).
Net height has also become more standard

### Net volume by height (in thousands)

<table>
<thead>
<tr>
<th>Height</th>
<th>Volume (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>190x180x170</td>
<td>13,150</td>
</tr>
<tr>
<td>190x180x180</td>
<td>5,915</td>
</tr>
<tr>
<td>190x160x180</td>
<td>3,225</td>
</tr>
<tr>
<td>190x180x150</td>
<td>2,844</td>
</tr>
<tr>
<td>160x180x170</td>
<td>2,375</td>
</tr>
<tr>
<td>180x190x170</td>
<td>2,068</td>
</tr>
<tr>
<td>180x160x180</td>
<td>1,645</td>
</tr>
<tr>
<td>180x190x150</td>
<td>665</td>
</tr>
<tr>
<td>195x160x200</td>
<td>510</td>
</tr>
<tr>
<td>180x160x170</td>
<td>269</td>
</tr>
</tbody>
</table>

- Average of last three years of procurement data
- PMI capped height in alignment with Global Fund to 180 cm in 2016
- Majority of nets procured are 170 cm height

Agenda

- PMI Background
- Overview
  - LLIN SKU Rationalization
    - Contracting and Tendering Approach
    - Timeline and Next Steps
    - Discussion
GHSC-PSM conducted a SKU rationalization exercise to identify cost and lead-time drivers based on supplier feedback and in-depth analysis.

As a result, PMI is considering the following actions to standardize LLIN procurements and minimize order customization:

- **Color**: Standardize to white
- **Dimensions**: Standardize to a limited set of LxWxH specifications, based on country preferences, appropriate use evidence, and production economics
- **Artwork/Packaging**: Standardize artwork and replace custom languages with picture-based instruction to the extent possible
- **Accessories**: Cease procurement of co-packaged hooks and strings
SKU standardization, paired with a multi-award IDIQ will enable PMI to achieve significant savings and lead time improvements

Leading to:

• The potential to procure additional nets
• More timely delivery of nets for routine and campaign distribution
• Greater interchangeability of stock in cases of emergency need
Agenda

- PMI Background
- Overview
- LLIN SKU Rationalization
- **Contracting and Tendering Approach**
- Timeline and Next Steps
- Discussion
GHSC-PSM’s best value award strategy and multi-award IDIQ contract vehicle will be structured to achieve the following objectives

- Pursue near and long-term **best value**
- Deliver critical health commodities **on time** in accordance with programmatic needs (i.e. campaign and routine LLIN distribution)
- Cultivate a sustainable, **healthy market** that can provide quality products and meet evolving public health needs with next generation products
- Operate an **efficient** and effective supply chain and minimize level of effort
- Increase **visibility** and predictability
- Promote **competition**
- Retain **flexibility** in order to be responsive to changing needs and priorities
- Reap the benefits of **SKU rationalization**
Evaluation criteria will feed a best value determination, emphasizing supply assurance, lead time, past performance, value-add innovation

<table>
<thead>
<tr>
<th>Assurance of Supply</th>
<th>Service</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Production capacity</td>
<td>• Lead time (stock, fresh production, loading capacity and lead time)</td>
<td>• QA requirements: Transition from WHOPES to WHO PQ</td>
</tr>
<tr>
<td>• Past performance</td>
<td>• Customer service</td>
<td></td>
</tr>
<tr>
<td>• Potential Impact on Other Orders</td>
<td>• Product Identification</td>
<td></td>
</tr>
<tr>
<td>• Supply Diversity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Quantity in stock (when required)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Innovation</th>
<th>Regulatory</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Packaging optimization</td>
<td>• Administrative requirements</td>
<td>• Unit price</td>
</tr>
<tr>
<td>• New/improved products</td>
<td>• Registration in country</td>
<td>• Unique distribution requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Also examine landed cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Additional costs for specific/unique labeling and/or artwork</td>
</tr>
</tbody>
</table>
Agenda

- PMI Background
- Overview
- LLIN SKU Rationalization
- Contracting and Tendering Approach
  - Timeline and Next Steps
- Discussion
GHSC-PSM intends to issue an RFP for a multi-award IDIQ in early Calendar Year 2018.

- **GHSC-PSM**
  - **2017**
    - Jul: SKU analysis & recommendations
    - Aug: Develop new sourcing strategy
    - Sep: Place orders against IDIQs
  - **2018**
    - Jan: Negotiate Subcontracts
    - Feb: Evaluate bids / identify best value awards
    - Mar: Issue IDIQ RFP
    - Apr: PMI SKU Decision
    - May: QA review & testing
    - Jun: IDIQs in place
    - Jul: Execute spot tenders against 12-month EOI extension
    - Aug: Respond to RFP
    - Sep: Negotiate
    - Oct: Respond to RFP

- **Suppliers**
  - Engage in discussions with GHSC-PSM on innovation, product rationalization, etc. to inform strategy
  - Ongoing supplier meetings
Agenda

▪ PMI Background
▪ Overview
▪ LLIN SKU Rationalization
▪ Contracting and Tendering Approach
▪ Timeline and Next Steps
▪ Discussion
How can PMI alter its sourcing strategy to alleviate the challenges associated with clustered GADs?

1. How can we smooth production planning and reduce delays?
   - Can we leverage innovative packaging schemes and/or advanced manufacturing to enable flexibility in holding stock?

2. How can we work with suppliers to streamline bottlenecks in the production, loading and shipping processes?

3. Can we coordinate with other global procurers to smooth demand?

4. What other suggestions do you have?
How can we develop a “win-win” strategy that enables suppliers to operate more efficiently and effectively and pass savings to PMI?

1. How can we adjust our contracting and tendering approach to…
   - promote increased visibility?
   - promote market health?
   - recognize “value-add innovation”?
   - streamline bottlenecks in the procurement process?

2. What other suggestions do you have?
QUESTIONS?
Appendix
GHSC-PSM PROCUREMENT
Current State

• EOI Extension (July 2017) resulted in pre-selected LLIN manufacturers

• For each requisition order:
  – Conduct simplified Request for Quotations to receive best prices, lead time, etc.
  – Evaluate bids
  – Award subcontract
EXPRESSIONS OF INTEREST (EOI)

- GHSC-PSM issued a request to identify potential suppliers for pre-selection to support malaria prevention.
- Suppliers who produce LLINs must have a World Health Organization Pesticide Evaluation Scheme (WHOPES) interim recommendation (Phase II) as a minimum requirement.
LLIN TECHNICAL REQUIREMENTS

• Must use one of the six WHOPES-recommended pyrethroid treatments:

  ✓ Alpha-cypermethrin  ✓ Cyfluthrin
  ✓ Deltamethrin       ✓ Etofenprox
  ✓ Permethrin         ✓ Lambachalothrin

• Expected to retain biological activity for up to 20 washes under laboratory conditions and up to three (3) years of recommended use under field conditions, defined by WHOPES.

• Produced in a factory that has stringent quality assurance procedures in place and that is operating with proper safety and environmental controls.
## LLIN TECHNICAL REQUIREMENTS

The physical characteristics of the LLINs must adhere to international standards.

<table>
<thead>
<tr>
<th>Test</th>
<th>Description/Specification</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fabrication</td>
<td>Warp knitted</td>
</tr>
</tbody>
</table>
| 2      | Dimensional Stability                                         | Shrinkage or expansion less than 5% in both dimensions | ISO 3759 (1994)  
ISO 5077 (1984)  
ISO 6330 (2000) |
| 3      | Bursting Strength                                             | >250 kPa                                      | ISO 13938-1 (1999)  
| 4      | Seam Strength                                                  | >250 kPa                                      | ISO 13938-1 (1999)  
| 5      | Fire Safety                                                   | Meets non-flammable Class I requirement       | 16 CFR 1610         |
Quality Assurance Achievements, Challenges, and the way forward

Alain Prat – Quality Assurance Specialist

Global Fund, PMI and UNICEF LLIN Suppliers and Partners Meeting - 25/10/2017
Drastic changes in the QA Ecosystem of Health Pesticides

- Pre-Marketing Requirements
- Pre-Shipment Inspection & Testing

2016 & bef.

2019 & aft.
Drastic changes in the QA Ecosystem of Health Pesticides Approved Products

Differentiation

- WHOPES
- WHO PQ
Drastic changes in the QA Ecosystem of Health Pesticides
GF Support this transitioning of QA Ecosystem

- Increase communication to GF stakeholders
- Support the strengthening of National Regulators, Regional initiatives and collaborative mechanisms
- Increase GF QA Post-marketing surveillance activities such as market control & vigilance activities
- Facilitate exchanges of information and feedback from countries to WHO PQ
- Option to provide financial support to WHO PQ via Strategic Initiative
Remaining challenges and uncertainties

- Maintaining two different standards providing two levels of assurance
- Harmonization of the practices of quality control laboratory at global level
- Lack of specialized Quality Management systems for regulatory purpose
- Preparedness to enforcement consequences such as suspension, withdrawal
- WHO Capacity to absorb the amount of work needed from norms & standards development, expertise consolidation, …
UNICEF Supply Division. Copenhagen.

Stuart Turner, Quality Inspection Unit
The Past

- UNICEF procures LLINs based on products obtaining and maintaining a WHOPES Recommendation.
- Procurement numbers for 2016 were 41.3 Million
- Procurement to date for 2017 is at 15 M (not more than 20M)
- Pre Delivery Inspections carried out
  - 2016 - 63 inspections
    - PDI Cost - $57K. Lab Costs $57K
  - 2017 - 70 inspections to date (Ivory Coast)
    - PDI Cost - $63K, Lab Cost $45K
- Limited or no feedback from end users!
The Present
The road to standard PDI process

- **Aug 2011**: Large UNICEF SD, LLIN order rejected at country level
- **Sep 2015**: Procedure reviewed by UNICEF to include informal input from other agencies
- **Oct 2016**: Agreement to standardise LLIN PDI
- **Dec**: Procurement, I2I QA/QC gathering at WHO VCPAG Meetings Geneva
- **Feb 2017**: Formal feedback sought from PMI, PSI and the GF

2011 | 2017
--- | ---
**Launch of WHO PQ of Vector Control Products**

Document available for use
All feedback received, Clarifying questions sent

**Procedure reviewed by UNICEF to include informal input from other agencies**
The Future and the Transition

• Current UNICEF LTA’s Extended to cover 2018 requirements...
  • This means the existing requirement for WHOPES recommendation for procurement of LLINs will continue...

• Transitional considerations to WHO-PQ
  • Be pro active in maintaining an oversight of all suppliers performance in respect of QA/QC and where possible conduct more active Post Market Surveillance to gather end user feedback.
  • Continue with QA “assessment” visits to new suppliers, new facilities and any other high risk manufacturing until PQ conduct their Factory Inspection(s).
The Future

• UN - Sustainable Procurement
  • Three pillars to SP
    • Environmental (ISO 14001)
    • Quality (ISO 9001)
    • Social Accountability (AS8000)
• Manufacturer Assessments will now start to look at the above 3 aspects.
  • Questionnaires
  • Ongoing UNICEF Supplier Visits (even after PQ)
PMI’s Durability Monitoring
October 25, 2017
Overview of LLIN Durability Monitoring

12 Countries
52 sites
~17,077 LLINs
Summary of Indicators Analyzed

Determinants of Durability
- Environmental/HH Risk Factors
- Net Handing: Care & Repair
- HH Exposure/Recall of messages

Net Use and Ownership
- Use of Cohort Nets
- Use of Non-Cohort Nets

Durability of Cohort Nets
- Attrition
- Integrity

Insecticidal Effectiveness
- Bio-assay
- Chemical Testing
Study Design

Prospective, longitudinal

Baseline (establish cohort)

0

6

Assess
Attrition Integrity

12

Assess
Attrition Integrity

Subsample: Bio-assay

24

Assess
Attrition Integrity

Subsample: Bio-assay

36

Assess
Attrition Integrity

Subsample: Bio-assay

Sampled from outside the main cohort – from neighboring households (or from a separate tagged cohort at baseline)

Sampled from main cohort

PMI
President’s Malaria Initiative
Fighting Malaria and Saving Lives
<table>
<thead>
<tr>
<th>Countries</th>
<th>Implementing Partner</th>
<th>Brand of LLIN</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>CREC</td>
<td>Permanet 2.0, DAWA Plus 2.0, DuraNet</td>
<td></td>
</tr>
<tr>
<td>DRC</td>
<td>VectorWorks</td>
<td>DuraNet, DAWA Plus 2.0</td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td>SMMES</td>
<td>MAGnet, Permanet</td>
<td></td>
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<tr>
<td>Guinea</td>
<td>Stop Palu/RTI</td>
<td>Netprotect</td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td>CDC/IAA Kemri</td>
<td>Olyset, Permanet 2.0, Yorkool, DuraNet</td>
<td></td>
</tr>
<tr>
<td>Madagascar</td>
<td>PSI/IPM</td>
<td>Permanet 2.0</td>
<td></td>
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<tr>
<td>Mozambique</td>
<td>VectorWorks</td>
<td>Royal Sentry, MAGnet</td>
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<td>Myanmar</td>
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<td>MAC</td>
<td>Yorkool, Royal Sentry, DuraNet</td>
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<td>HDS-Africa and UCAD</td>
<td>Permanet (con. &amp; rect), Netprotect,</td>
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<td>Interceptor, Olyset, Magnet, Yorkool,</td>
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<td>Bayer</td>
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<td>Tanzania</td>
<td>VectorWorks</td>
<td>Olyset, Permanet 2.0</td>
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<td>Zimbabwe</td>
<td>PSI &amp; ZAPIM</td>
<td>DAWA, DuraNet</td>
<td></td>
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</tbody>
</table>
Causes of Attrition – from previous OR

Why are Nets Absent? Reasons given by Users

- Do Not Know
- Other Use
- Other
- Replaced (New LLIN Distribution)
- Taken from house/Moved
- Lost/Stolen
- Sold/Given away
- Eaten by Rats
- Discarded–Not killing mosquitoes
- Discarded–Too torn up
- Destroyed–Burned by fire
- Destroyed
- Damaged
- Being Washed

PMI President’s Malaria Initiative
Fighting Malaria and Saving Lives
Nets Surviving in Serviceable Condition

% nets in found in serviceable condition (pHI ≤ 642)

% serviceable condition

0 20 40 60 80 100

0 6 12 18 24

month

President’s Malaria Initiative
Fighting Malaria and Saving Lives
Bioassay vs. Chemical content

Bioassay – proportion dead

chemical content – mg/m²

brand A
brand B
brand C
brand D
Prequalification of Vector Control Products

Marion Law, Group Lead
Dominic Schuler, Case Manager

WHO Prequalification – Vector Control
Welcome

- PQT-VC involvement for the first time in Global Fund and UNICEF LLIN Supplier and Partner Meeting
- PQT-VC is now a stream within the Prequalification Team
- Recognize the significant interest and involvement from suppliers and procurers of vector control products
- This meeting is a welcome opportunity to encourage dialogue and provide updates
Background – Vector Control Products

• Reduction in malaria and other neglected tropical diseases mortality over the past 20 years has been significant.

• Vector control products have played a vital role in reducing transmission of disease.

• Despite this significant impact, vector-borne diseases continue to be one of the leading causes of mortality especially among children under five years in specific regions of the world.

• Addressing this is now a global priority and vector control products will continue to play a critical role in achieving this goal.

• An efficient and transparent prequalification system for vector control products which is based on evidence is one of the contributing factors to ensure timely access to effective and modern products.
Purpose of the presentation

• Provide an overview of the role and responsibilities of the PQT-VC

• Share our workplan, priorities and progress to date
Outline of the presentation

• Transition from WHOPES to Prequalification
• Regulatory Role
• PQT-VC Team
• Mandate, Guiding Principles
• Progress we have made to date
• Submission Management: Processes and Timelines
• Identified Priorities
• Successes
• Challenges
• Next steps
Transition from WHOPES to Prequalification

- Harmonize approaches to product evaluation throughout WHO
- Encourage evolution of the WHO regulatory function to incorporate best regulatory practices based on experience in regulation of pesticide and medical products
- Provide clear, transparent, and consistent evaluation of VCPs
- Conduct QA activities to benefit procurers and ensure quality products to end users
- Maintain the validity of prequalification decisions throughout the product’s life cycle – review changes and incorporate post market surveillance feedback
Regulatory Role

• VCPs are often not regulated by established National Regulatory Authorities
• This is a significant difference between VC and other PQT product streams (Mx, Dx, Vx)
• PQT-VC is being requested to fill this regulatory gap – to assess products for quality, safety and efficacy
PQT-VC Team

• Established team
  - Group Lead
  - Case Manager
  - Consultants – Regulatory and Inspection
  - Administrative support
  - Inspector

• Staffing
  - Entomologist
  - Product Chemist

• Pool of Assessors
  - Interviews completed
  - First assessors meeting in November - Orientation
Mandate

Increase access to safe, high quality, efficacious vector control products (VCPs)

- Prequalify VCPs that are safe, effective and manufactured to a high-quality, and publish a list of these prequalified products
- Ensure prequalification validity of products throughout their life-cycle
- Contribute to building assessment capacity of member states (NRAs)
  - Training of assessors from Member States through the actual WHO assessments
  - Harmonizing quality and regulatory systems
  - Supporting collaborative registrations
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
- 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
Progress to date

- Established Single Point of Entry to WHO: PQT-VC
- WHO vector control evaluation process established
  - New intervention pathway
  - Prequalification pathway
- Prequalification process procedures posted
- Data requirements determined
- Guidance documents developed and posted
- Information notes developed and posted
- Feedback from the October 2016 workshop posted
- Established working systems with partners, e.g. GMP and NTD
- 75 manufacturers meetings
- 8 product applications for conversion received for PQ listing
- Participated in JMPS; will be co-secretariat with NTD in 2018
- Attended and planned a number of meetings
- Initiated the process of forming a group of experts
Submission Management: Processes and Timelines

• Conversion
  • Phase 1 – Administrative review
    • Applications for Conversion due 31 December 2017
    • PQT-VC to ensure product is supported by existing Specifications and WHOPES evaluation reports
    • Initiation of baseline file for PQT-VC management of product in the future
  • Phase 2 – Inspection and Assessment
    • To be completed for all converted products within 5 years
    • Desk audits to be performed on all SMFs to identify priority on-site inspections
    • Assessments to be prioritized and conducted based on an ASVCP review of the existing supporting information in the product dossier

http://www.who.int/pq-vector-control/resources/conversion/en/
Submission Management: Processes and Timelines

• New Product
  • **Timeline**
    • Time 0 no longer begins before development of data
    • The timelines are only based on the WHO screening, assessment/inspection and decision making once a dossier has been submitted

• **Pathway**
  • The timeline of the PQ process for VCPs is dependent on volume of submissions and the determination if an on-site inspection is necessary

• **Inspection Procedures**
  • Will be posted for comment by the end of November
Submission Management: Processes and Timelines

• New Equivalent (Me-too) Product
  • An application for an equivalent product must indicate the prequalified product to which it is claiming equivalence
  • Determination of equivalency will be based on formulation, physical/chemical characteristics, and efficacy data, if applicable based on current guidelines
Identified Priorities

- Product evaluation – New applications
- Conversion of products
- Establishment of the pool of experts
- Staffing
- Finalize draft guidance documents and continue development
- Increased communication and engagement with stakeholders, especially Member States and manufacturers
- Protocol reviews
Successes

- Support and goodwill from stakeholders
- Interaction with other PQ groups
- Input from highly experienced people
- Experienced, knowledgeable and enthusiastic PQT-VC
Challenges

• Orchestrating a culture shift to a PQ approach
• Respecting and acknowledging the decisions of the past and carrying this forward to the envisioned process
• Addressing misinformation and perceptions
• Building a system that is robust and ensures access to safe, effective and high quality products and at the same time flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs
Next steps

- Focus on product conversion
- Continue to dialogue with manufacturers to encourage the submission of applications for listing
- Improve and increase our communication with stakeholders
- Continue efforts to provide good policy decisions and guidance documents
Thank You

Questions?
WHOPESE Recommendations removed from WHO website
GFATM Supplier and Partner Meeting

24th October 2017, Dubai

Angus Spiers, i2i Director
The vector control ecosystem must overcome challenges of coverage, resistance & gaps in protection to meet global malaria & NTD disease goals.

Incomplete access to and insecticide resistance threatens current tools and new tools needed to protect across settings.

To solve these challenges, we must improve innovation, efficiency and quality.

- **Dis-incentives for innovation and investment** in the development of novel vector control tools.
- **Long delays** in product evaluation and introduction to market.
- **Lack of systematic quality assurance** systems to ensure efficacious and safe products are delivered to the field sustainably.

Backup: simplified version created for broader stakeholder communication focuses on collaborative nature of structure.

I2I Advisory Board (AB)
- Sets strategic direction
- Provide thought partnership to solve critical challenges

I2I Leadership Team (LT)
- Helps workstreams deliver on the overall goal and workstream specific objectives
- Coordinates across workstreams and partners with workstreams to solve challenges

Workstreams
- Lead implementation of I2I vision

Vision area
- Time-limited workstreams

I2I Leadership Team (LT)
I2I Advisory Board (AB)

- Innovation
- Impact
- Industry engagement
- Country-level impact
- WHO transformation
- Procurement plans
- Pathway for new AIs
- GLP site accreditation

Innovation to Impact
Outcomes from the June i2i Convening
General takeaways

Significant policy, structural and procedural issues still need to be clarified and, in some cases, justified
  • Current interpretation of epidemiological studies for new ITNs is still a very contentious issue
  • Roles and responsibilities between PQT and VCAG are still unclear
  • PQT approach to labelling and fee structure

WHO communication
  • Clearer communication on policy and process is needed from WHO to applicants, procurers and countries
  • PQT making concerted effort to now communicate its new system and giving timelines for updates
  • Need urgent, clear country communications of the new system

Country activities now coming into focus
  • Country/Regional registration engagement now a priority
  • Interpretation of IRM policy and integration of new tools into programs

NTD focus
  • Recognize the need for addressing non-malaria vector borne diseases
Key Takeaways & Priorities

GLP
• Address sustainability issues and forecasting site capacity to avoid bottlenecks
• Evaluate GCP testing capacity for epi trials
• Explore using model contract agreements to overcome data ownership vs. publication issues

Priorities
• Continue support for GLP compliance
• Conducting analysis of site sustainability and business approach
• Development of standardised SOPs
Key Takeaways & Priorities

Country Registration
- Lack of consolidated information on country level vector control regulators
- Varying requirements to attain country registration
- Lack of information about the new PQT system vis-à-vis WHOPES

Priorities
- Work with WHO RSS & PQT to assimilate regulatory data from target countries
- Use data to develop concept note for regulatory harmonization
- Work with WHO PQT on country communication approach
- Coordinate regulatory activities with ALMA & APLMA
- African engagement workshop, Q2 2018
Key Takeaways & Priorities

Procurement

• Need to identify criteria for value based procurement

• Are WHO policy recommendations clear and actionable?

• Align on post market monitoring approach

• What are the procurement implications of Insecticide Resistance Management?
Policy Recommendations & Product Evaluation

New Intervention Pathway
(GMP, NTD, PQT)

Concept review and determination of data requirements
Review of concept and determination of data required to assess public health value and support formulation of a WHO policy recommendation

Development of assessment standards and requirements
Development of efficacy test guidelines, SOPs, quality and safety standards and criteria

Manufacturer-led data generation

PQT Inspection
Manufacturing facilities inspected to ensure compliance with WHO-recommended quality standards

Assessment and recommendation to MPAC / STAG
Evaluation of evidence and (a) completion of the TPP for new product class or (b) claim validation for new product claim

WHO policy recommendation
(WHO-GMP + WHO-NTD, MPAC/STAG support)

Operational guidance on conditions for use in disease control programmes
(WHO-GMP and WHO-NTD, VCTEG / TWG support)
Malaria Policy Recommendations

Note: Diagram only illustrative. For latest content of text boxes please consult:
Product Class Definitions

Unclear definitions have caused confusion with regards to product classes

• Entomological effect particularly important:

  “A product class in vector control is a group of products that share a common entomological effect by which it reduces pathogen transmission and thus reduces infection and/or disease in humans”

• Significant pushback from MPAC on how these definitions are being interpreted by VCAG in the case of LLINs
PBO + pyrethroid net recommendations

“Based on the epidemiological findings and the need to deploy products that are effective against pyrethroid-resistant mosquitoes, pyrethroid/PBO nets are being given an interim endorsement as a new WHO class of vector control products.”

- Still questions as to specifics of recommendation e.g. resistance mechanism and numerous qualifiers
- Recommends that other approved WHOPES PBO nets are included under this policy
- Unclear as to how this new class will be defined and managed
- Questions in MPAC as to why PBO nets would be considered a separate class based on ‘entomological effect’
- Need to consider how actionable these recommendations are for implementers and procurers
Potential Policy & Implementation Issues

Policy is still focused on managing pyrethroid resistance. Mindset needs to change to proactive management of public health active ingredients.

• What data are needed to evaluate new tools?
  • Product claims need clarification
  • How is ‘non-inferiority’ defined?
  • Need rationalisation of the LLIN product class
  • Need clarity on the purpose of epidemiological data

• How will Resistance Claims be managed?
  • SumiShield has IRS recommendation, but not for resistance management
  • Unclear what data are needed
  • What does ‘insecticide resistance’ mean considering the various mechanisms, intensities and AIs?
  • How will they be interpreted at country level for procurement/implementation purposes?
Potential Policy & Implementation Issues

Policy is still focused on managing pyrethroid resistance. Mindset needs to change to proactive management of public health active ingredients.

- Proactive rotation of insecticides is recommended in GPIRM
  - Even when thinking of LLINs, countries MUST consider IRS rotations when developing rotation strategies
  - Are policy recommendations clear enough to implement value based procurement?
  - Are country data strong enough and how should they be interpreted?

- How will proactive rotation be managed on a geographic, temporal and delivery channel basis?
  - What are the logistical implications of rotation for ITNs and IRS?
  - Are procurement mechanisms sensitive enough to manage rotation at a national and/or sub-national level?
Potential Policy & Implementation Issues

Policy is still focused on managing pyrethroid resistance. Mindset needs to change to proactive management of public health active ingredients.

• Financing
  • New products likely more expensive than existing LLINs
  • Cost effectiveness data is needed, although definition is still unclear
  • The coverage/cost issues needs to be addressed head on
  • Need proactive approach to bridging financing gap, which starts with defining it
  • Can we achieve more reliable forecasting with a proactive policy?
  • Does capacity exist to meet demand for new tools?
Workstreams and Sub-streams (updated from original strategy)

GLP
- Pathways for New AIs
- GLP Site Accreditation
- Best Practice SOPs
- Sustainability and Forecasting

WHO PQ
- Procurement
- Industry
- Industry
- WHO PQ

Industry
- GLP Site Accreditation
- Best Practice SOPs
- Sustainability and Forecasting

Procurement
- Pathways for New AIs
- GLP Site Accreditation
- Best Practice SOPs
- Sustainability and Forecasting

Country-Level Impact
- GLP Site Accreditation
- Best Practice SOPs
- Sustainability and Forecasting

Key:
- Workstream
- Work Area
- New Work Area

Reporting line of sub-stream into parent workstream
Content Overview

1 Rationale for the initiative
2 Objectives
3 Partnership
4 Implementation and management approach
Rationale for the initiative

• Pyrethroid resistance is widespread, spreading further and increasing in intensity
• New tools are needed, including new LLINs that show increased efficacy against resistant mosquitoes
• Industry and academia have been moving forward with innovation in LLIN technologies
• The process through evaluation, policy recommendation and market entry to widespread roll out is slow
  • Once recommended, uptake for more costly products will remain slow until data are available on incremental cost effectiveness in different settings
• This initiative aims to catalyze the process of market entry and expansion for new LLIN products
Innovation to implementation and market

New candidate LLIN available

WHO policy recommendation

WHO evaluation process

INNOVATION

Proving public health value requires robust trials over several transmission seasons

Bottlenecks

LLINs never procured at scale

Incremental cost effectiveness evidence not built

Prices remain higher

New LLIN is not procured because: the cost is higher and the procurer has no information as to whether the additional cost is worth it

Malaria control progress continues to worsen

Pyrethroid resistance worsens

Pyrethroid only LLINs begin to fail

Malaria control progress stalls or reverses

WHO policy recommendation

LLIN procured and scaled up

Healthy market – sustainable availability of new LLINs

Malaria control progress continues

INNOVATION

TheGlobalFund LeFondsmondial ElFondoMundial Глобальныйфонд 全球基金 الصندوق العالمي

152
Objectives

Act on the bottlenecks to catalyze the process through evaluation to implementation

i. Support the completion of VCAG evaluation process for products close to the end of their evaluation pipeline, resulting in a policy recommendation for effective products

ii. Pilot implementation to set the stage for market expansion once a policy recommendation is in place

- Primarily through a time limited co-payment approach - allowing some procurement of more expensive new tools in place of pyrethroid only LLINs, with the project paying the cost difference. **Countries can deploy new tools without compromising coverage.**

The pilot implementation aims specifically to:

a. Generate incremental cost effectiveness data in a range of settings
   - so that when policy recommendations are in place countries have the decision making information they need

b. Support early market introduction alongside product evaluation
   - so that if/when a WHO policy recommendation is made, time to scale-up can be reduced
Partnership

The Global Fund
- Initial funding
- Human resources
- Steering role
- Link to countries
- Link to Global Fund sourcing

UNITAID
- Grant making machinery
- Grant management
- Funding possibility
- Steering role

PMI
- Link to PMI countries
- Operational research
- Steering role

Bill & Melinda Gates Foundation
- Steering role
- Funding possibility
- Operational research

Memorandum of Understanding
Implementation and management approach

• UNITAID Call for Proposals to be launched this month

• A steering committee of these and other key partners will guide the strategic direction of the project including in areas of evaluation design, product selection, country selection

• Implementation will be through a UNITAID grantee or grantees with close involvement of the Global Fund sourcing department.

• Final design of the project in terms of implementation approaches, funding flow, respective roles of the grantee/ Global Fund sourcing department, will depend on grantee proposed approaches and project elaboration with steering committee input
Vector Control Product Development Pipeline

Tom McLean
October 2017
Vector Control Pipeline Agenda

- What do we need from the vector control product development pipeline
- How does IVCC develop products
- What is the pipeline for IRS and LLINs
- What else is in the pipeline
- What are the key barriers to bringing these products into beneficial use.
Impact of Vector Control on Malaria Incidence
Resistance increasing in distribution and intensity

Source: IR Mapper (www.irmapper.com) June 2016
First programme use of Actellic CS: Impact in a region of high pyrethroid resistance

**Bunkpurugu-Yenyoo 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.
- For children under 5, height, weight and temperature measured, and capillary blood collected and tested for malaria parasitaemia and anaemia.

**Caveats:**
- Not controlled, no confidence intervals.
- EIR falling throughout.
- High Net usage until 2013?

![Graph showing the impact of IRS and Actellic CS in Bunkpurugu-Yenyoo district, Northern Ghana.](image_url)

Data from Abt and PMI, In preparation for publication
Outdoor Biting

(A) 6 PM to 6 AM

- 10 PM to 6 AM: GAP

(B) 6 PM to 6 AM

- “Risk behaviour”

ITNs/IRS

GAP
IVCC’s Portfolio Strategy for Product Development

To develop a toolbox of products to enable NMCPs to operate vector control sustainably and effectively

• Products are efficacious
• Products maintain efficacy through IRM programmes

Interpreting GPRIM: Notional six year product rotation plan

<table>
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<tr>
<th>Year</th>
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<th>4</th>
<th>5</th>
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<td>B</td>
<td>C</td>
<td>A</td>
<td>B</td>
<td>C</td>
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</table>

- **The principles of this scheme:**
  1. The same insecticide should not be used for IRS and LLIN in the same setting
  2. Long term exposure to insecticides on LLIN requires, a minimum of, full rate mixture of 2 different insecticides
  3. Insecticide rotation should be practised as much as possible to avoid population accumulation of resistance
  4. This scheme indicates the use of 7 different classes of insecticide is required
So What is IVCC doing?

Public health insecticides with new modes of action to secure a long term platform for insecticide resistance management.

Long lasting IRS formulations and dual active ingredient LLINs to improved field performance and preserve existing tools against the threat of resistance.

Effective solutions to protect against outdoor disease transmission by insect vectors.

Market shaping initiatives to accelerate uptake, availability and affordability of novel vector control interventions, providing evidence of cost effectiveness and impact.

Stakeholder partnerships that create a path to market and the rapid development of transformative vector control interventions, encourage innovation and reducing time to impact.

Improvements in the reliability and consistency of vector control laboratory and field trials data.

Spray application devices to deliver targeted, more effective IRS.

Build evidence to support recommendations for IVM, IRM and Integrated Tools Management.

Note: UKaid is also supporting the development of DDMS.
Progress of IVCC ‘Developing’ Strategy

**Impact Modelling**

**Novel a.i.s**
- 4.5 million chemical compounds
- 27 classes identified
- 9 classes optimisation
- 6 classes different MoA

**Repurposed a.i.s**
- XX existing insecticides YY classes
- XX leads

**IRM Best Practices on choice of chemistries**
- New Dual LLIN
- New LLIRS

**New AI IRS**
- +3 years if Epidemiology

**BMG F grant**
- Identify and Engage Partners

**Timeline**
- 2005
- 2008
- 2013
- 2017
- 2020
- 2024
- 2027

**Chemical Compounds**
- 4.5 million
- 27 classes identified
- 9 classes optimised
- 6 classes different MoA

**Insecticides**
- XX existing
- XX leads

**Development**
- Polyzone
- Actellic CS
- SumiShield
- Intercepto r G2
- Fludora Fusion
- BMG F grant
- New AI IRS

**Engagement**
- Identify and Engage Partners

**Years**
- 2005
- 2008
- 2013
- 2017
- 2020
- 2024
- 2027
## Established Product Classes for Malaria

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<th>Now - 2020</th>
<th>2020 - 2025</th>
<th>2025 -</th>
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<td>Limited IRM Options</td>
<td>Some different MoAs</td>
<td>Intervention programmes will have the choice of many chemistries to implement IRM</td>
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<td>‘Pyrethroid Plus’ LLIN</td>
<td>IRM programmes are possible</td>
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<tr>
<td>Little choice for IRS</td>
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<th>Established Product Classes for Malaria</th>
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<tbody>
<tr>
<td>Pyrethroids</td>
<td>widespread resistance</td>
<td></td>
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<tr>
<td>OPs</td>
<td>emerging resistance</td>
<td>✓</td>
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<tr>
<td>Carbamates</td>
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**Suitability for Product Class**

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<th>IRS</th>
<th>LLIN</th>
<th>ATS</th>
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**Limited IRM Options**

- ‘Pyrethroid Plus’ LLIN
- Little choice for IRS

**New Active Ingredients**

- New Active Ingredient 1
- New Active Ingredient 2
- New AI Mixtures
- New Al
- New Al

**Intervention Programmes**

- Some different MoAs
- IRM Programmes are possible

**Suitability for Product Class**

- IRS
- LLIN
- ATS
- B
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<tr>
<td>Bayer—Fludora Fusion (clothianidin + deltamethrin)</td>
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<td>BASF—Syland (chlorfenapyr)</td>
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<td>organophosphate CS (At Risk)</td>
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### WHO recommended long-lasting insecticidal nets

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product type</th>
<th>Status of WHO recommendation</th>
<th>Status of publication of WHO specification</th>
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<tbody>
<tr>
<td>DawaPlus 2.0</td>
<td>Deltamethrin coated on polyester</td>
<td>Interim</td>
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<tr>
<td>DawaPlus 3.0</td>
<td>Combination of deltamethrin coated on polyester (side panels), and deltamethrin + PBO incorporated into polyethylene (roof)</td>
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<td>DawaPlus 4.0</td>
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<td>Alpha-cypermethrin and chlorfenapyr coated on polyester</td>
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<td>Not yet</td>
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<td>LifeNet</td>
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<tr>
<td>MAGNet</td>
<td>Alpha-cypermethrin incorporated into polyethylene</td>
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<td>MiraNet</td>
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<td>Olyset Net</td>
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<td>Olyset Plus</td>
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<td>Panda Net 2.0</td>
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<td>PermaNet 2.0</td>
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<td>Royal Sentry</td>
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<td>SafeNet</td>
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<tr>
<td>Yorkool</td>
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<td>Full</td>
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**PBO LLINs**
- PBO is a synergist not a second insecticide
- Blocks Cytochrome P450 metabolic pathway
- Tanzania trial shows
  - good reductions in malaria prevalence relative to pyrethroid only nets
  - Works well in areas of moderate intensity metabolic resistance
  - Modelling suggests will not work in areas of high intensity resistance
- Interceptor G2
- True Dual Active ingredient
• BASF Interceptor G2
  • Alpha-cypermethrin and Chlorfenapyr coated on Polyester
  • Effective against all Pyrethroid resistant mosquitoes.
  • Interim WHOPES approval as a pyrethroid net
  • VCAG / MPAC Requirement for 2 epidemiological studies
  • Scaling up for trials and intervention supply in 2018
  • Epi modelling suggests 20-30% decrease in incidence in areas with pyrethroid resistance.
Sumitomo Olyset Duo

- Permethrin + Pyriproxifen (insect growth regulator)
- Kills susceptible and prevents reproduction of pyrethroid resistant mosquitoes
- First in class of a completely new vector control product class.
- 1 Epidemiological trial completed confidently awaiting full analysis
- Not yet In PQ/policy process
- Requirement for second trial anticipated
- Availability for trial implementation 2018 /19 (if an interim listing is granted on the basis of the current trials)
- Conservatively Forecast PQ and scale up 2022 (assuming no interim PQ)
Product Pipeline

- Many companies working on LLIN containing new classes of insecticide. (alphabetical)
  - A to Z
  - Disease Control Technologies
  - Tana Netting
  - Vestergaard
  - Others not ready to disclose

- Willingness / viability to progress strongly dependent on WHO policy on:-
  - Need for Epi trials
  - Data Protection for first in class
  - Willingness to pay for return on R&D investment.

- Developments at various stages. Not yet ready to declare timing.
- IVCC estimates launch dates ranging from
  - With interim approval based on entomology 2020 to 2027
  - If Epidemiology required before policy adoption 2023- 2030
Attractive Targeted Sugar Bait (ATSB)

A vector control technology that works by presenting an attractive sugar-meal laced with a lethal toxicant to mosquitoes and other flying, biting insects.

Key Elements of TPP

1. Kills >95% of mosquitoes that feed on it
2. Attracts at least 30% of standing population of mosquitoes per day, resulting in up to 85% reduction of total population
3. Does not affect pollinators
4. Provides continuous effectiveness for 6 months
5. Cost appx. $5 per year for 4 devices (includes delivery)
Eaves Tubes

- 80% of mosquitoes around a house fly into tubes.
- Cost: $2.5-4.7 pppy.
- 1800+ houses completed in Tanzania – excellent community acceptance.
- Indoor climate not compromised.
- Extremely safe: No contact by house occupants; passive technology.
- >95% reduction in insecticide use compared to IRS.
- Screening reduces indoor density of mosquitoes by 80-90%.
- Electrostatic coating with actives kills 100% for 3-6 months.
- Easy servicing and resistance management options.
- Exploits natural host-seeking behavior.

• Previous methods to block eaves only partially successful.
  • Depends on sealing doors and windows.
  • Large trials in progress.
### Barriers to adoption

<table>
<thead>
<tr>
<th>Workstream</th>
<th>Non Pyrethroid IRS</th>
<th>Dual AI LLINs</th>
<th>New AI IRS / LLINs</th>
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<tbody>
<tr>
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<td>Target Product Profile</td>
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- Proximate barrier to adoption of new products in the pipeline is the need 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
Conclusion

• There is a rich potential pipeline of new products

• The pipeline 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 product through development