

Indoor Residual Sprays (IRS)

Supplier Conference

Geneva

15 April 2014



Objectives of the day

- To initiate the dialogue
 - ...between The Global Fund and suppliers of Indoor Residual Spraying (IRS) products and other interested partners
- To understand the current situation
- To share future plans and expectations
- To identify key actions to progress

Agenda

Time	Title and Objectives	Lead)
08.30 - 09.00	Registration and coffee	Marika Plasson
09.00 - 09.15	Welcome, objectives and agenda	Chris Game
09.15 - 09.45	Introductions	Steve Hornsby (facilitate)
09.45 - 10.15	Introduction to the Global Fund and to Procurement 4 impact (P4i) Initial Q&A	Chris Game
10.15 - 10.45	<i>Morning break</i>	
10.45 - 11:05	Actions to Fight Malaria and IRS context	Dr Jan Kolaczinski
11:05 – 11:30	Global Fund Quality Assurance and testing / inspection requirements	Dr Joelle Daviaud / Dr Olivier Pigeon
11:30 - 11:45	Current position – suppliers, history, forecasts	Steve Hornsby
11:45 - 12:00	Global Fund funding model and organisational structures and roles	Sophie Logez
12:00 - 12:15	Q&A Panel	Jan/ Joelle/ Sophie/ Chris
12:15 - 13:15	<i>Lunch</i>	
13:15 - 14:30	Widening the discussion - presentations from partners - PMI, WHO, UNDP, IVCC, RBM Plus Q&A Panel	Kristen George (PMI) Dr Emmanuel Temu (WHO) Guy Rino Meyers (UNDP) Dr Tom McLean (IVCC) Dr Jan Van Erps (RBM)
14:30 - 15:00	Current performance (delivery/quality) – PPM orders, procurement process, case studies	Stephanie Xueref / Judy Macleod, / Erin Seidner
15:00 - 15:30	Current performance (delivery/quality) – other/ overall	Dr Joelle Daviaud / Dardane Arifaj-Blumi
15:30 - 15:45	<i>Afternoon break</i>	
15:45 - 17:15	Root cause analysis / priority actions – group and presentations	Steve Hornsby (facilitate)
17.15 - 17.30	Re-cap on the day and next steps - tomorrow and Q3/Q4.	Aziz Jafarov

Who's in the room?

- Who are you?
- What do you do?
- Why are you here?



- *“At 17:30 today I would like.....”*



Introduction to The Global Fund and to Procurement 4 impact (P4i)

Christopher Game
Chief Procurement Officer

RESULTS AT END 2013

Today, the Global Fund to Fight AIDS, Tuberculosis and Malaria is supporting more than 142 countries to fight these diseases here.

Effectively Access Efficiency Innovation



6 MILLION
PEOPLE ARE CURRENTLY
ON ANTIRETROVIRAL THERAPY

As of end 2013, 1.6 million more people than the 2012 target are receiving ART through the Global Fund support.

Providing 6 months of ART to 1 million people receiving ART in 2013



11.2 MILLION
NEW SMEAR-POSITIVE TB
CASES DETECTED AND TREATED

This year, programs supported by the Global Fund have treated 1.2 million people for tuberculosis.

Treating one of the 12 million people living with tuberculosis in 2013



360 MILLION
INSECTICIDE-TREATED
NETS DISTRIBUTED

This year, programs supported by the Global Fund have distributed 36 million ITNs for malaria prevention.

360 million of the 350 million children and children under five under 5 years old received ITNs



Strategies to fight AIDS, tuberculosis and malaria are working

With continued support, we can be the generation to defeat these pandemics.



The Global Fund

To Fight AIDS, Tuberculosis and Malaria

“An international financing institution that provides resources to low and middle-income countries in the fight against AIDS, TB and malaria”.

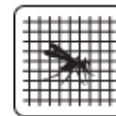
Key Results



PEOPLE CURRENTLY ON ART
6,100,000

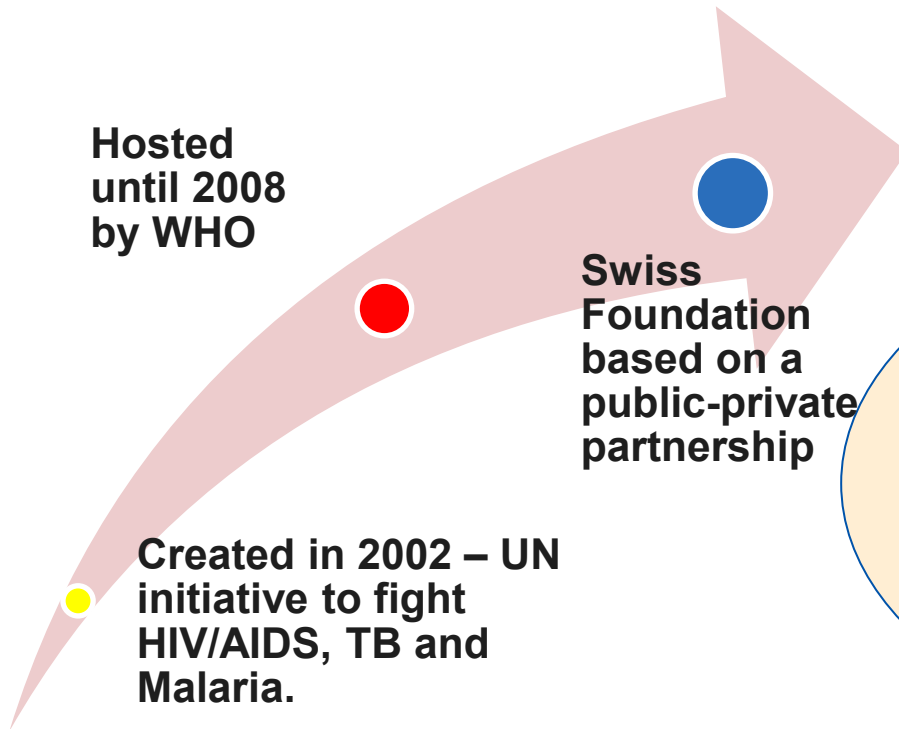


NEW SMEAR-POSITIVE TB CASES DETECTED AND TREATED
11,200,000

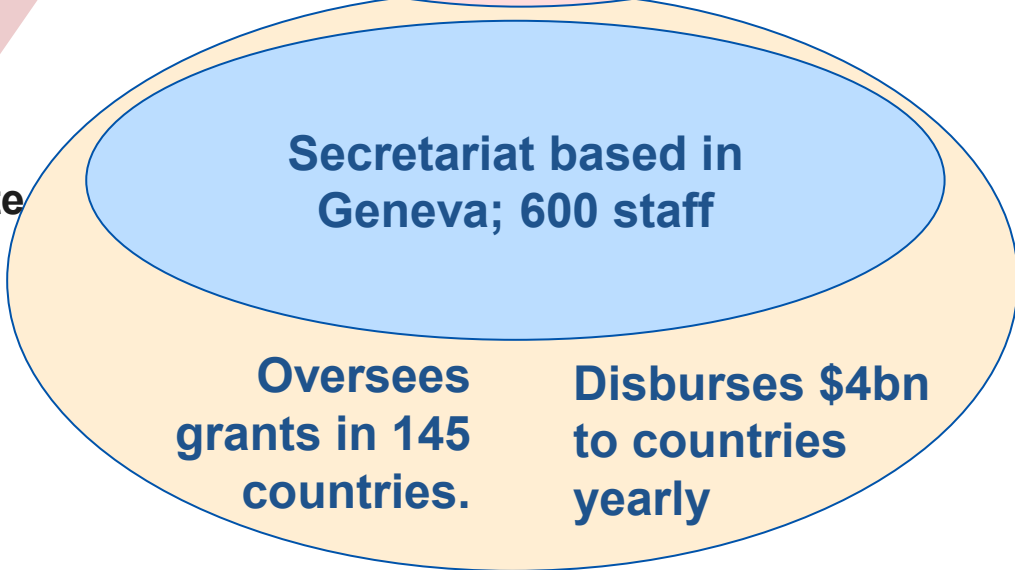


NETS DISTRIBUTED (ITNS & LLINs)
360,000,000

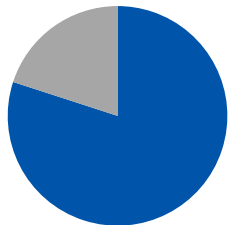
Who are we?



Governed by a Board representing donor and recipient countries, people living with the diseases, the private sector, NGOs from developing and developed countries and technical agencies such as WHO, UNAIDS, RBM.

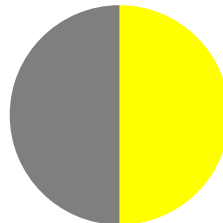


TB



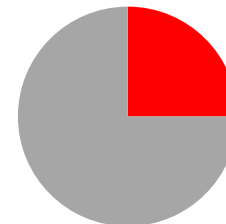
■ GF
■ Other

Malaria



■ GF
■ Other

HIV



■ GF
■ Other

Global Fund Guiding Principles

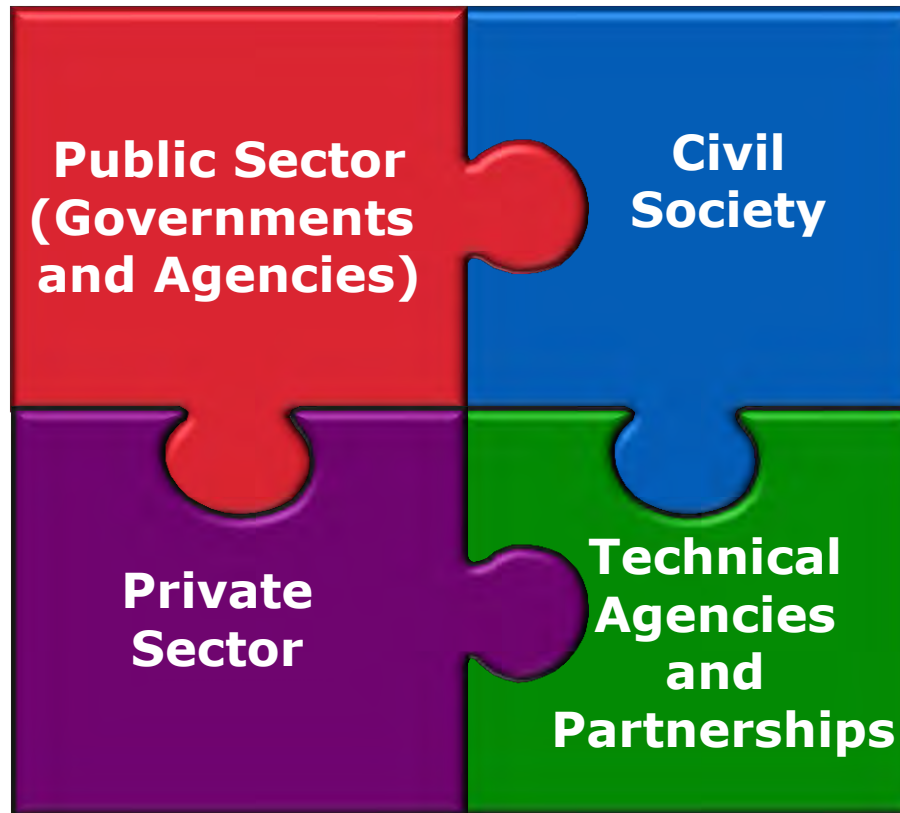
1. Operate as a **financial instrument**, not as an implementing entity
2. Make available and leverage **additional financial resources**
3. Support programs that reflect **country ownership** and respect country-led formulation and implementation in 145 countries
4. Operate in a **balanced manner** in terms of different regions, diseases and interventions
5. Pursue an integrated, balanced approach to **prevention, treatment and care**
6. Evaluate proposals through **independent review processes**
7. Focus on **performance** by linking resources to the achievement of clear, measurable and sustainable results.

Partnership Approach to Governance

A diverse partnership reflected in the Board and Country Coordinating Mechanisms

- Donors
- Recipient Countries

- Private Sector
- Private Foundations



- NGOs
- Communities living with, and affected by, the diseases

- WHO
- UNAIDS
- World Bank
- UNITAID
- RBM
- Stop TB Partnership...

The Global Fund Strategy



Based on 5 core principals

Invest more strategically in areas with high potential for impact and strong value for money, and fund based on countries' national strategies;

Evolve the funding model to provide funding in a more proactive, flexible, predictable and effective way;

Actively support grant implementation success through more active grant management and better engagement with partners;

Promote and protect human rights in the context of the three diseases; and

Sustains the gains, mobilize resources – by increasing the sustainability of supported programs and attracting additional funding from current and new sources.

Procurement 4 Impact: Our Objectives

Are directly aligned to the Global Fund's strategy

The Global Fund will become the benchmark organisation in the sector for Sourcing and Procurement

Using simple, clear leading edge processes and tools designed by and for the organisation



Minimising waste and eliminating non value adding activities

With measurable performance in value and lives saved

Ensuring effective governance and watertight compliance

Building collaborative relationships with partner agencies suppliers and donors

The Principles of Our Approach

Fundamentally changing the way we work across the supply chain to
increase access to products



Earlier involvement and closer collaboration with manufacturers

Improving our purchasing capability and changing our contracting models

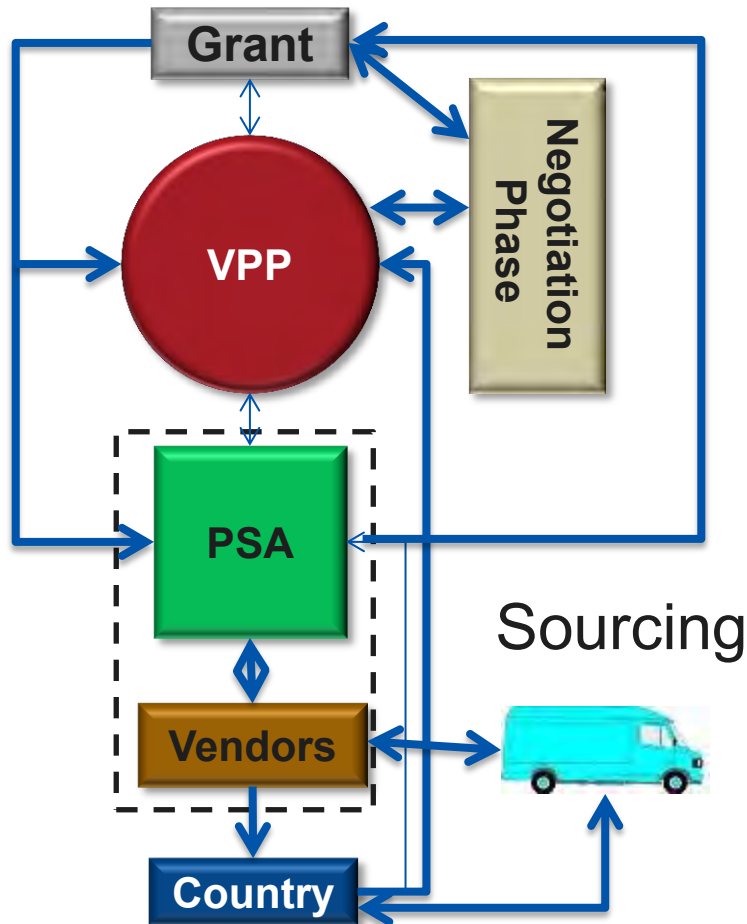
Optimising the international supply chain to reduce cost

Better planning and scheduling to support continuity of supply

Delivering more products at the right time and place to more people

Previously Direct Spend... "Voluntary Pooled Procurement"

Current State:



What could improve :

- Poor Penetration (Its Voluntary!!)
- Lack of Control
- High Agency Costs
- Wrong Agency Incentive model
- Agency 'local versus Global' expertise
- Poor visibility of innovation
- Lack of ownership / supplier relationships
- Poor funds flow
- Time / difficult to plan
- Mediocre internal customer service
- Little competition in pricing
- Role of Global Fund largely executorial
- No volume leverage/Many spot purchases

'It feels as though the roles have reversed and we have the agencies performing the sourcing, and the Global Fund is executing'

What will change: Core Products

Today

- Reactive procurement based on grant disbursement
- Spot tendering through PSA
- Minimal cross agency leverage
- Multiple negotiation processes
- Stock-outs and missed delivery windows
- Lack of standardised processes between Sourcing and PSM
- Wide discrepancy in prices between VPP and non VPP purchasing



12 Months

- Procurement based on forecast demand
- Long term, multi agency, collaborative contracts
- Single negotiation process
- 'Remote' inventory forecasting for Pooled Procurement
- A standardised project based approach.
- Contractually assured best price promulgated to all PR

Improving our forecasting accuracy

To support our new planning process we will change the way we interact with our primary recipients. This approach will also be facilitated by the new funding proposals

Today	The Future
<p>Demands are triggered by PSM plans which are presented in an inconsistent format.</p>	<p>Overall demand will be calculated from available funding</p>
<p>Overall demand is calculated reactively by hand</p>	<p>This demand will be placed on manufacturers as an underwritten volume</p>
<p>Orders are placed on PSA for onward transmission to manufacturers</p>	<p>Detailed PR requirements will be presented in a consistent format</p>
	<p>We will use a planning tool to convert our forecast in to specific orders by type</p>



The Commercial Relationship

To ensure we maintain a competitive price in a longer term contractual framework we will need to change our commercial model.



The Implications for our Suppliers

1

A Closer, more strategic relationship

With appropriate governance and regular reviews.

2

Longer term contracts

supported by increased focus on planning and scheduling

3

Collaboration to drive continuous improvement

Joint teams working together to achieve specific objectives

4

A fair return

Based on market norms and with the opportunity for incentivisation.

5

Our Commitment

We are committed to this way forward and will ensure our people have the right skills and attitude to make it work.



Sourcing Achievements 2013

Organization

- New organization created by merging AMFm, Corporate & Voluntary Pooled Procurement
- New capabilities created, Business Planning and analysis, Active Pharmaceutical Ingredients and Formulation

Process

- Sourcing in-sourced from the Procurement Agents
- Procurement Agents re-purposed as Logistics Agents and placed in-house. New contracts to KPI Logistics agents further downstream and increase accountability

Market Dynamics

- All outstanding Market Dynamics performance issues resolved (WHO ARV guidelines & Paed. ARV's)
- Coalitions / consortiums formed with other donors and funders to leverage spend, specification and demand
- Indirect spend control initiated with grant teams (vehicles, civil works, IT & Lab supplies)

Performance

- 137 Million value / savings delivered in year to-date
- Lead-times reduced from 9 to 6 months
- LLIN global strategy successfully rolled out with tender savings of \$ 70Mil/annum)
- Training produced and delivered to FPM's and PSM's
- Spend through pooled procurement increased from \$300M to \$1Bn.

Supply Chain

- Supply Chain capabilities :
 - Ability to forecast
 - Track and trace system up and running
 - Ability to measure delivery performance (OTIF)
 - In country supply mapping for hi-impact countries under-way
 - Rapid Supply Mechanism defined for all three diseases and in process

Sourcing Objectives 2014

Organization

- Integrate Purchasing and Supply Managers(PSM's) into Sourcing organization
- Re-structure to segregate operations from strategy
- Strengthen Indirect spend area

Process

- Launch E-Procurement toolset (reverse auctions etc.)
- Launch country catalogue / application tool and implement in High-Impact countries
- Launch pooled disbursement

Market Dynamics

- Complete market strategy for Tenofovir combination drugs
- Leverage Indirect spend into partner organizations
- Introduce new Chinese and Indian vendors to the Aid sector
- Create repeatable capability by partnering in depth with Market Dynamic focused organizations

Performance

- Deliver 8% value / savings
- Achieve 60% OTIF
- Lead-times reduced from 6 to 5 months
- Roll out Global strategies on ACT's, Diagnostics & ARV's
- Implement Rapid Supply Mechanism

Supply Chain

- Complete Supply Chain mapping for High-Impact Countries
- Establish common platforms for traceability at beneficiary level (Counterfeit /theft /diversion)
- Create base level training for in-country partners

Overall Progress to Plan - Procurement 4 Impact – Goals



- Just over \$ 137M value added
- 5 more countries have **asked** to join pooled procurement
- Current OTIF disappointing at 36.8% - but for the first time it is measurable

1. Develop and implement comprehensive ● reengineering of the Procurement Operating Model and Organization.
2. Develop Procurement as a strong ● partner to create and facilitate Best in Class solutions and delivery for the Global Fund.
3. Create additional Value of 8% per ● annum
4. Increase spend penetration by 20% per ● annum
5. On Time and In Full (OTIF) service to ● countries to exceed 75 %

Malaria Portfolio & Priorities

Dr Jan Kolaczinski
Senior Disease Advisor
Strategy, Investment and Impact Division

Signed Proposals

32%

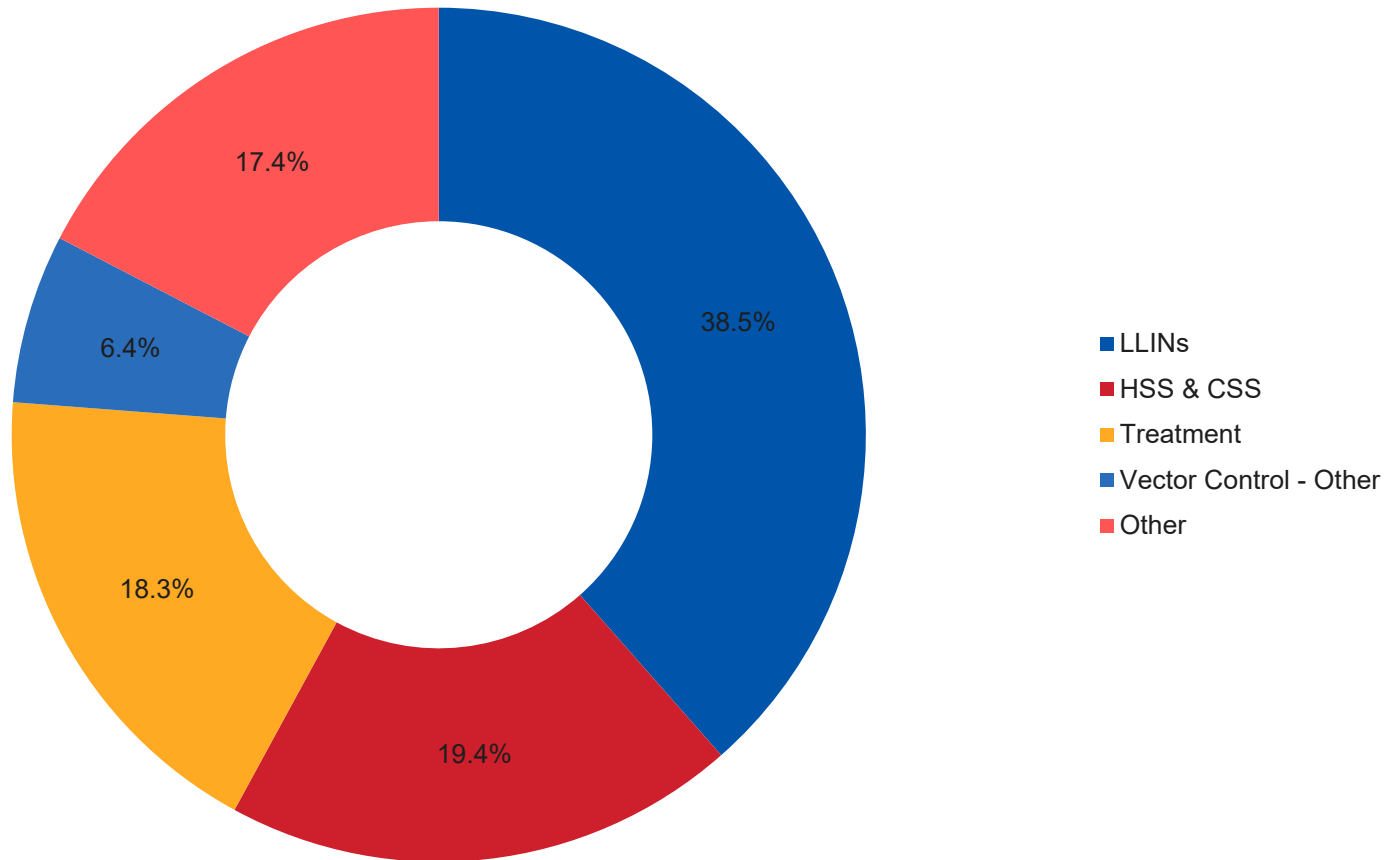
Disbursed Funding by Disease and Region (cumulative, End-2013)

Region	HIV (US\$)	TB (US\$)	Malaria (US\$)
Africa - High Impact I	1,600,899,190	300,673,188	1,310,766,934
Africa - High Impact II	3,189,751,953	325,120,432	1,653,597,193
Africa - Central Africa	1,093,772,424	106,321,403	591,179,002
Africa - Western Africa	486,000,967	81,732,392	478,497,332
Africa - Southern/Eastern Africa	1,162,383,222	142,417,705	560,129,809
Asia - High Impact	1,941,551,670	1,383,191,621	684,319,052
Asia - South/East	455,764,456	244,132,119	478,661,296
Eastern Europe and Central Asia	1,176,170,770	579,461,845	36,611,709
Middle East and North Africa	424,273,779	207,403,778	294,678,332
Latin America and Caribbean	1,095,148,590	235,731,848	200,368,074
Total	12,625,717,022	3,606,186,329	6,288,808,733

Malaria Grants

- 80 countries are eligible
- 298 active malaria grants (56% in WHO AFRO Region)
- 2 regional grants:
 - Regional Artemisinin Initiative (Greater Mekong Sub-Region)
 - Malaria Elimination in Central America + Hispaniola
- 1 Multi-country grant in Western Pacific

Expenditures by Service Delivery Area



Countries Currently Delivering IRS With Global Fund Resources

Global Fund Region	Countries
SSA: East Africa and Indian Ocean	Comoros, Eritrea, Ethiopia, Rwanda, Madagascar
SSA: Southern Africa	Mozambique, Namibia (Spray Equipment only), Zimbabwe
SSA: West and Central Africa	Gambia, Ghana, Sao Tome and Principe
East Asia and Pacific	Korea (Democratic Peoples Republic), Philippines, Solomon Islands, Timor Leste, Viet-Nam
Eastern Europe and Central Asia	Kyrgyzstan, Tajikistan, Uzbekistan
Latin America and Caribbean	Bolivia (Plurinational State), Guyana, Nicaragua
Middle East and North Africa	Sudan, Yemen, Iran
South and West Asia	Pakistan

Current Insecticide Choice

Country	Pyrethroid	Carbamate	OP	DDT	Rotation
Bolivia	✓	✓			
Comoros	✓				
Eritrea	✓	✓			✓
Ethiopia		✓			
Gambia		✓	✓		✓
Ghana			✓		
Guyana	✓				
Iran	✓				
Korea (DPR)	✓				
Kyrgyzstan	✓				
Madagascar	✓	✓			
Mozambique		✓			
Nicaragua	Etofenprox				
Pakistan	✓				
Philippines	✓				
Rwanda	✓	✓			✓
Sao Tome & Principe		✓			
Solomon Islands	✓				
Sudan		✓			
Tajikistan	✓				
Timor Leste	✓				
Uzbekistan	✓				
Yemen		✓			
Zimbabwe	✓		✓	✓	✓

Global Fund Priorities

The Global Fund Strategy Framework 2012-2016: “Investing for impact”

Vision	A world free of the burden of HIV/AIDS, tuberculosis and malaria with better health for all		
Mission	To attract, manage and disburse additional resources to make a sustainable and significant contribution in the fight against AIDS, tuberculosis and malaria in countries in need, and contributing to poverty reduction as part of the MDGs		
Guiding principles	<ul style="list-style-type: none"> • Being a financing instrument • Additionality • Sustainability • Country ownership 	<ul style="list-style-type: none"> • Multi-sectoral engagement • Partnership • Integrated, balanced approach • Promoting human right to health 	<ul style="list-style-type: none"> • Performance-based funding • Good value for money • Effectiveness and efficiency • Transparency and accountability
Goals	<p>10 million lives saved¹ over 2012-2016</p> <p>140-180 million new infections prevented over 2012-2016</p>		
	Global plan	Global Fund leading targets for 2016	Indicators for other selected services
Targets² (2016)	HIV / AIDS	UNAIDS 2011-2015 Strategy, 2011 Investment Framework, and UNGASS June 2011 Declaration	<ul style="list-style-type: none"> • 7.3 million people alive on ARTs
	TB	Global Plan to Stop TB 2011-2015	<ul style="list-style-type: none"> • 4.6 million DOTS treatments (annual) • 21 million DOTS treatments over 2012-2016
	Malaria	RBM Global Malaria Action Plan 2008 and May 2011 updated goals and targets	<ul style="list-style-type: none"> • 90 million LLINs distributed (annual) • 390 million LLINs distributed over 2012-2016

1. Based on impact of provision of ART, DOTS and LLINs using methodology agreed with partners. 2. Targets refer to service levels to be achieved in low- and middle-income countries. Note: Goals and targets are based on results from Global Fund-supported programs which may also be funded by other sources; targets are dependent on resource levels

Global Fund Priorities

- Follow WHO normative guidance:
 - WHO Global Malaria Program, 2014 Policy Brief
<http://www.who.int/malaria/publications/atoz/who-policy-brief-2014/en>
 - Roll Back Malaria Harmonization Working Group, Malaria Implementation Guidance in Support of the Preparation of Concept Notes for the Global Fund
http://www.rbm.who.int/partnership/wg/wg_harmonization/docs/HWG-2014-country-briefing-note.pdf

Global Fund Priorities

Key Priorities:

- Scale up of 'Test.Treat.Track.'
- Replacement of quinine with artesunate as first-line treatment for severe malaria
- Maintaining the gains in vector control coverage:
 - Regular LLIN replacement
 - Use of IRS as an alternative to LLINs, particularly in the context of insecticide resistance management
 - Monitoring insecticide resistance



**World Health
Organization**

GUIDANCE FOR DEVELOPMENT OF NATIONAL INSECTICIDE RESISTANCE MONITORING AND MANAGEMENT PLANS

DRAFT FOR LIMITED CIRCULATION

April 2014

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Dr Joelle Daviaud / Dr Olivier Pigeon



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Global Fund Quality Assurance requirements Responsibilities and implications

**The Global Fund:
IRS Supplier Conference: 15th / 16th April 2014**



Invirtiendo en nuestro futuro

El Fondo Mundial
De lucha contra el SIDA, la tuberculosis y la malaria



投资于我们的未来

全球基金
抗击艾滋病、结核和疟疾



Investing in our future

The Global Fund
To Fight AIDS, Tuberculosis and Malaria



Investissons dans notre avenir

Le Fonds mondial
De lutte contre le sida, la tuberculose et le paludisme



Вклад в наше будущее

Глобальный фонд
для борьбы со СПИДом, туберкулезом и малярией



استثمار لمستقبلنا

الصندوق العالمي
لمكافحة الإيدز والسل والملاريا



Global Fund's PSM Principles

- Procure **quality assured products**
- in a **transparent and competitive** manner
- In the most adequate form to **support adherence** (fixed dose combinations, children forms)
- At the **lowest possible price**
- In adherence to applicable **National Laws** and international agreements
- Supply Systems: capacity to ensure an uninterrupted supply of health products while minimizing risk of wastage and diversion



General principles while executing procurement:

- Best value for money
- Fairness, Integrity, Transparency
- Effective competition

**Pharmaceutical Products
(since December 2010)**

**Condoms
WHO/UNFPA Procurement
Guidelines (2010)**

**Global Fund
Quality Assurance
for Health Products**

**Diagnostic Products
(since March 2011)**

**Long Lasting Insecticidal Nets,
IRS**

**WHOPES recommendations
2012 WHO Public Health
Pesticides Procurement
guidelines**

Quality Standards for LLINs/ Pesticide products

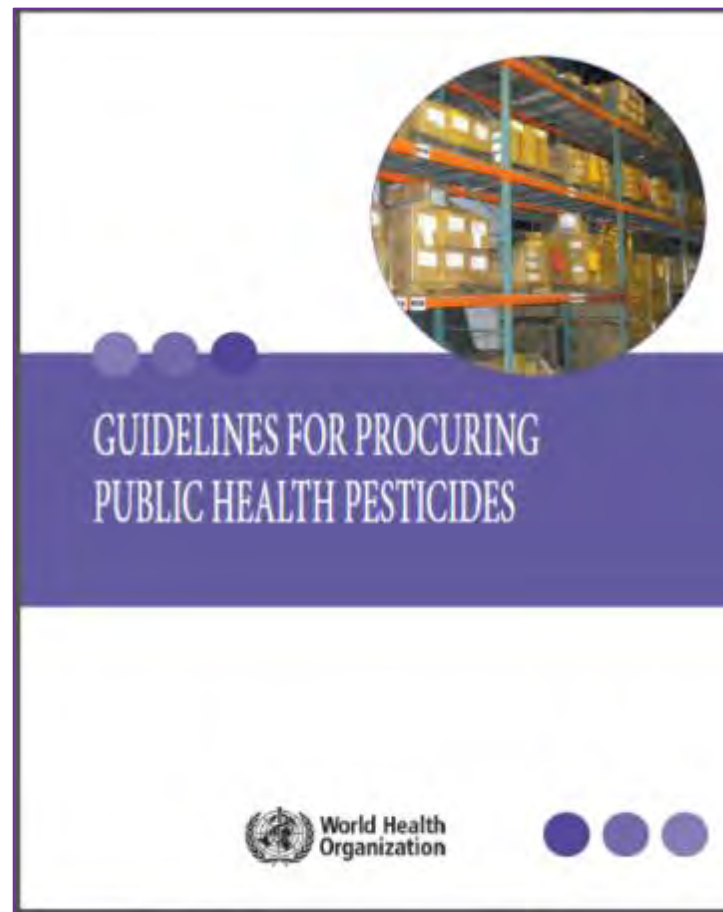
Quality Standards :

Grant funds may only be used to procure pesticides that are recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES)

Reference Guidelines:

Guidelines for procuring public health pesticides on our web page at

<http://www.who.int/whopes/resources/en/>



Global Fund quality requirements for procurement of IRS products

1. **Select IRS approved by WHO PES (formulations/manufacturers)**
2. **Systematic Manufacturers CoA review at pre-shipment level**
3. **Random pre-shipment testing by an independent QC lab**
 - Sampling to be done by an **independent** sampling agent
 - Testing:
 - QC testing by **ISO 17025 certified laboratory**, WHO Collaborating Centre for QC of Pesticides
 - According to **WHO Methods and Specifications**
4. **Post shipment testing if risk identified after the receipt of the products**

IRS approved by WHOPEs : Global Fund List of IRS

- Purpose:

- tool to assist Principal Recipients (PR) of Global Fund grants in procurement.
- published in GF website in the following URL:
<http://www.theglobalfund.org/en/procurement/quality/health/>

- Content:

- insecticide for IRS listed by WHOPEs and published at:
http://www.who.int/whopes/Insecticides_IRS_Malaria_09.pdf
- prepared based on the WHOPEs evaluation report.
- only IRS products for which QC methods specifications are published in WHOPEs website
<http://www.who.int/whopes/quality/newspecific/en/>
- updated as and when changes happen in the WHOPEs website
- non exhaustive list

Monitoring the Quality of Pesticides

Why? How?

WHO specifications for pesticides

- define the essential chemical and physical properties associated with the efficacy and the risk of use of a product

Poor-quality pesticides

- can result in inadequate application of the product
- increase the risk for users and the environment
- lead to ineffective control and potential development of resistance

QC essential to

- minimize risks associated with their handling and use
- guarantee their efficacy and stability during storage

9. QUALITY CONTROL: PRESHIPMENT AND ARRIVAL INSPECTION

Quality control of pesticides is essential to minimize risks associated with their handling and use and also to guarantee their efficacy and stability during storage. Poor-quality pesticides can result in inadequate application of the product, increase the risk for users and the environment and lead to ineffective control and potential development of resistance.

WHO specifications for pesticides provide an international point of reference against which products can be judged, either for regulatory purposes or in commercial dealings, and thus prevent the trade of substandard products. They define the essential chemical and physical properties associated with the efficacy and the risk of use of a product.

All public health pesticides offered for sale should meet the WHO specifications, when they exist. When WHO specifications do not exist, any other relevant internationally accepted or national specifications should be considered. The bidder must provide evidence that the product offered complies with the relevant specification. A certificate of analysis should be provided by the supplier for each batch of product at the time of delivery. The independent control of the quality of the product has to be determined through independent analysis by the procurement entity.

Quality of Pesticides: WHO recommendations (1)

- **All public health pesticides** offered for sale should **meet the WHO specifications**, when they exist.
- When WHO specifications do not exist, any other relevant internationally accepted or national specifications should be considered.
- The bidder must provide **evidence** that the product offered **complies with the relevant specification**.
- A **certificate of analysis** should be **provided** by the supplier for each batch of product at the time of delivery.

Quality of Pesticides: WHO recommendations (2)

- **Independent control of the quality** of the product to be determined through independent analysis by the procurement entity:
 - choosing an **independent certified or accredited** laboratory,
 - **each batch should be tested for compliance** with the specification.
 - **random sampling** of samples when appropriate
 - shipment of samples to the selected laboratory,
 - quality control according to methods referenced in the WHOPES pesticides specifications/other international spec if needed.
 - the **analysis should not be limited to the active ingredient** content but include **all the physical and chemical properties** specified in the WHO specifications or other relevant specifications.
 - reporting by the selected laboratory.

Responsibilities when pesticides are procured with Global Fund resources (1)

PRs/PAs responsibilities

1. to inform the manufacturer on QA requirements in tender specifications/ contract/ PO steps;
 - Only WHOPEs products could be procured
 - Quality control according to specifications published by WHOPEs
 - Products to be shipped only when the GF secretariat issued the approval letter based on CoA review / QC results
2. When POs issued, to requests manufacturers
 - to provide the PRs/PAs/the GF Secretariat the details of all the batch numbers allocated for the purchase order
 - the Certificate of Analysis of all batches to be supplied

The Secretariat/PAs responsibilities

- to send the CoAs for review to the selected Quality Control Laboratory
- to issue final approval letter, based on QC lab results, for shipment or not of the IRS lots

Responsibilities when pesticides are procured with Global Fund resources (2)

The Quality Control Laboratory responsibilities

- to review the CoAs and based on the review, to select the lots to be tested
- to perform QC tests according to WHOPES recommended methods
- to issue CoAs review/ QC report and address them to the Global Fund

The Manufacturers responsibilities

- to provides the list of batches and CoAs to PR/PA/ GF
- to inform in advance pn the date of expecting release of the vbatches for sampling planning
- to set aside the consignment to enable the sampling agency to perform Consignment Inspection in the location of storage.
- to ship the batches quarantined, inspected, sampled and tested/skipped only on receipt of clearance from the PR/GF Secretariat/ PAs.

Implementation

- Process systematically followed for all VPP/PPM procurements since 2012
- Process today implemented by most of the PRs

Challenges encountered

- Low number of IRS formulations WHOPEs approved
 - difficulty to get appropriate formulation as requested by the country
 - delay in delivery of appropriate IRS
 - difficult to replace the IRS selected in case of quality failure
- Complete CoAs not provided
 - no randomization of lots tested could be applied, increase of QC , and delay in shipping the IRS
- Shipment sent and distributed in country before sampling
 - Considerable delay in sampling and QC testing
- Significant Quality failures

Conclusion

- Procurement of appropriate IRS in due time is still challenging for many programs
- The lack of pesticides of assured quality has delayed the use of LLINs and IRS by countries and in some cases for more than one year:
 - no spraying before the raining season
 - great public health significance in particular by contributing to insecticide resistance.
- Quality of Pesticides cannot be compromised:
 - The Global Fund is increasing the quality monitoring of pesticides
- Improve collaboration with WHO, Partners, Quality Control Laboratory and communication with Manufacturers should lead to increase the access to assured quality pesticides by the programs in country

Quality Control of pesticide formulations

Olivier Pigeon & Marie Baes
Walloon Agricultural Research Centre (CRA-W),
Gembloux, Belgium

**The Global Fund, IRS Supplier Conference,
Geneva, 15 April 2014**

Centre wallon de Recherches agronomiques
Département Agriculture et Milieu naturel

Unité Physico-chimie et Résidus des Produits Phytopharmaceutiques et des Biocides
Bât. Carson Rue du Bordia, 11 - B-5030 GEMBLoux - Tél : ++ 32 (0)81 62 52 62 - Fax : ++ 32 (0)81 62 52 72
pesticides@cra.wallonie.be - <http://www.cra.wallonie.be>

Contribution of CRA-W to the Quality Control of pesticide formulations



Plant Protection Products and Biocides Physico-chemistry and Residues Unit (U10)

WHO Collaborating Center for
Quality Control of Pesticides



- ✓ Has a long experience in pesticides physico-chemistry and residues ;
- ✓ Gives support to WHO, FAO, CIPAC, ESPAC, GF, UNDP ...

GLP Certified

ISO 17025 Accredited

Quality Control of pesticide formulations



Importance to control the quality of pesticides

Poor-quality pesticides :

- are unlikely to serve the intended purpose;
- are likely to provide poor value to users;
- are likely to be more harmful, directly or indirectly, to humans and the environment;
- may be phytotoxic to treated crops.

Quality Control of pesticide formulations



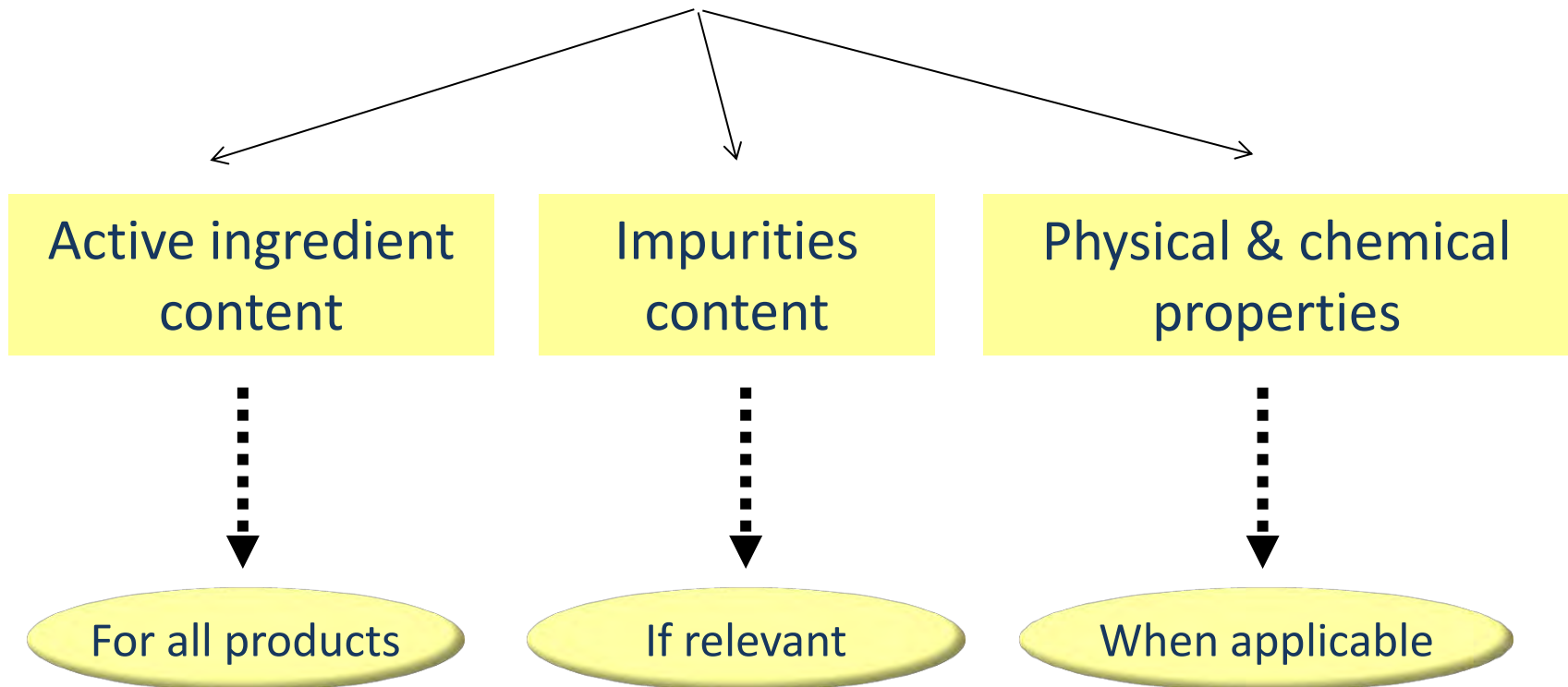
Importance to control the quality of pesticides

Examples of adverse effects of poor-quality pesticides :

- Excessive level of a hazardous impurity increases risks of adverse effects on users and/or the environment.
 - Poor suspensibility of dispersions may produce uneven distribution of active ingredient in the spray tank and uneven application.
 - Insoluble particulates present in products intended for spray application may block nozzles and/or filters.
 - Granular formulations which are too fragile may produce respirable dust when handled and applied, increasing the risk of user exposure to active ingredient.
- Any of the above consequences will usually have a negative impact on the marketability of a pesticide product and its registration could be withdrawn or restricted

Quality Control of pesticide formulations

What does pesticide quality control involves ?



According to FAO/WHO specifications

FAO and WHO specifications for pesticides



Manual on development
and use of FAO and WHO
specifications for
pesticides

November 2010 - second revision of the
First Edition

Second
Revision



Scope of specifications

- to provide unique, robust and universally applicable standards for quality of agricultural pesticides (FAO) and public health pesticides (WHO)
- Jugement of the quality of products
- Enhance confidence in the purchase and use of pesticides
- Better pest control
- Ensure public and environmental safety

FAO and WHO specifications for pesticides



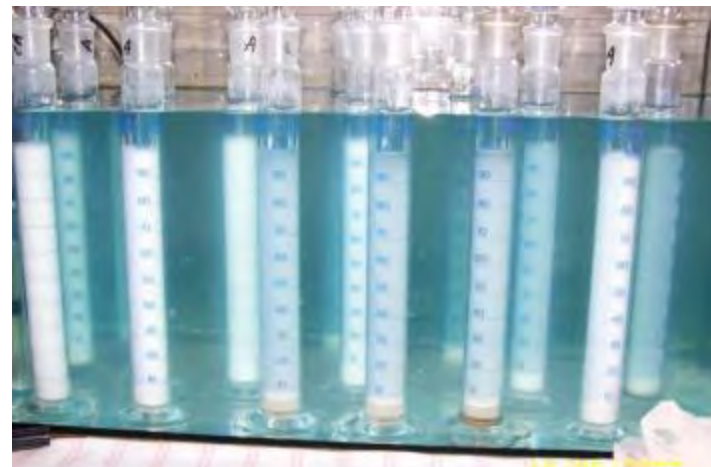
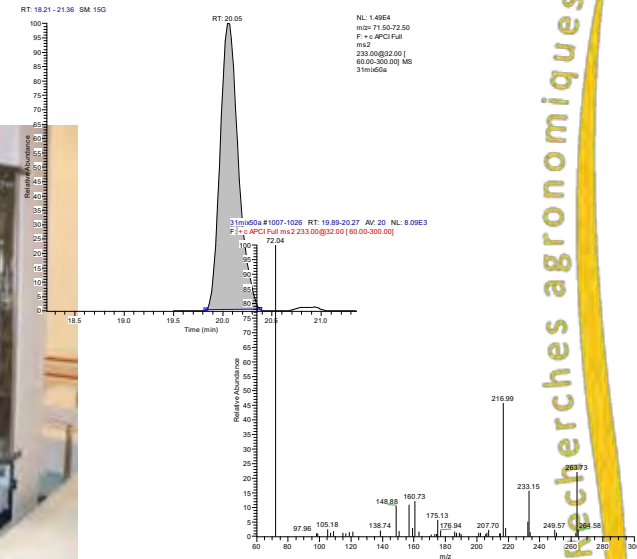
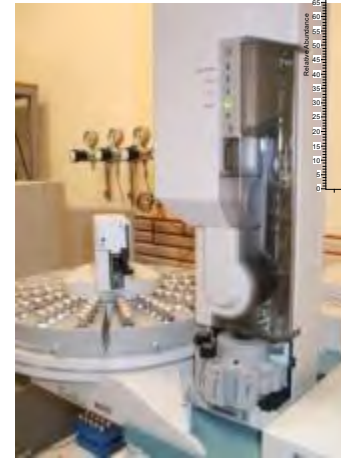
What is a pesticide specification ?

- A list of basic quality criteria for distinguishing between products having acceptable and non-acceptable quality (of the same type).
- But it does not define the best product, nor that the product is suitable or safe for a particular purpose.
- FAO/WHO limits of specification includes the uncertainty of measurement : this means that a product which is outside or at the limit for a parameter cannot be considered as a good quality product.

FAO and WHO specifications for pesticides

Pesticide specification criteria

- Description of the product
- Active ingredient identity and content
- Relevant impurities
- Physical properties
- Storage stability



FAO and WHO specifications for pesticides



Use of specifications

- as part of a contract of sale, so that a buyer may purchase a pesticide with some guarantee of the quality expected;
- by the competent authority to check that the quality of the formulation on the market is the same as that registered.

NB : FAO/WHO specifications may be used by national authorities as an international point of reference but are not intended to replace national or international registration requirements.

FAO and WHO specifications for pesticides



Publication and revision of specifications

- FAO/WHO development of specifications has changed to a “new procedure” in recent years.
- Evaluation by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS)
- Specifications for TC and formulated products + evaluation report
- <http://www.who.int/whopes/quality/en/>

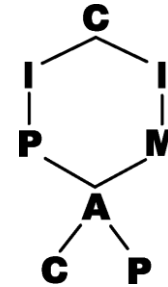
Test methods for Quality Control of pesticides

Test methods supporting specifications

- Widely-accepted, well-validated test methods are essential.
- Test methods should be straightforward and robust.
- Well-trained technicians and a suitably-equipped laboratory are required for reliable results.

Test methods for Quality Control of pesticides

CIPAC = Collaborative International Pesticides Analytical Council



- CIPAC is an international, non-profit-oriented and non-governmental organization devoted to:
 - promote the international agreement on methods for the analysis of pesticides and physico-chemical test methods for formulations.
 - promote inter-laboratory programmes for the evaluation of test methods
- The methods are proposed by companies and are tested by laboratories all over the world. After evaluation of the results and adoption, the methods are published in the CIPAC Handbooks.
- <http://www.cipac.org/>

Thank you for your attention



cra-w

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Département Agriculture et Milieu naturel

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Bât. Carson Rue du Bordia, 11 - B-5030 GEMBLoux - Tél : ++ 32 (0)81 62 52 62 - Fax : ++ 32 (0)81 62 52 72
pesticides@cra.wallonie.be - <http://www.cra.wallonie.be>

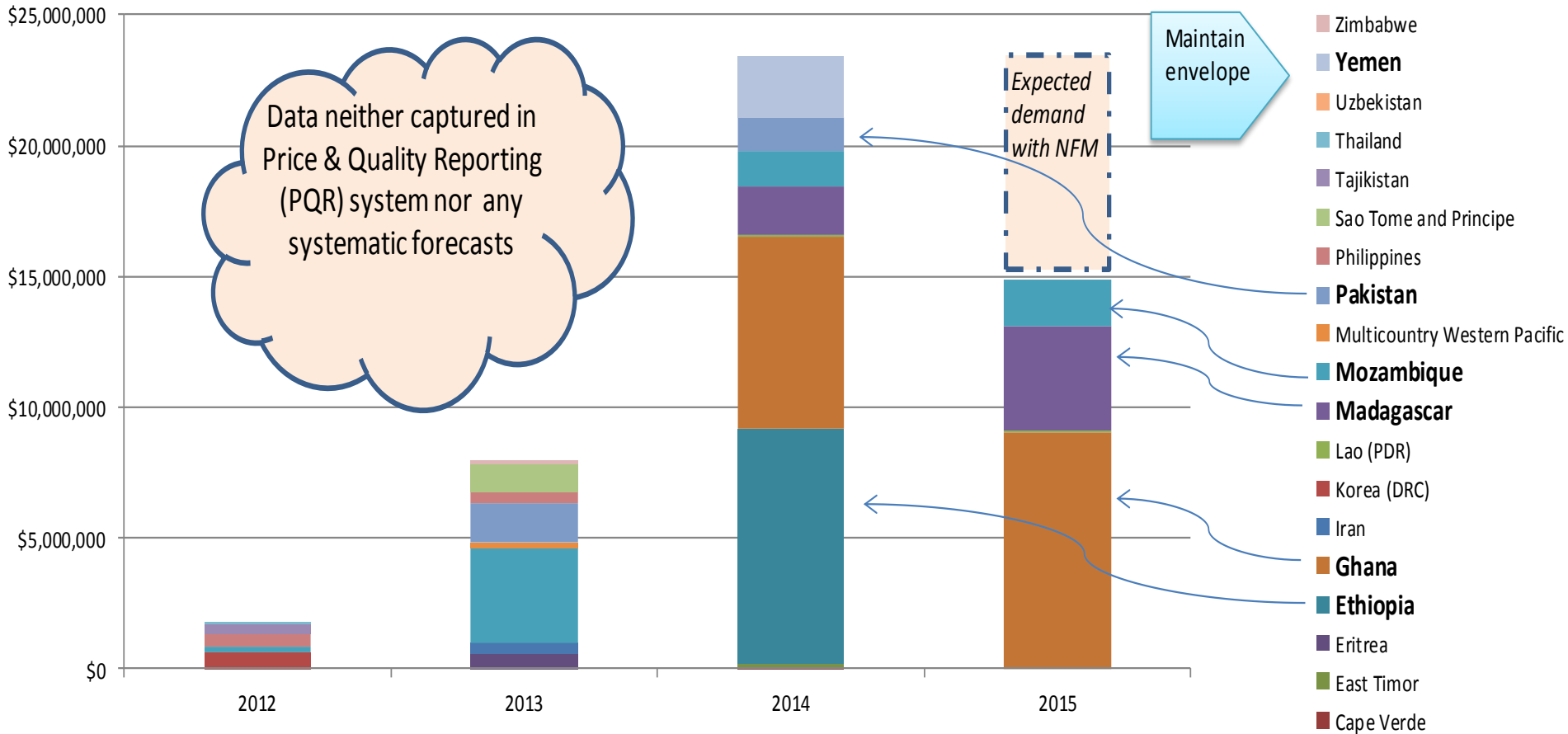
Current position – suppliers, history, forecasts

Steve Hornsby

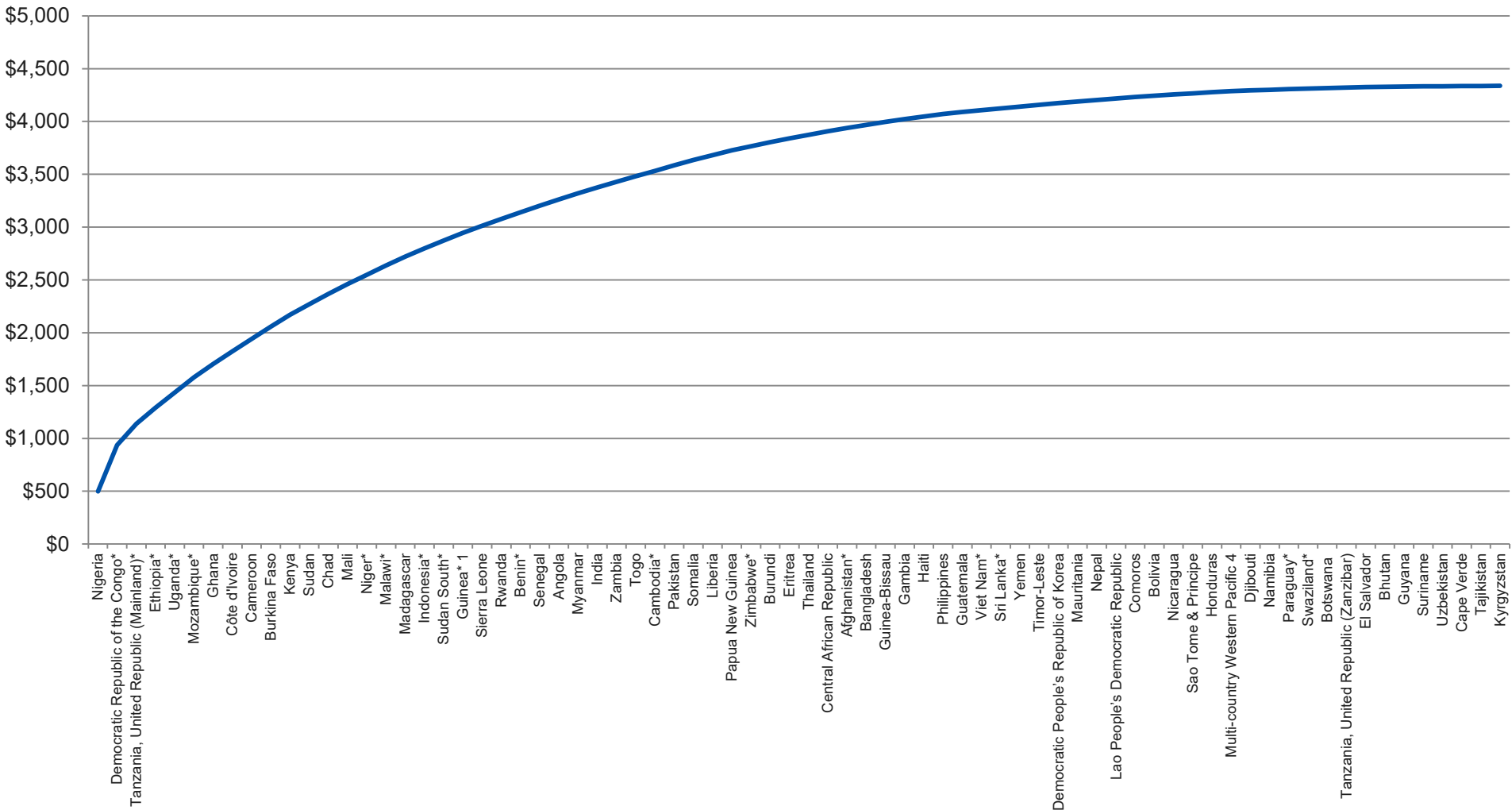
Historical and forecast GF IRS demand

Potential \$100m spend over 2014 - 2018

Annual GF IRS funding \$



NFM Envelope includes \$4.4bn for Malaria over next 3 years



Recommended pesticides for IRS and approved manufacturers (and current GF suppliers)

Pesticides listed by WHOPEs	Pesticides recommended for use as IRS	Formulations approved by WHOPEs	Tagros India-	BASF (Agro)	Megmani India	Gharda India (Paar Impex)	Heranba India (Paar Impex)	Bharat Rasayan	Sumitomo Japan	Bayer Corp Sciences	FMC Corp	Chemina	Agros South Africa	Isagro Italy	Mitsui Chemicals	Syngenta
Alpha-Cypermethrin	Pyrethroids	TC,WP,SC	√ TC,WP,SC	√ TC,WP,SC	√ TC,WP,SC	√ TC,WP,SC	√ TC,WP,SC	√ TC,WP,SC								
BIFENTHRIN	Pyrethroids	TC,WP									√ TC,WP					
CYFLUTHRIN	Pyrethroids	TC,EW,WP								√ TC,EW,WP						
Deltamethrin	Pyrethroids	TC,DP,WP,SC,EC,UL,WG,EW,WT	√ TC,DP,SC,EC,WP,UL,WG			√ TC,WP,SC,EC,UL,WG	√ TC,DP,SC,EC,WG,WP,UL,EW			√ TC,DP,SC,EC,EW,WP,WT,UL,WG			√ TC,DP,SC,EC,WP,UL,WG	√ TC,EC		
Etofenprox	Pyrethroids	TC,WP,EW													√ TC,WP,EW	
Lambda-Cyhalothrin	Pyrethroids	√ TC,EC,WP,CS	√ TC,EC,WP					√ TC								√ TC,EC,WP,CS
Fenitrothion	Organophosphates	TC,WP,EC							√ TC,WP,EC							
Malathion	Organophosphates	TC,DP,EC,UL										√ TC,DP,EC,UL				
Pirimiphos-Methyl	Organophosphates	TC,EC,CS														√ TC,EC,CS
BENDIOCARB	Carbamates	TC,WP								√ TC,WP						
Propoxur	Carbamates	TC,WP								√ TC,WP						
p,p'-DDT	Organochlorines	TC,DP,WP														

The Global Fund New Funding Model

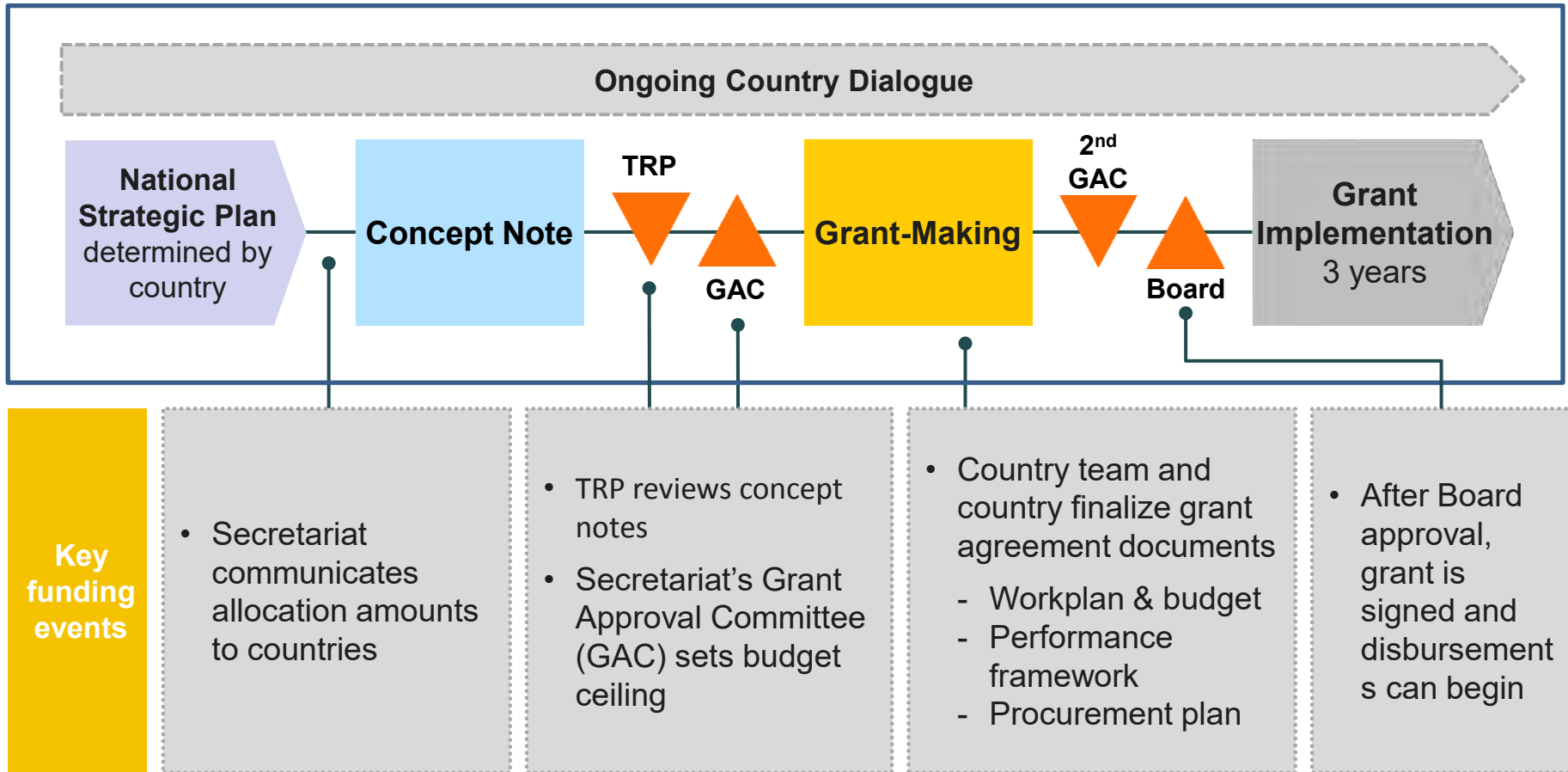
IRS meeting ,Geneva ,15 April 2014

Principles of the new funding model

Principles of the new funding model

- **Bigger impact:** focus on countries with the highest disease burden and lowest ability to pay, while keeping the portfolio global
- **Predictable funding:** process and financing levels become more predictable, with higher success rate of applications
- **Ambitious vision:** ability to elicit full expressions of demand and reward ambition
- **Flexible timing:** in line with country schedules, context, and priorities
- **More simple:** for both implementers and the Global Fund

Overview of the new funding model



5 areas to prepare for the new funding model

1

Plan ahead

2

Strengthen national strategies

3

Involve key groups

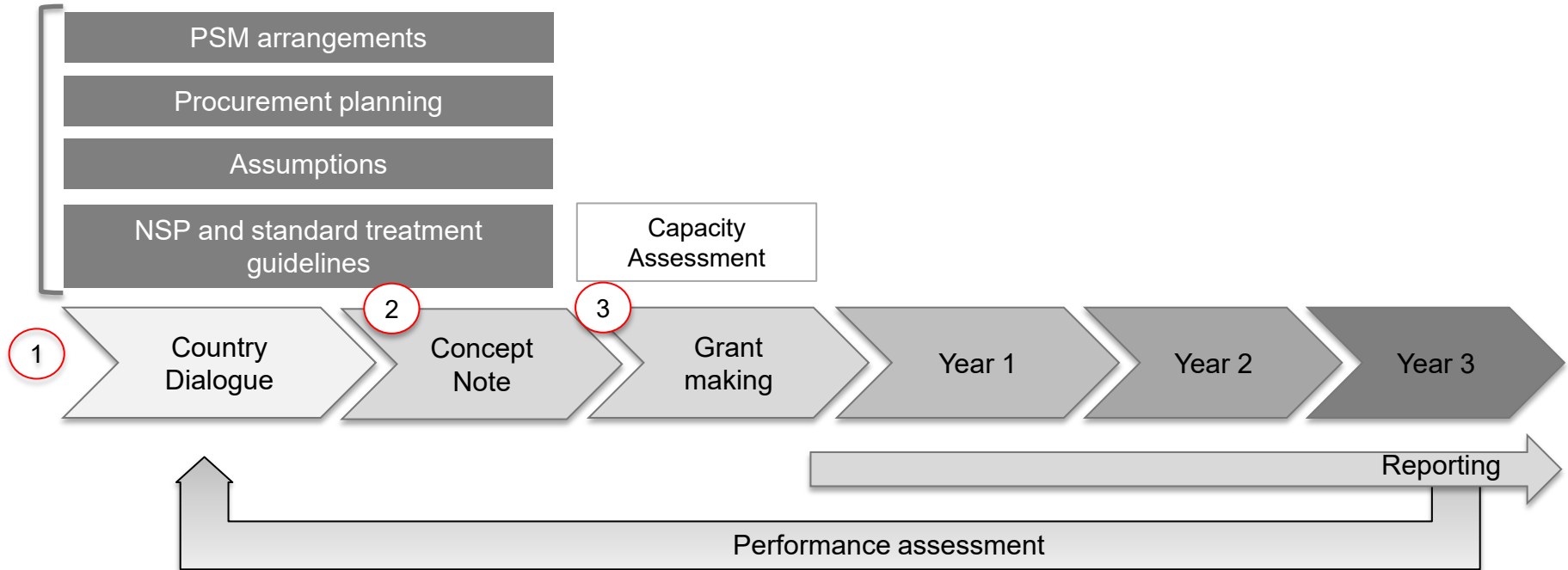
4

Consolidate information and use updated data

5

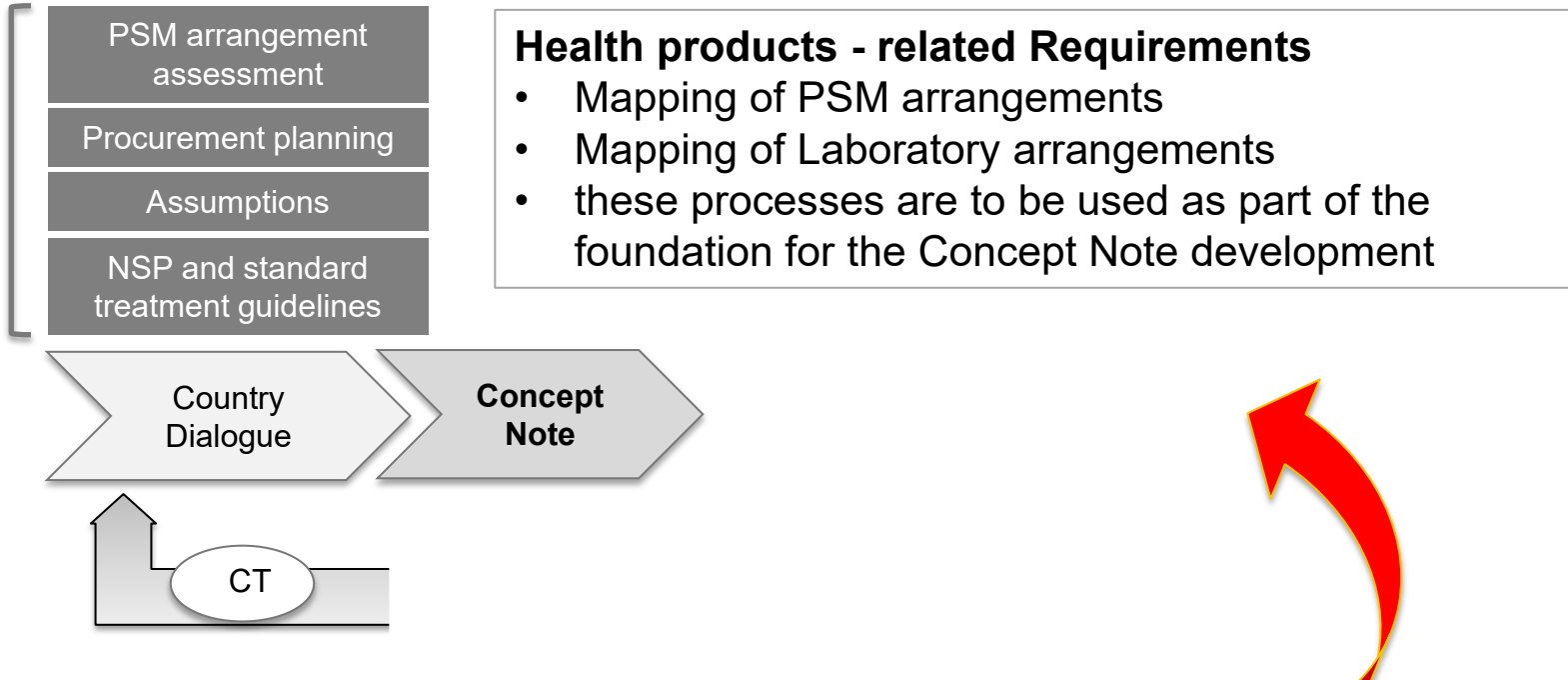
Ensure inclusion of PSM component in the Concept Note

NFM: Health Product Management requirements



- PSM coordination mechanism
- Health product management
- Supply chain strategy/
Health Systems Strengthening

Health Product Management requirements: Country Dialogue

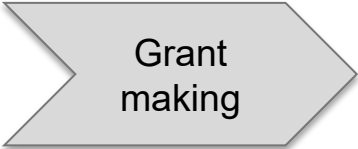


Rationale

The Country Dialogue process is meant to ensure that requests to the Global Fund:

- Are integrated into the broader disease strategy and National Strategy for Pharmaceutical System Strengthening
- Build upon the lessons learned from past grant implementation
- **Are inclusive and reflect inputs of diverse stakeholders, including the regulatory authorities, supply chain stakeholders and lab authorities**

Health Product Management: Grant Making Step



Grant
making

PSM-related Requirements

- Finalized estimated needs (quantification aligned with program targets)
- Defined PSM arrangements and the specific activities to address the systemic gaps

PSM Preparation for the Concept Note

Countries

Work on defining a Pharmaceutical System Strengthening Strategy (with costed implementation plan and short/long term priorities) aligned with HSSP

Define the system for estimating health products' requirements

Ask for TA and contact PSM Specialists in the Global Fund for guidance

Global Fund

Options for flexibilities (extensions and/or other provisions) to deal with challenges related to timing

Country-specific discussions GF- Country Programs- Partners recognizing the different country-specific situations

Support Countries to prepare for the Concept Note

Partners

TA in:

- Pharmaceutical System Strengthening (PSM optimization; RUM; QA;PV etc)
- Quantification for HIV, TB and Malaria medicines and commodities

Global Fund's PSM Principles

- Procure **quality assured products**
- in a **transparent and competitive** manner
- In the most adequate form to **support adherence** (fixed dose combinations, children forms)
- At the **lowest possible price**
- In adherence to applicable **National Laws** and international agreements

- Supply Systems: capacity to ensure an uninterrupted supply of health products while minimizing risk of wastage and diversion



General principles while executing procurement:

- Best value for money
- Fairness, Integrity, Transparency
- Effective competition

Global Fund Q & A Panel

Agenda

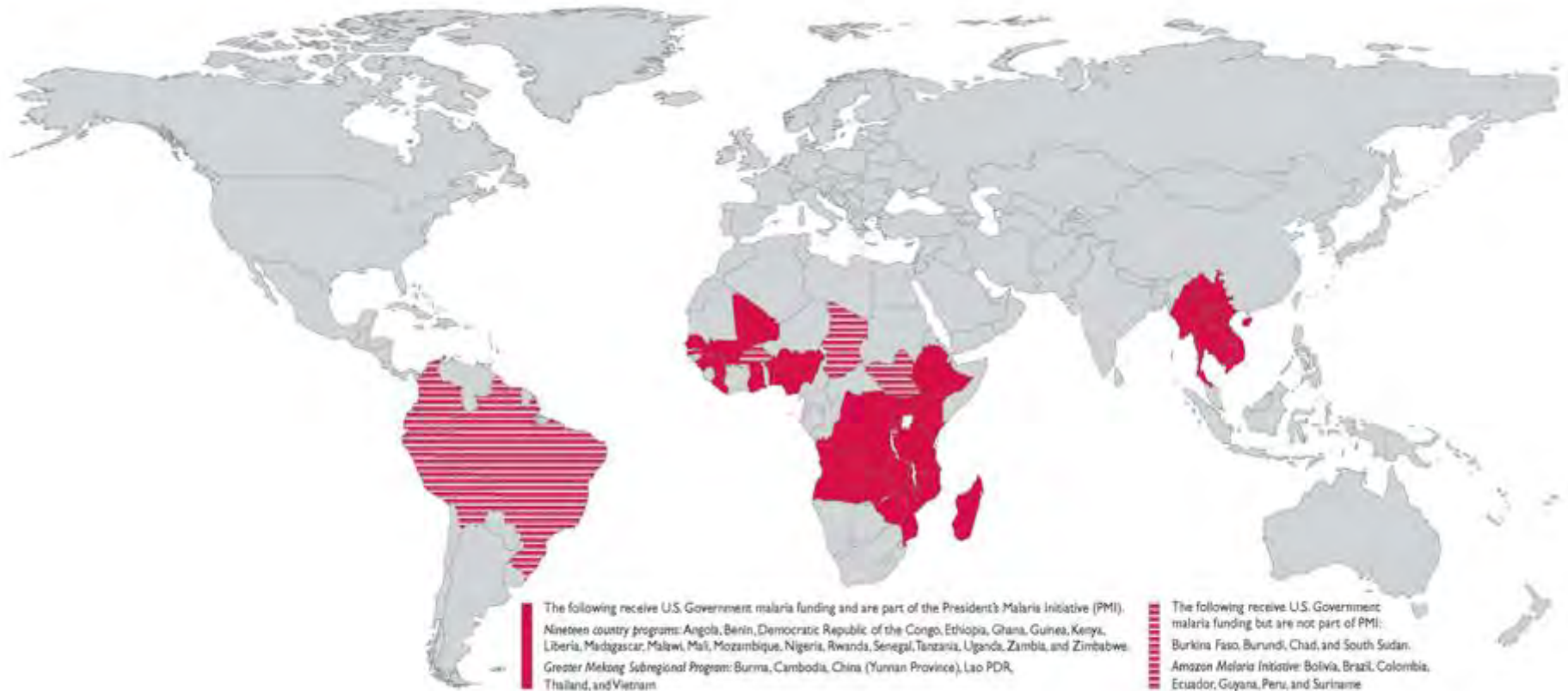
Time	Title and Objectives	Lead)
08.30 - 09.00	Registration and coffee	Marika Plasson
09.00 - 09.15	Welcome, objectives and agenda	Chris Game
09.15 - 09.45	Introductions	Steve Hornsby (facilitate)
09.45 - 10.15	Introduction to the Global Fund and to Procurement 4 impact (P4i) Initial Q&A	Chris Game
10.15 - 10.45	<i>Morning break</i>	
10.45 - 11:05	Actions to Fight Malaria and IRS context	Dr Jan Kolaczinski
11:05 – 11:30	Global Fund Quality Assurance and testing / inspection requirements	Dr Joelle Daviaud / Dr Olivier Pigeon
11:30 - 11:45	Current position – suppliers, history, forecasts	Steve Hornsby
11:45 - 12:00	Global Fund funding model and organisational structures and roles	Sophie Logez
12:00 - 12:15	Q&A Panel	Jan/ Joelle/ Sophie/ Chris
12:15 - 13:15	<i>Lunch</i>	
13:15 - 14:30	Widening the discussion - presentations from partners - PMI, WHO, UNDP, IVCC, RBM Plus Q&A Panel	Kristen George (PMI) Dr Emmanuel Temu (WHO) Guy Rino Meyers (UNDP) Dr Tom McLean (IVCC) Dr Jan Van Erps (RBM)
14:30 - 15:00	Current performance (delivery/quality) – PPM orders, procurement process, case studies	Stephanie Xueref / Judy Macleod, / Erin Seidner
15:00 - 15:30	Current performance (delivery/quality) – other/ overall	Dr Joelle Daviaud / Dardane Arifaj-Blumi
15:30 - 15:45	<i>Afternoon break</i>	
15:45 - 17:15	Root cause analysis / priority actions – group and presentations	Steve Hornsby (facilitate)
17.15 - 17.30	Re-cap on the day and next steps - tomorrow and Q3/Q4.	Aziz Jafarov

President's Malaria Initiative Indoor Residual Spraying Program



Kristen George, Malaria Technical Advisor
PMI/USAID
April 15, 2014

PMI Program Worldwide



History of PMI Support to IRS

- IRS was included as one of the core elements of PMI's strategy from the start of the Initiative
- PMI helped to re-introduce IRS as an effective tool in SS Africa for malaria control
- PMI provides a comprehensive package of support for IRS



FY 2013 Results

>5.6 Million Houses

sprayed in 15 countries

>22 Million Residents

protected by IRS

>29,000 Personnel Trained

as spray operators, team leaders, or supervisors

High Coverage

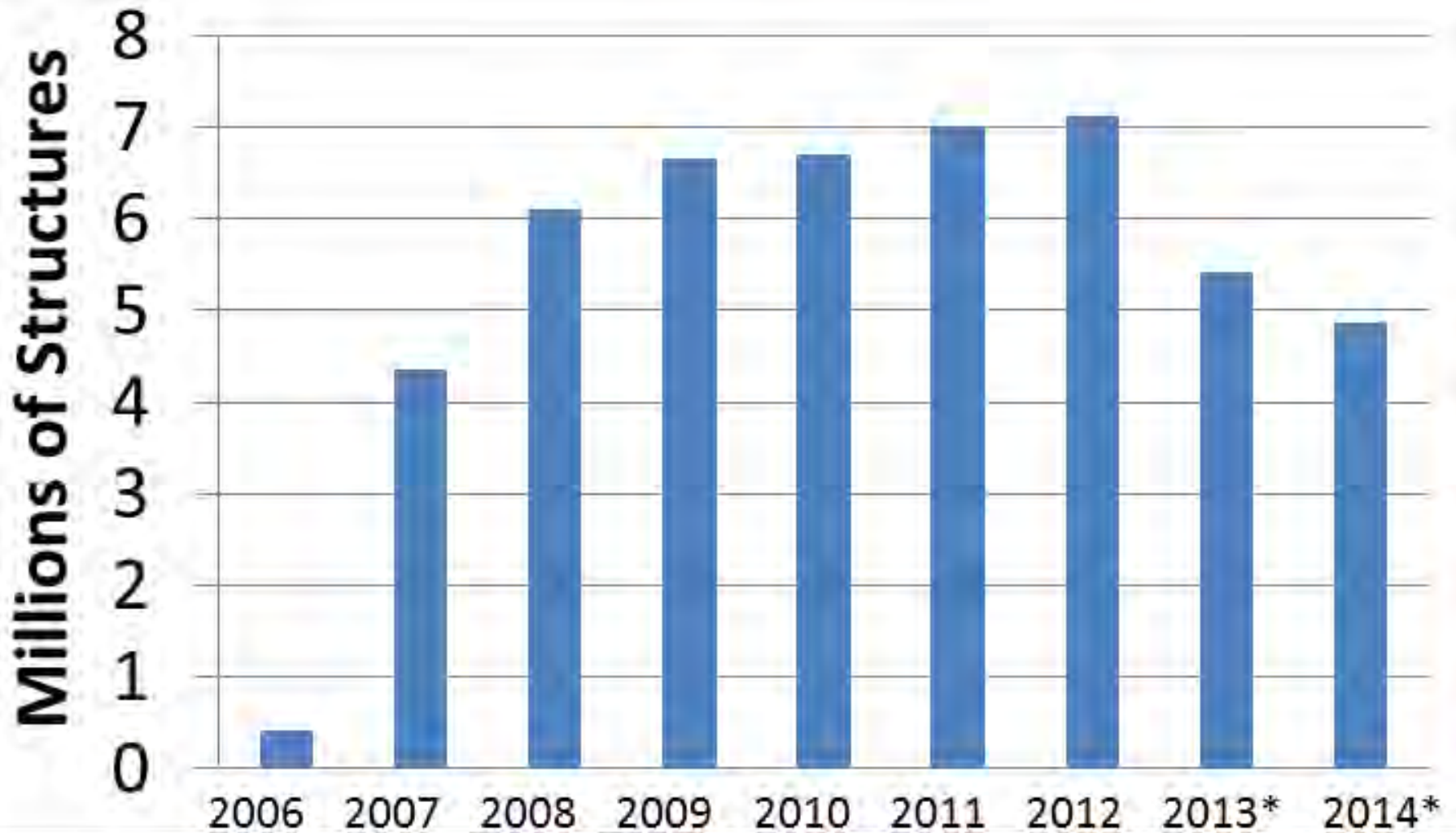
Average of 95% coverage across all countries

FY 2014 Program Focus



Proposed total IRS budget:
\$89.7 million

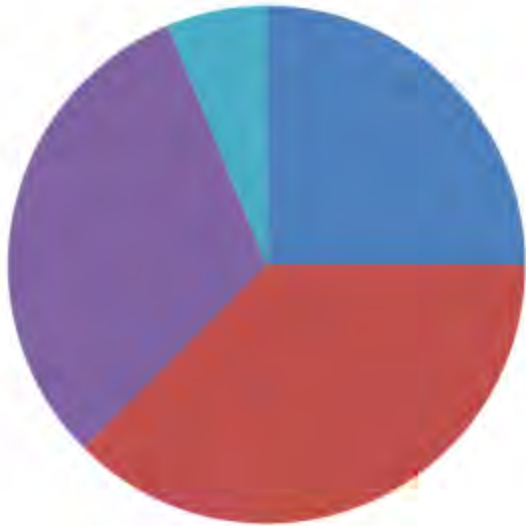
Adjusting IRS Results to Settings - 2014



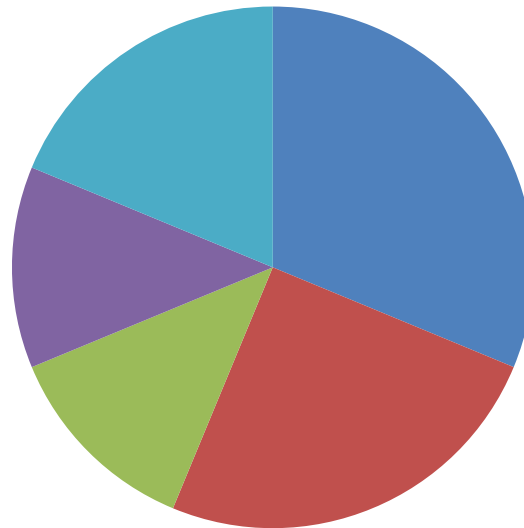
* Indicates projected targets

Insecticide Evolution

2012



2013



2014



- carbamate
- pyrethroid
- organophosphate
- Mix with pyrethroids
- Mix of non-pyrethroids

Insecticide Resistance: Ghana

Example

- Used pyrethroids from 2008 – 2011 as program scaled-up from 5 to 9 districts
- Emerging insecticide resistance and the transmission season necessitated a switch to a long lasting organophosphate
- Higher cost of the organophosphate forced a reduction in program size from 9 to 4 districts
- Preliminary study results comparing pyrethroid & organophosphate spray rounds show 56% reduction in parasitemia

PMI's Insecticide Procurement Process & Policies

- WHOPEES approval required
- Based on annual ento data, among other factors
- Country-led decision
- Procurement by insecticide class, RFQ to all known vendors
- Competitive process
- QA/QC pre-shipment testing

Updated: 25 October 2013

WHO recommended insecticides for indoor residual spraying against malaria vectors

Insecticide compounds and formulations ¹	Class group ²	Dosage (g a.i./m ²)	Mode of action	Duration of effective action (months)
DDT WP	DC	1-2	contact	>6
Malathion WP	OP	2	contact	2-3
Fenitrothion WP	OP	2	contact & airborne	3-6
Pirimiphos-methyl WP & EC	OP	1-2	contact & airborne	2-3
Pirimiphos-methyl CS	OP	1	contact & airborne	4-6
Bendiocarb WP	C	0.1-0.4	contact & airborne	2-6
Propoxur WP	C	1-2	contact & airborne	3-6
Alpha-cypermethrin WP & SC	PY	0.02-0.03	contact	4-6
Bifenthrin WP	PY	0.025-0.05	contact	3-6
Cyfluthrin WP	PY	0.02-0.05	contact	3-6
Deltamethrin SC-PE	PY	0.02-0.025	contact	6
Deltamethrin WP, WG	PY	0.02-0.025	contact	3-6
Etofenprox WP	PY	0.1-0.3	contact	3-6
Lambda-cyhalothrin WP, CS	PY	0.02-0.03	contact	3-6

Relevant Issues

- Long lead times
- Manufacturers desire to have multi-year commitments
- High cost of newer compounds resulting in program size reduction
- Current environment isn't conducive to development of new insecticides

Looking Ahead

- **Concentrate IRS focus on:** Data driven decisions - IRS targets, insecticide choice, other vector control interventions
- Support new product development
- Commitment to improving WHOPEs process



Thank you!



A high-contrast, black and white profile of a person's face, looking to the right. The lighting is dramatic, highlighting the contours of the nose, lips, and chin against a dark background.

vector
saving lives
control

Tom McLean

INNOVATION AND ACCESS

GFATM
INDOOR RESIDUAL SPRAY
CONSULTATION

Geneva April 2014



IVCC
COMBATING INSECT
BORNE DISEASE

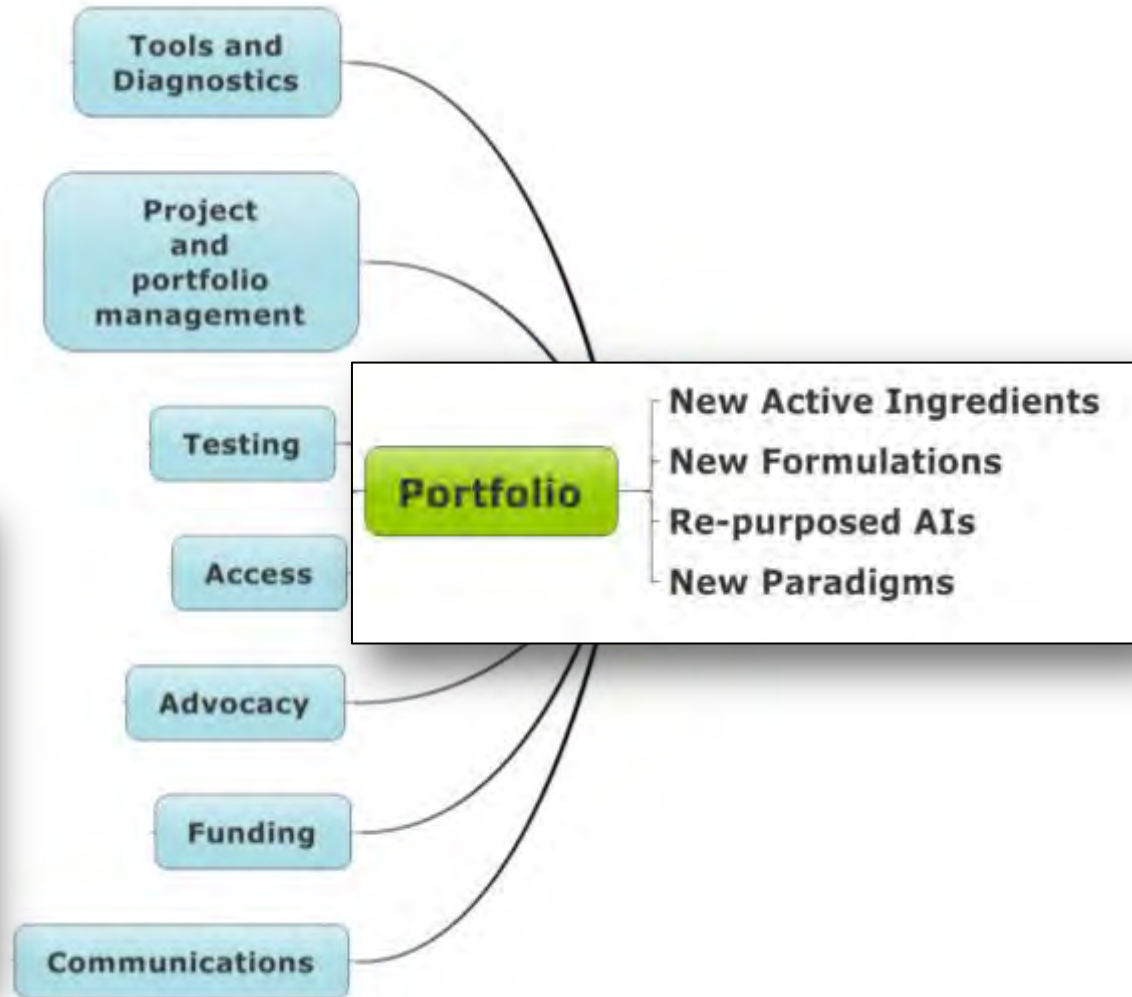
Innovative Vector Control Consortium

IVCC Formed in 2005 to Meet the Challenge of Innovation in Vector Control

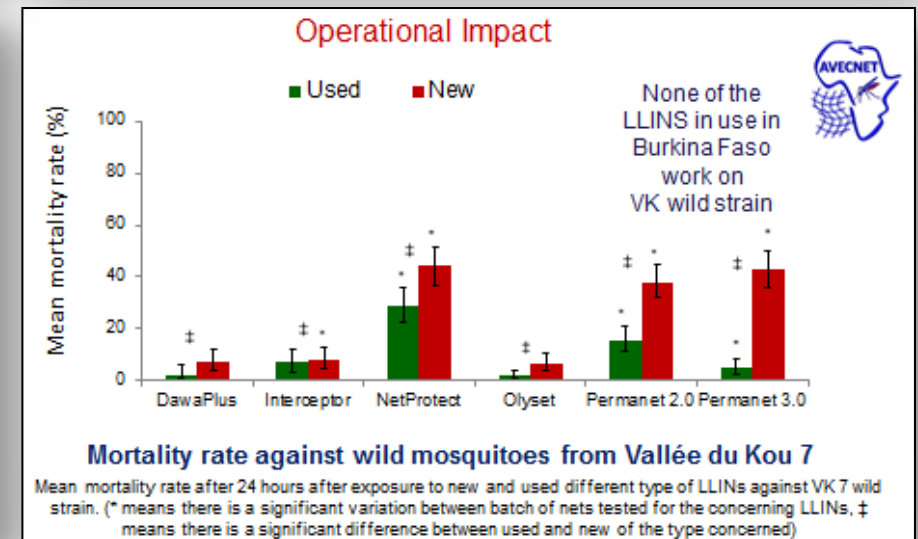
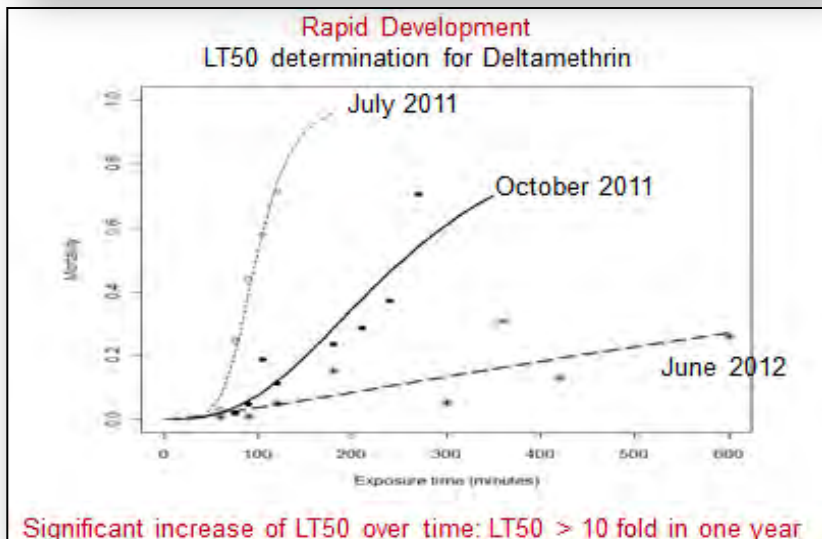
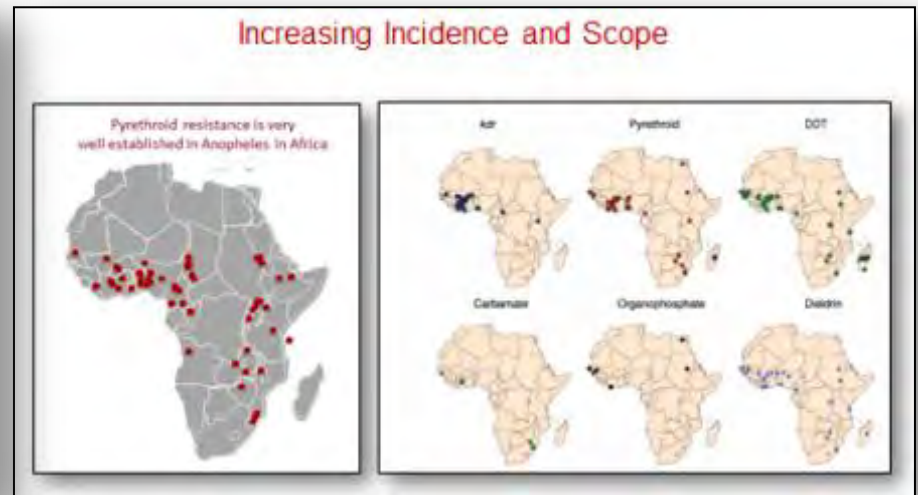
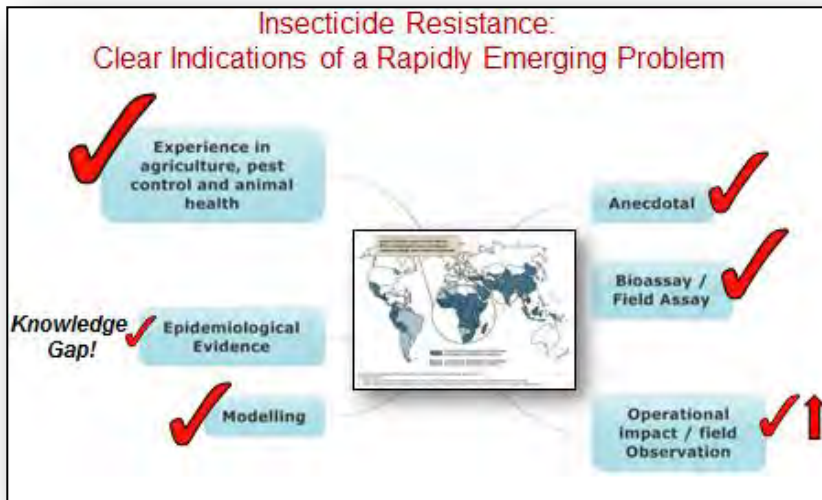


IVCC is a Product Development Partnership investing donor funds in R&D to overcome barriers to innovation in vector control

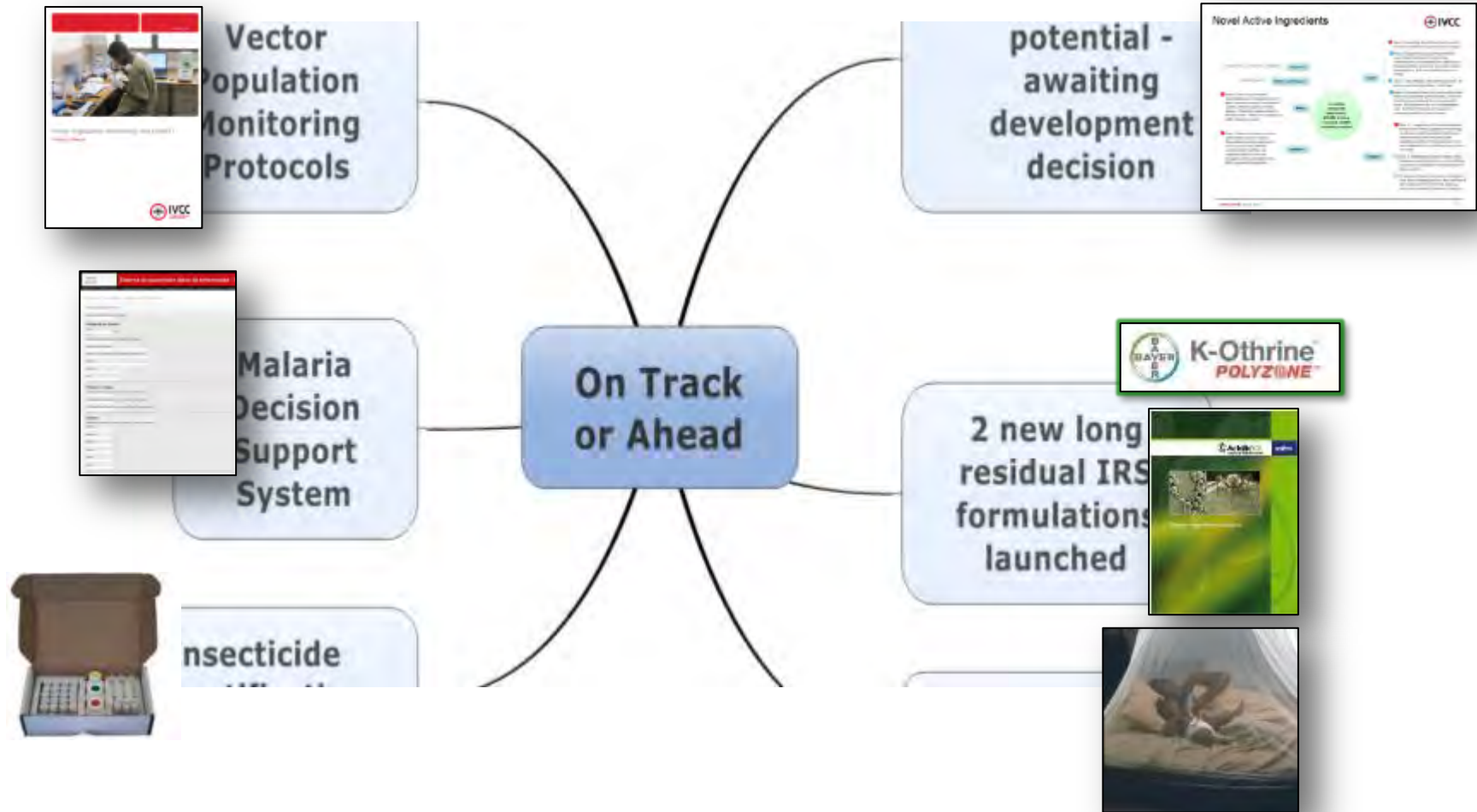
Not for Profit Company and Charity



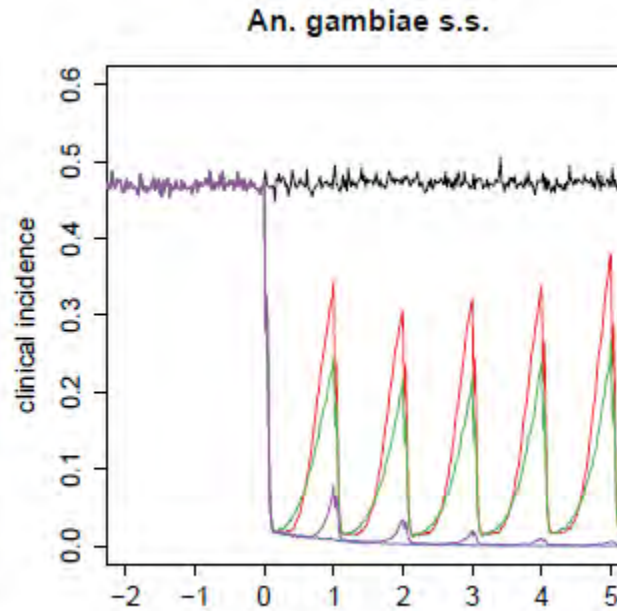
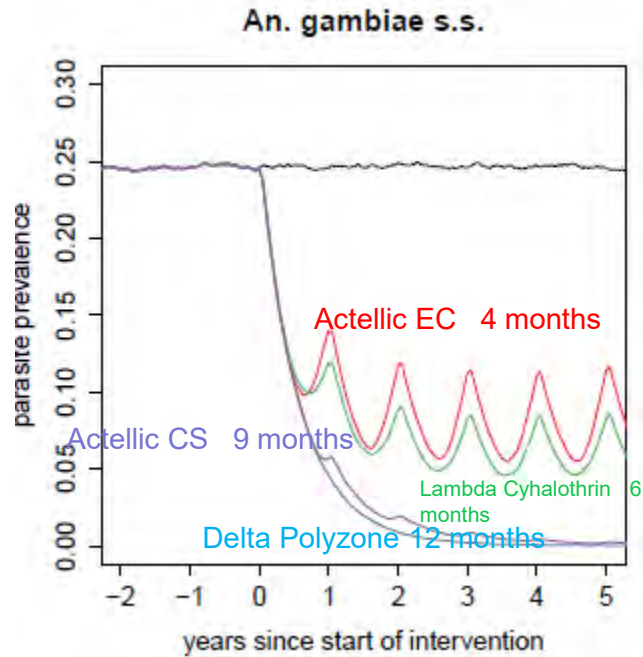
Insecticide Resistance at The Tipping Point



Portfolio of Products



Modelling short and long lived IRS



12 month season
No resistance
Equal Repellency
Realistic lifetime curves
from IVCC data.

Bioko Island data on resurgence of prevalence with short lived insecticide (Bendiocarb)

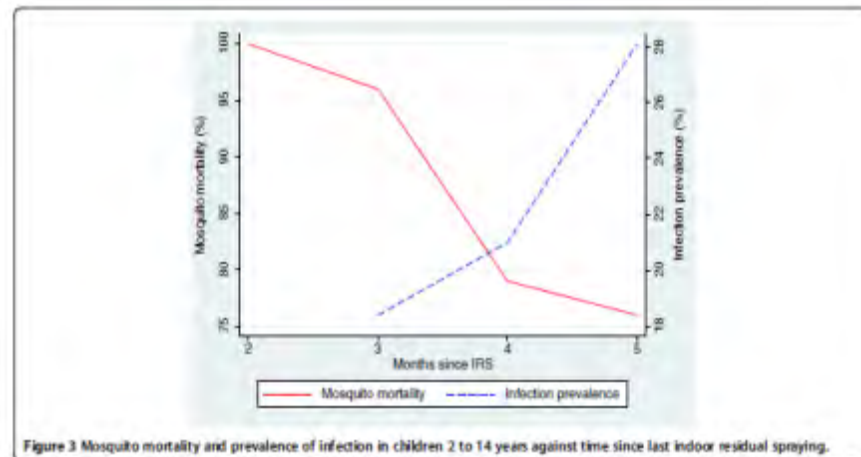
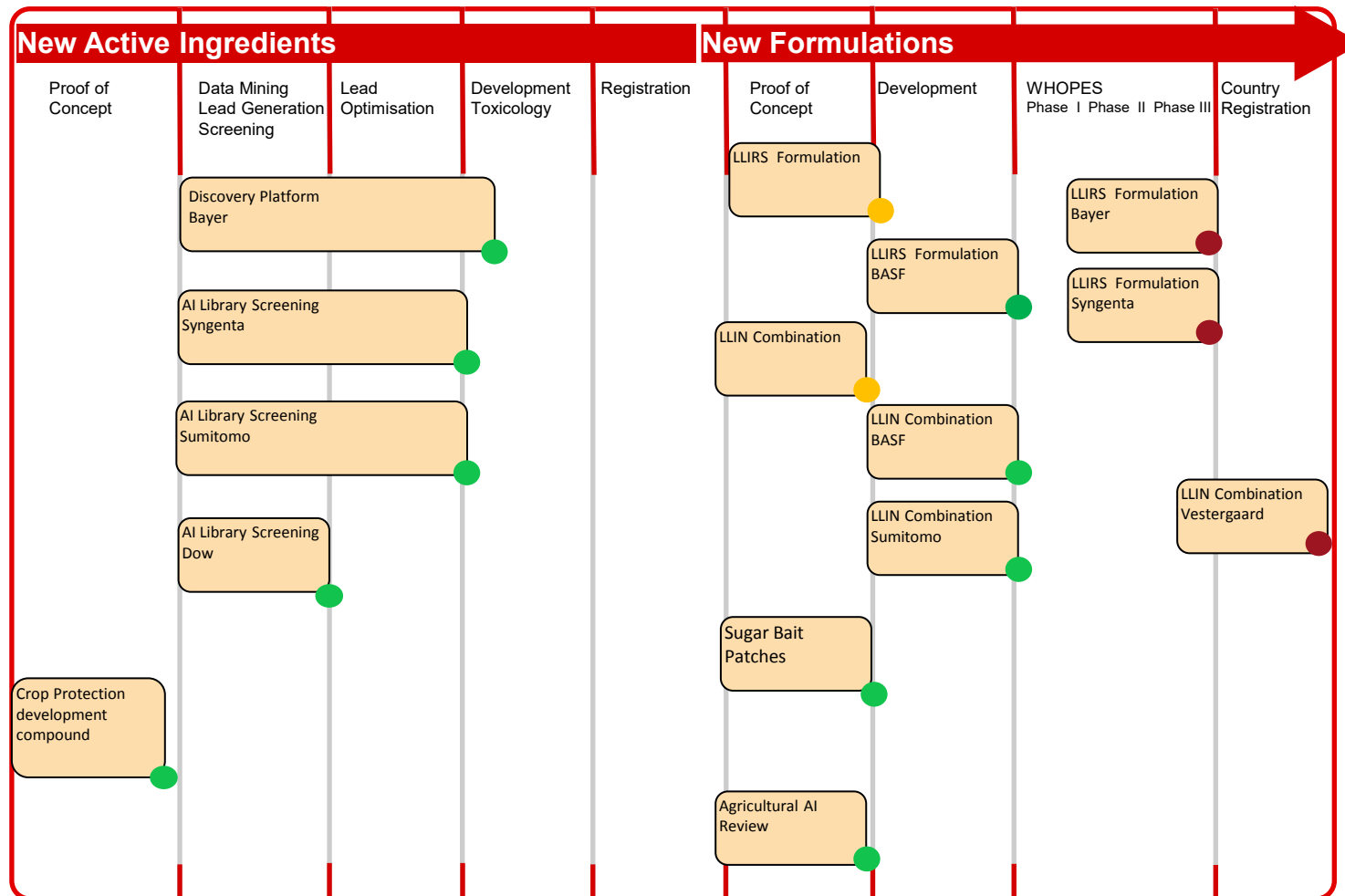


Figure 3 Mosquito mortality and prevalence of infection in children 2 to 14 years against time since last indoor residual spraying.

IVCC Public Health Insecticides Portfolio:

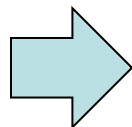
March 2014



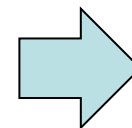
IVCC Funding



2005- 2012



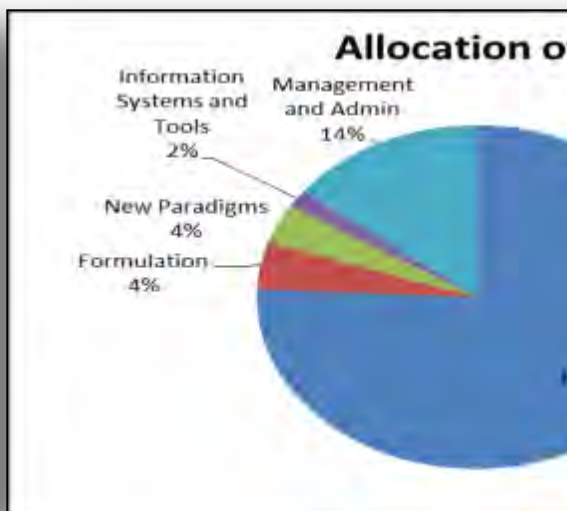
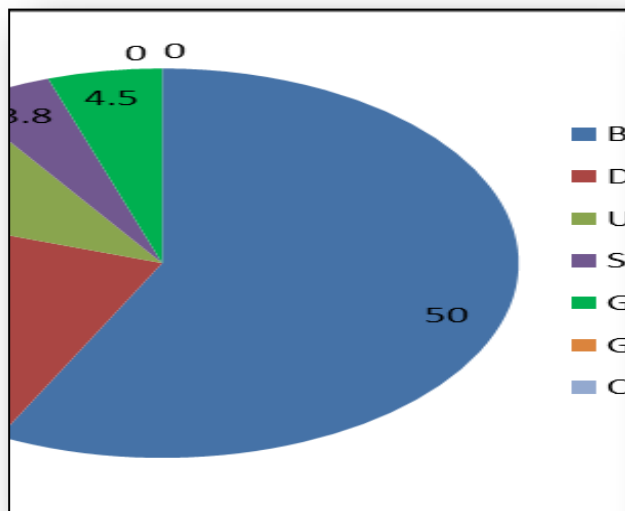
2013



2014



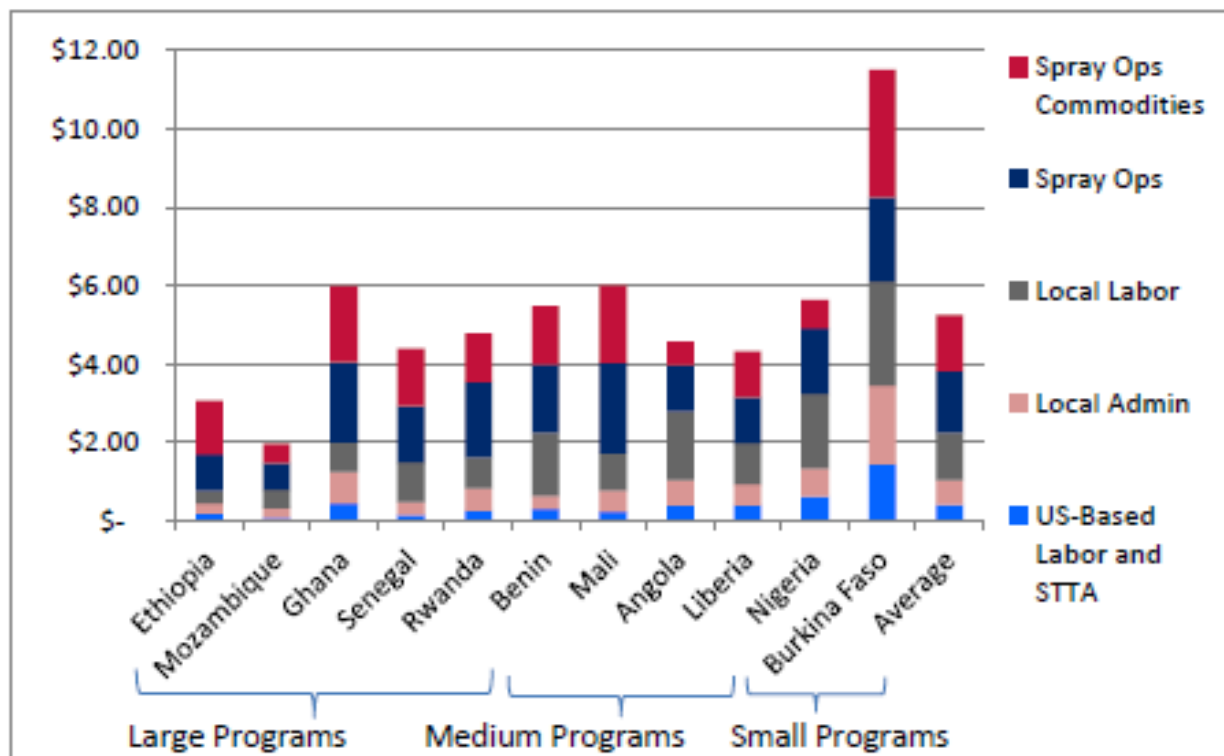
Global Health Innovative Technology Fund



IRS Application Costs are a substantial part.



FIGURE CC4: IRS COUNTRY UNIT COSTS PER PERSON PROTECTED, BY COST CATEGORY



Data from PMI / Abt AIRS costs report.

IQK™ “Insecticide Quantification Kits”



Five facts about IQK™

- **Innovative** QA technologies for IRS
- **Rapid** results
- **Low cost**
- **Easy** to use
- **Proven** in the field



Fully packaged kit, includes everything needed to carry out 20 tests

Simple and robust for reliability in the field

Reagents and dispensers are **colour coded** for clarity and accuracy

Packaging acts as a rack so **holds components securely** during testing

Clearly labelled to show target insecticide, including class and formulation



So What Do We Need ?



- **A market place that values Prevention and Innovation.**
- **Capacity on the ground for insecticide resistance management.**
- **Product Innovation and competition from manufacturers.**
- **Processes to bring products quickly to registration and use.**
- **Policy and Guidelines for effective interventions**

A high-contrast, black and white profile of a woman's face, looking to the right. The lighting highlights her features against a dark background.

vector control
saving lives

Thank you



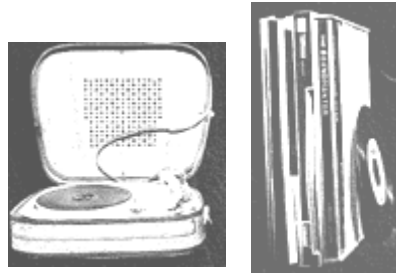
IVCC
COMBATING INSECT
BORNE DISEASE

Market Rupture Needed Pascal Day Bayer 2006



1956

Music:
Vinyl Disc



Telephone:
Wire Phone



Television:
Cathode Ray Tube



2006

Music:
CD and MP3



Telephone:
Mobile+Camera+



Television:
Plasma/LCD HD



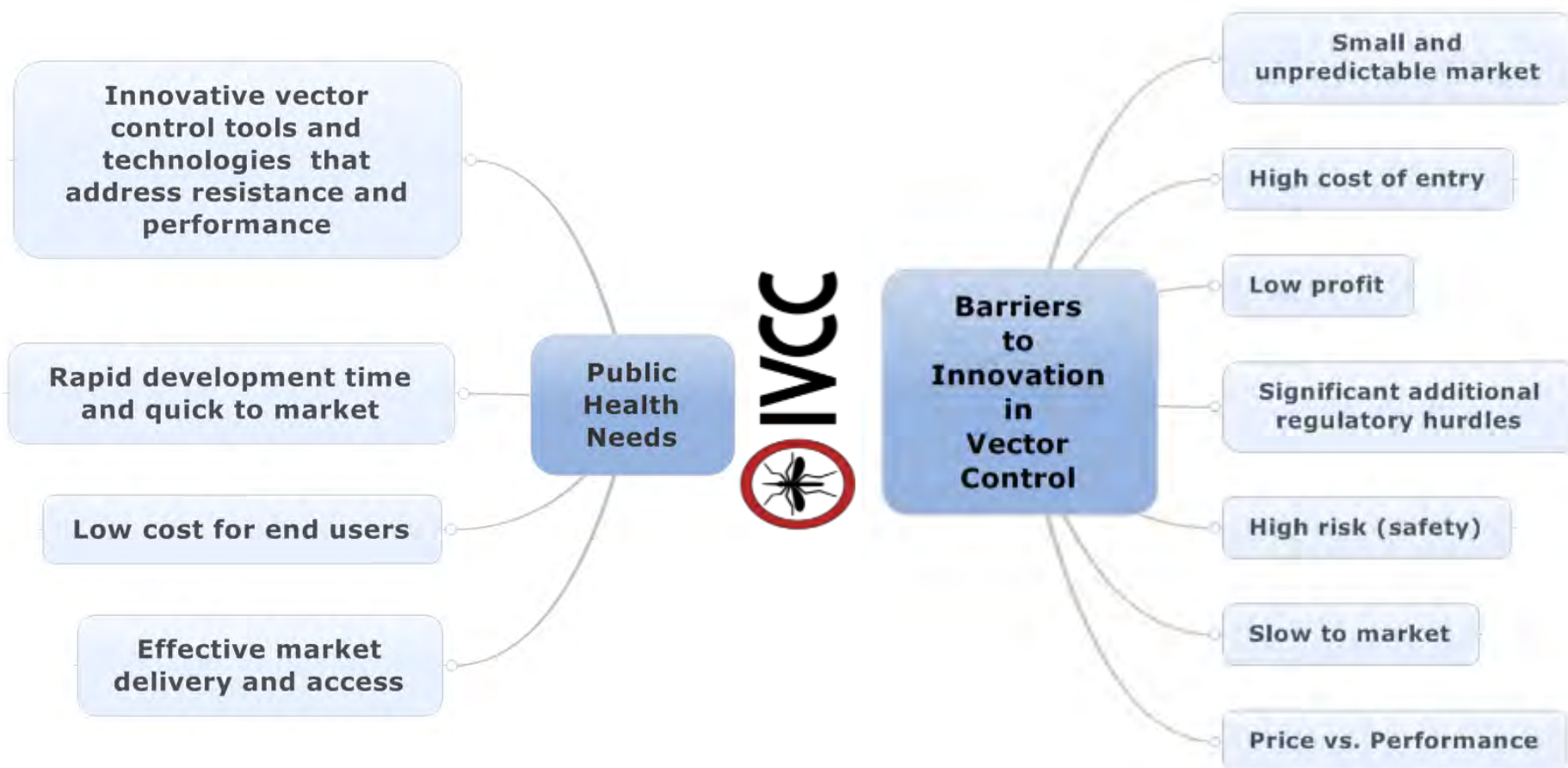
IRS:
Hudson Sprayer
WP formulation
2000 mg DDT/m²



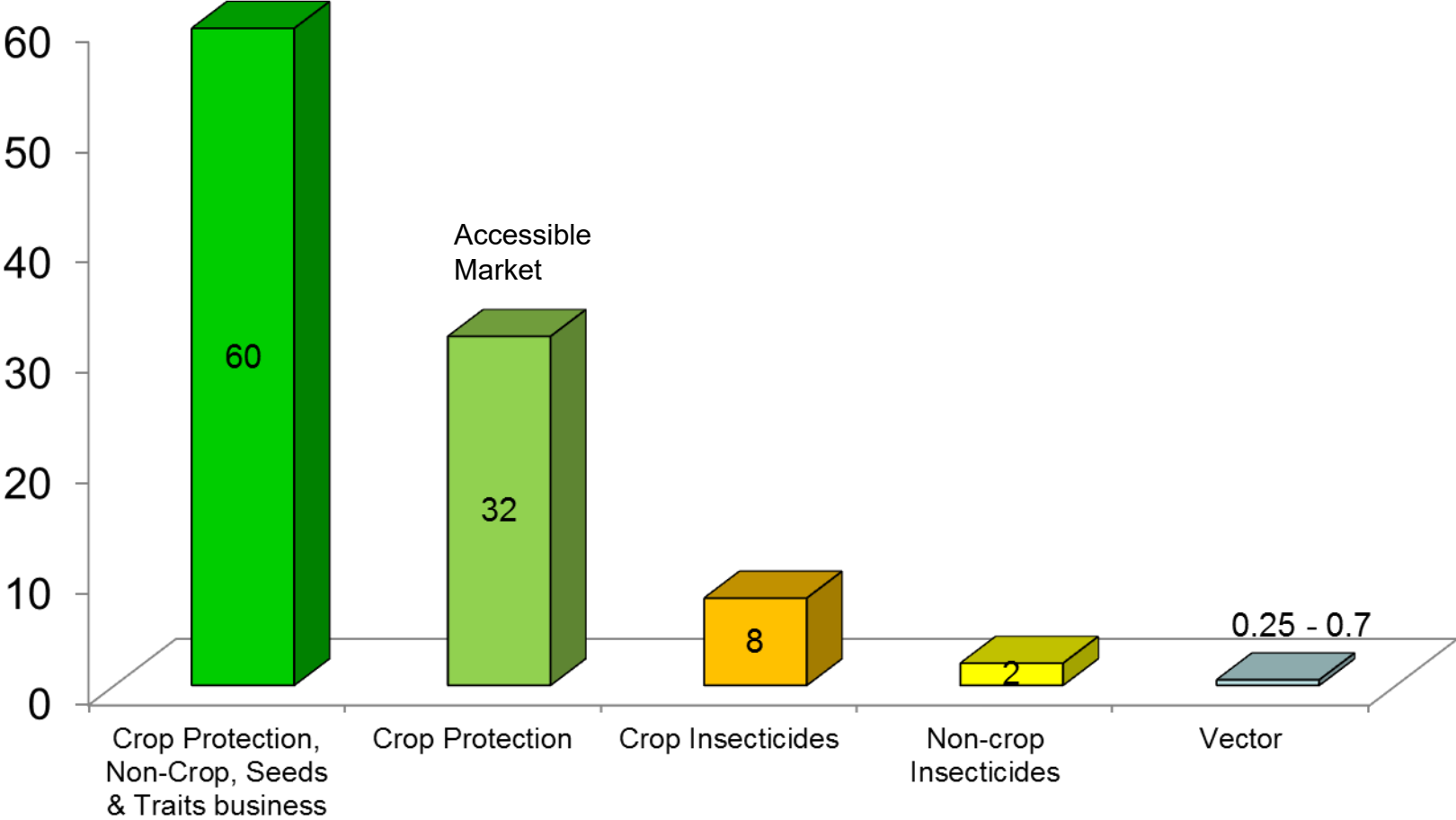
IRS:
Hudson Sprayer
WP formulation
2000 mg DDT/m²



Why IVCC Exists



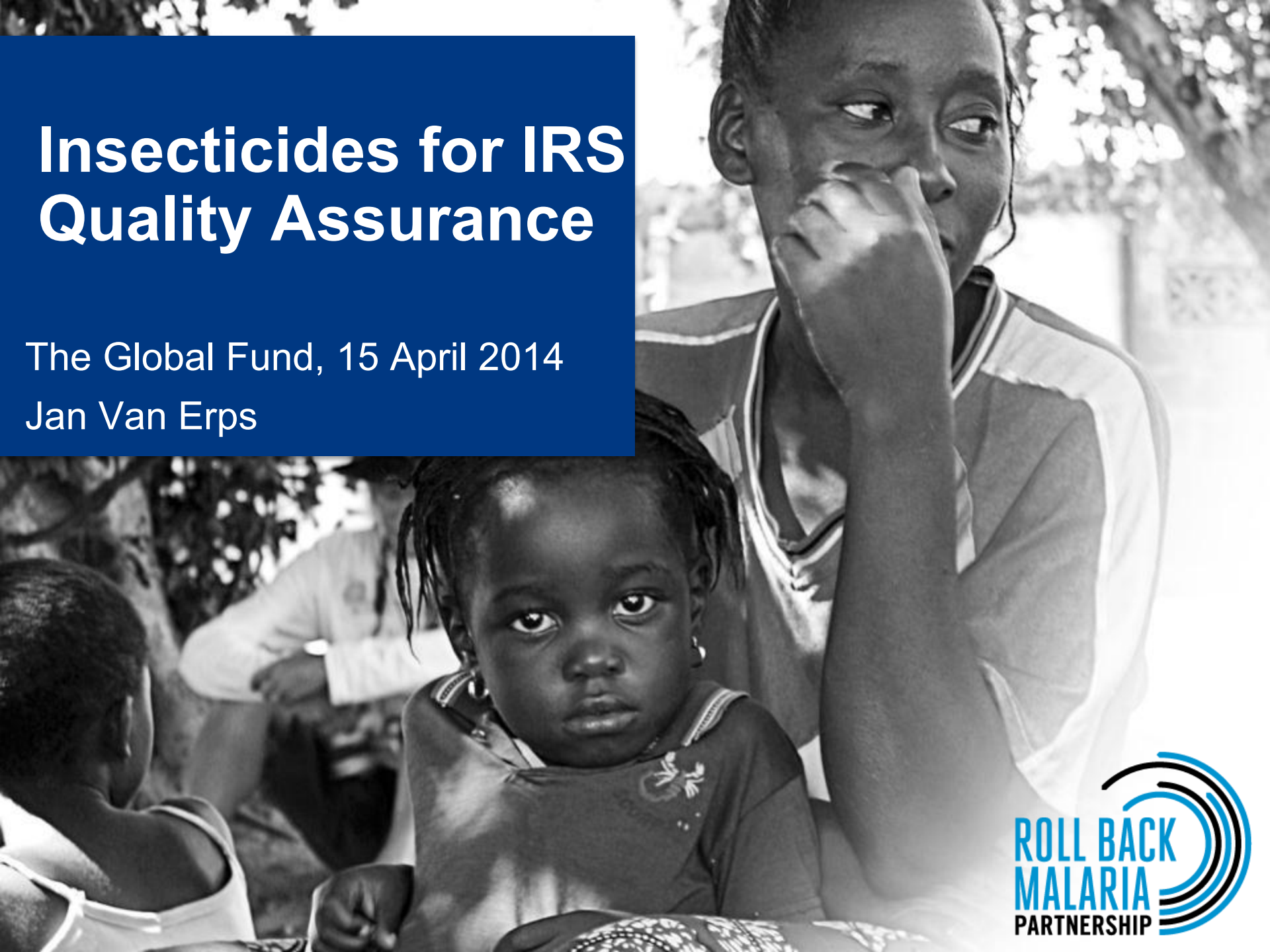
Estimated Global Agrochemical Market (\$bn)



Insecticides for IRS Quality Assurance

The Global Fund, 15 April 2014

Jan Van Erps



8 / 9

UNDP experience 2010-2011

8 out of 9 purchase orders had failing batches

WHOPES laboratory Gembloux, Belgium

All are manufacturers of products with WHO recommendations and specifications

8 POs for 440 tonnes worth 5 million USD

Several tests

Appearance

Content

pH (hydrolysis)

Wet sieving test (nozzles)

Suspensibility (equal spraying)

Persistent foam (rincing, cleaning, spilling over)

Pourability

Prolonged storage stability test (soluble bags)

Testing modalities

PRE-SHIPMENT (WHOPES and GLOBAL FUND)

Post-shipment

1 batch with persistent foam failure pre-shipment had content totally decomposed post-shipment

2 batches OK pre-ship had failing soluble bags post-ship

Testing and sampling to be done by an independent agent

Supplier declared failure but did not share results

Average testing time 9 days – 3,5 weeks (10-14w PSST)

How did other buyers do?

UNICEF:

tender for QC reference lab : no problems !

RTI :

62 orders 2006 – 2011 :

CDC approved lab in Nairobi : no problems !

Countries:

countries with local QC labs: no problems !

Why? "UNDP newcomer"? Are all tests performed?

Questions

Why also originators?

Deterring competition?

Pressure on quality due to pressure on lead times and price?

**Equilibrium : Quality – Lead Time – Price
out of balance?**

Conclusions

Pre-shipment and independent sampling!

Is the bar of the WHO specs too high?

If not why failures against full testing?

Striking the balance between:

Quality – Lead Time – Price

Thank you !





IRS Procurement

PSM Group of GF Partnership Team
UNDP, Geneva

15 April 2014

IRS meeting Geneva



Which Insecticides

1. **Pyrethroids: Deltamethrin, Alpha-Cypermethrin, Lambda-Cyhalothrin**
2. **DDT**
3. **Bendiocarb**



Which countries?

1. **Zimbabwe**
2. **Tajikistan**
3. **Kyrgystan ***
4. **Soa Tome and Principe ***
5. **Sudan**
6. **Iran**

Process and principles

- **Only WHO PEST approved suppliers and products**
- **Open competitive process**
- **Process starts minimum 9 months before planned spraying**
- **Registration is a standard requirement where applicable**
- **All batches are tested for the first two years of supply**
- **Testing is done pre-shipment**

Process and principles

- **Suppliers are informed of the pre-shipment tests**
- **Testing will be done on the specifications and standards provided by the supplier**
- **COA is a standard requirement**
- **All QC tests done in Gembloux Laboratory WHO partner**
- **Results of the tests are shared with national authorities**
- **Waste management guidelines need to be provided. (for DDT including disposal of residual volumes and packaging)**

What were the issues

- **Few WHOPEES approved suppliers**
- **The different formulations are not always available (batch size, risk of non compliance)**
- **QC testing takes a long time. (best QC lab only QC lab)**
- **Non compliance with at least one of the requirements**
- **All suppliers indicated that their non compliance was not relevant.**
- **When can a product still be used if it is non compliant?**

What were the issues

- **But most agreed to replace batches some desisted to further supply**
- **100 % compliance was reached after second or third replacement**
- **Pressure from programs to not miss spraying season**
- **No time for stability testing so only quantities for use within 9 months after arrival**
- **Need for better waste management tools and environmental friendly products and packaging**

What were the issues

wet sieving, suspensibility, content, content after storage stability tests. closure and dissolution rate of soluble bag, persistent foam, release of Lambda-Cyhalothrin, sealing of bags

Discussion

- **When can a product still be used if it is non compliant 100 % compliance was reached after second or third replacement**
- **Do we need more flexibility in specifications (lower the standards).**
- **How build more confidence in product and manufacturers**
- **Information about the impact on the environment**



Agenda

Time	Title and Objectives	Lead)
08.30 - 09.00	Registration and coffee	Marika Plasson
09.00 - 09.15	Welcome, objectives and agenda	Chris Game
09.15 - 09.45	Introductions	Steve Hornsby (facilitate)
09.45 - 10.15	Introduction to the Global Fund and to Procurement 4 impact (P4i) Initial Q&A	Chris Game
10.15 - 10.45	<i>Morning break</i>	
10.45 - 11:05	Actions to Fight Malaria and IRS context	Dr Jan Kolaczinski
11:05 – 11:30	Global Fund Quality Assurance and testing / inspection requirements	Dr Joelle Daviaud / Dr Olivier Pigeon
11:30 - 11:45	Current position – suppliers, history, forecasts	Steve Hornsby
11:45 - 12:00	Global Fund funding model and organisational structures and roles	Sophie Logez
12:00 - 12:15	Q&A Panel	Jan/ Joelle/ Sophie/ Chris
12:15 - 13:15	<i>Lunch</i>	
13:15 - 14:30	Widening the discussion - presentations from partners - PMI, WHO, UNDP, IVCC, RBM Plus Q&A Panel	Kristen George (PMI) Dr Emmanuel Temu (WHO) Guy Rino Meyers (UNDP) Dr Tom McLean (IVCC) Dr Jan Van Erps (RBM)
14:30 - 15:00	Current performance (delivery/quality) – PPM orders, procurement process, case studies	Stephanie Xueref / Judy Macleod, / Erin Seidner
15:00 - 15:30	Current performance (delivery/quality) – other/ overall	Dr Joelle Daviaud / Dardane Arifaj-Blumi
15:30 - 15:45	<i>Afternoon break</i>	
15:45 - 17:15	Root cause analysis / priority actions – group and presentations	Steve Hornsby (facilitate)
17.15 - 17.30	Re-cap on the day and next steps - tomorrow and Q3/Q4.	Aziz Jafarov

Procurement of IRS under PPM PFSCM's experience

April 15th, 2014

Partnership For Supply Chain Management and PPM

- **PFSCM a consortium of 13 private sector, nongovernmental and FBOs**
- **2 main projects**
 - ❑ Supply Chain Management System (SCMS) funded by PEPFAR since 2005
 - ❑ Pooled Procurement Mechanism (VPP) funded by the Global Fund since 2009
- **Under PPM**
 - ❑ PFSCM has to date provided procurement service to 60 countries
 - ❑ PFSCM supplies medicines and health products in support of two diseases
 - ✓ HIV/AIDS: ARVs, HRDTs
 - ✓ Malaria: ACTs, ANTM, MRDTs, IRS
- **PFSCM team working on PPM**
 - Service scope: procurement, transport, custom clearance, delivery to CMS
 - 40 people spread across the US, NL, UK and Switzerland with 3 key functions (Client relations, Operations, Freight and Logistics)
 - Direct relationship and communication with Principal Recipients
 - Daily coordination with GF secretariat (Sourcing teams, Regional teams)

PPM IRS orders at a glance

- ❖ **13 inquiries spread over 2 years**

- ❖ **6 countries**

Pakistan, Mozambique, Cape Verde, Timor Leste, Yemen, Gambia

- ❖ **Short procurement turnaround**

- ~ 20 weeks in average from requested delivery date
- ranging from 4 weeks and up to 36 weeks

- ❖ **4 different products from the WHO approved IRS list**

- Deltamethrin WG 25% and WP 5%
- Bendiocarb WP 125g and 62.5g
- DDT WP 670g and 75%
- Lambda Cyhalothrin 10 CS

Quality challenges of IRS products procured under PPM

- ❖ **Batch testing at WHO pre-qualified laboratory systematically carried out**
- ❖ **Independent sampling (RFP for inspection and sampling service - April 2014)**
- ❖ **PPM QC test failure > 55% (5 out 9 orders for which products have been tested)**
- ❖ **Quality failures**
 - Suspensibility - 3
 - Bag dissolution - 2
 - Active ingredient – 1
 - Persistent foam - 1
 - Wet sieve test - 1
 - Impurity – 1
- ❖ **Timeline for replacement: 7 to 12 weeks**
- ❖ **Impacts:**
 - **Programmatic**- spraying period missed
 - **Financial** - product replacement/destruction, ocean or road transport changed to air, level of efforts
 - **Reputational** – weaken trust in the reliability of suppliers and quality/safety of IRS

PFSCM procurement and evaluation process for PPM/IRS

Principal Recipient's request

- Receive enquiry and check for completeness – product identification/quantity
- Confirm it is a WHO recommended insecticide for IRS against malaria vectors
- Seek clarifications from the Principal Recipient if required

Open and competitive tender

- Issue RFQ to all eligible manufacturers / WHOPEs (1-2 wks response time)
- Evaluation of offers – price & technical factors (registration, lead time)

Offer to Principal Recipient

- Preparation of the Price Quotation & submission to Principal Recipient for approval
- Receive PR's approval and GF confirmation of funds' availability

Order placement

- Place Purchase order with the manufacturer

IRS Quality control carried out at WHO PQ lab

Analytical Methods

Common test carried on all IRSs

- **Appearance**
- **Content**
- **Wet Sieve test**
- **Suspensibility**
- **Persistent Foam**
- **Wettability (without swirling)**

Tests specific to certain IRSs

- **Acidity/Alkalinity**
- **Degree of Dispersion**
- **pH of a 1% suspension in water**
- **Dustiness**
- **Dissolution rate of water soluble bag**

Case study 1: Mozambique - Insecticide – WP – Water Soluble Sachets

❑ 1st Consignment :

- x6 batches procured
- Test Result:
 - x3 batches failed due to non-compliance with the following:
 - Wettability (x1 batch)
 - Dissolution rate of the water soluble bag (x2 batches)

❑ 2nd Consignment :

- x20 batches procured + 3 replacement batches
- Test Result:
 - x23 batches failed due to non-compliance with one or more of the following:
 - Wet sieve test (x23 batches)
 - Suspensibility (x23 batches)
 - Dissolution rate of the water soluble bag (x23 batches)

Case study 1: Mozambique - Insecticide – WP – Water Soluble Sachets

➤ **Resolution:**

- Re-testing arranged by manufacturer at 3 laboratories including WHO PQ Lab
- Results indicated that the samples were non-homogeneous and did not pass key parameters
- Manufacturer's Quality and Production teams undertook an investigation into the origins of that issue and developed a specific action plan. Same product has subsequently been supplied to another recipient country and the product passed all tests.

Case study 2: Pakistan - Insecticide – WG – Water Soluble Sachets

- **x54 batches procured**
- **Test Results:**
 - x37 batches: failed due to non-compliance with one or more of the following:
 - Active Ingredient content (x12 batches)
 - Persistent foam (x 30 batches)
 - Dissolution rate of the water soluble bag (x11 batches)
- **Resolution:**
 - The x8 batches which failed only on dissolution rate of the soluble bag were re-packaged into metallised sachets.
 - To decrease potential issues with the soluble bags, the other batches were replaced, packaged in metallised sachets and, following successful testing, dispatched as a second consignment to Pakistan.

Case Study 3: Cape Verde – Insecticide – WP – Metallised Sachets

- **x6 batches procured**

- **Test Result:**

x6 batches failed due to non-compliance on Suspensibility (i.e. 100% failure) strongly out of the limit of the WHO specification for suspensibility as per details below:

WHO Specification: Minimum 60%

Results (Mean of 2 Determinations): Batch 1: 31.1; Batch 2: 28.5; Batch 3: 25.1; Batch 4: 39.2; Batch 5: 29.1, Batch 6: 42.5

- **Resolution:**

- Results were clear and supplier proceeded with replacement

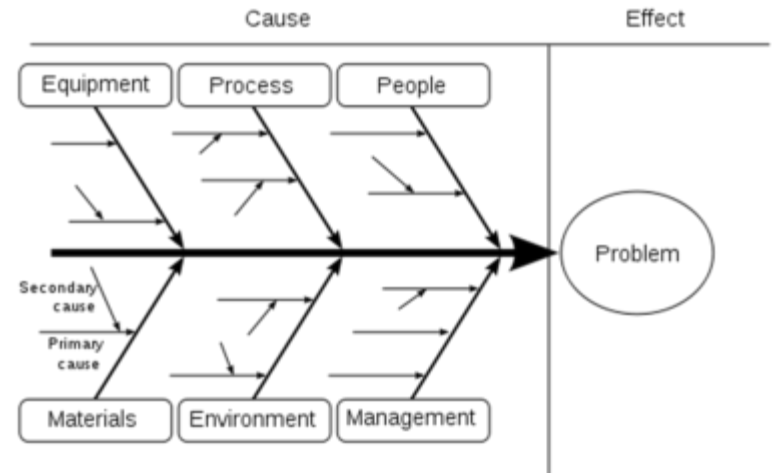
Root cause analysis / priority actions

Group and presentation

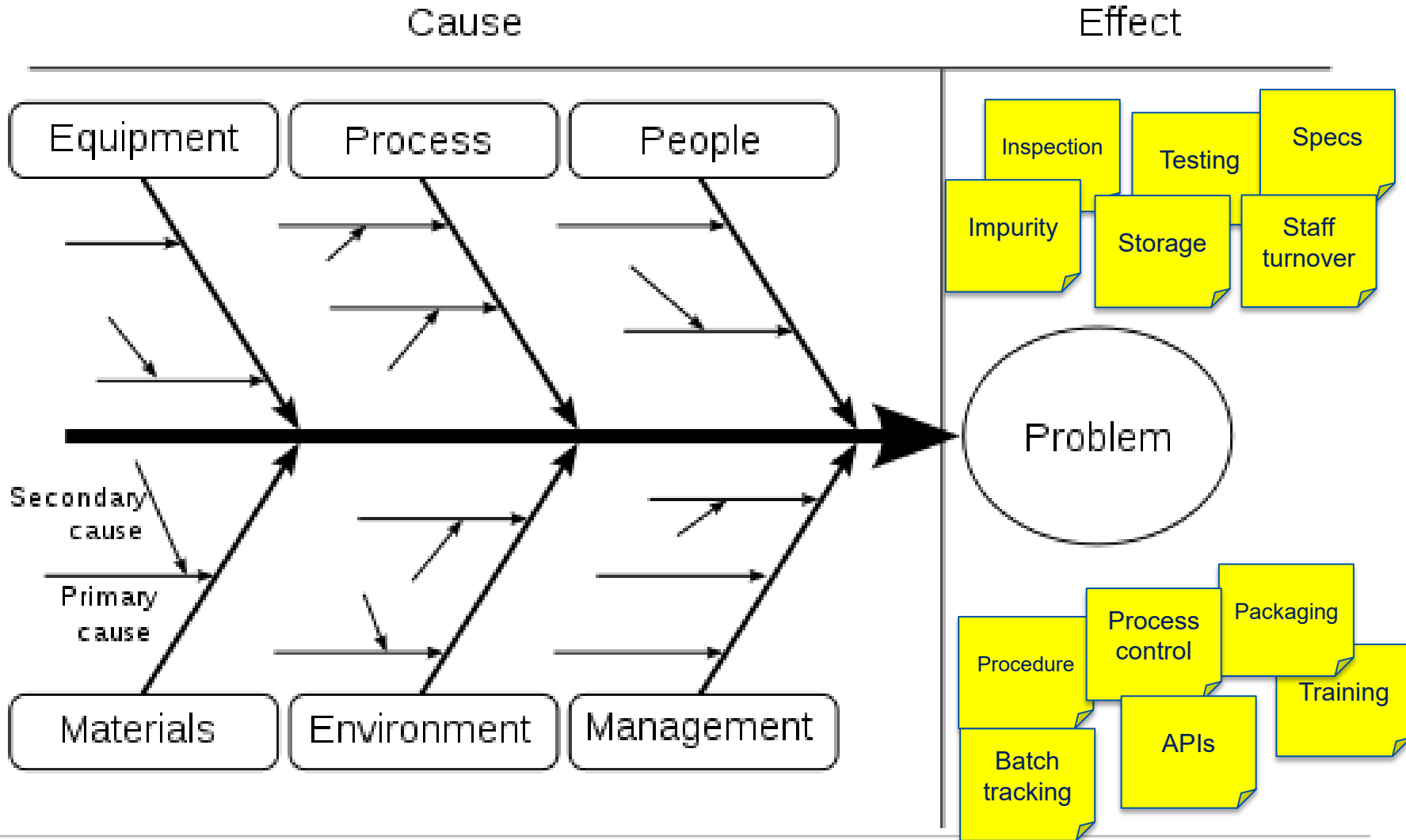


Your mission...

- Split into mixed groups on your tables and agree presenter (5)
- Root cause analysis (25)
 - Agree a problem statement (5)
 - Agree main cause groups (5)
 - Brainstorm potential primary and secondary causes (15)
- Prioritise actions (20)
 - Brainstorm potential actions to address causes (10)
 - Categorise based on effort and impact (10)
- Present back to wider group and respond to questions (4x10)



Root cause analysis



Prioritisation



Your mission...

- Split into mixed groups on your tables and agree presenter (5)
- Root cause analysis (25)
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