ACT/ RDTs

Collaboration in eradicating Malaria

10 July 2013

Christopher Game
Chief Procurement Officer
Introduction, Objectives and Agenda

Alan Court, Special Advisor, UN Special Envoy Office
# Today’s Agenda: am

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
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<tbody>
<tr>
<td>08.30-09.00</td>
<td><strong>Welcome coffee and registration</strong></td>
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<tr>
<td>09.00-09.30</td>
<td><strong>Introduction, objectives and agenda</strong></td>
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<td>- Alan Court, Special Advisor, UN Special Envoy Office</td>
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<td>09.30-09.45</td>
<td><strong>Welcoming remarks</strong></td>
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<td>- Christopher Game, Chief Procurement Officer</td>
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<td><strong>Keynote speech</strong></td>
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<td>- Dr. Mark Dybul, Executive Director</td>
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<td>09.45–10.15</td>
<td><strong>P4i: Procurement for Impact</strong></td>
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<td>Introduction to the Global Fund’s new approach to procurement</td>
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<td>- Christopher Game</td>
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<td>10.15–10.45</td>
<td><strong>Coffee break</strong></td>
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<td>10.45–12.30</td>
<td><strong>P4i and the new approach in the context of ACTs/RDTs and implications for suppliers</strong></td>
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<td>12.30–13.30</td>
<td><strong>Lunch</strong></td>
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<td>13.30-15.00</td>
<td><em>PMI : ACTs &amp; RDTs</em> - Sonali Korde, USAID Bureau for Global Health</td>
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<td><em>UNITAID : ACT Forecasting/ API activities / OR RDT Scale up</em></td>
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<td>- Alexandra Cameron, Technical Officer, Market Dynamics</td>
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<td>- John Cutler, Malaria Portfolio Manager</td>
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<td><em>FIND : RDT evaluation program</em> – Sandra Incardona, Project Manager</td>
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<td><em>RBM HWG : ACTs &amp; RDTs</em> – Melanie Renshaw, ALMA, Chief Technical Adviser</td>
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<td>Q&amp;A</td>
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<td>15.00-16.30</td>
<td><strong>The Supplier Perspective: Group Discussion and Plenary Presentation</strong></td>
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<td>16.30-16.45</td>
<td><strong>Executive Forum</strong></td>
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<td>16.45-17.00</td>
<td><strong>Re-cap and next steps</strong></td>
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Welcome: Christopher Game, Chief Procurement Officer
Introducing a mass murderer
Introduction

A reminder of what Malaria means
Malaria in Perspective

In Countries where Malaria is prevalent average life span can be as low as 30
Malaria in Perspective

Malaria has shaped Africa in terms of Colonization - Independence then shaped Malaria
Malaria in Perspective

Five times more men have been lost to Malaria than in any battle
Malaria in Perspective

- Affects 500 Million people worldwide
- 50 Million dead in the last 15 years
- 85% of those are children
- 1 Child dies every 60 seconds
Malaria in Perspective

And now a personal experience:

For those of you who have read Great Expectations by Charles Dickens, these are Pip’s graves. Dickens lived at Shorne, near to this Church in Cooling, Kent half an hour from London in the United Kingdom.

These graves are in fact those of the Comport Children, none is more than a meter long, and if memory serves me correctly there are 11 or 12 of them.

They died of Malaria, not far from one of the world's great cities.

200 years ago.
Keynote Address: Dr Mark Dybul, Executive Director
The Global Fund: Where we are today and our new approach to supplier management

Christopher Game

- Investing for Impact and The Global Fund Strategy
- Procurement for Impact: P4I
- ACT and RDT Procurement Facts and Figures
- The new approach in the context of ACTs and RDTs and the implications for suppliers
What is The Global Fund?

- 4.2 Million People currently receiving ARV therapy
- 9.7 Million New smear-positive TB cases detected and treated
- 310 Million Insecticide-treated nets distributed

Since its inception in 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria has become the main multilateral funder in global health. It channels 82 percent of the international financing for TB, 50 percent for malaria, and 21 percent of the international financing against AIDS. It also funds health systems strengthening, as inadequate health systems are one of the main obstacles to scaling up interventions to secure better health outcomes for HIV, TB and malaria.
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.
**Core Structures**

**Country Coordinating Mechanism** (CCM) is a partnership composed of all key stakeholders in a country’s response to the three diseases. The CCM is responsible for submitting proposals to the Global Fund.

**Global Fund Secretariat** manages the grant portfolio, including screening proposals submitted, issuing instructions to disburse money to grant recipients and implementing performance-based funding of grants.

**Technical Review Panel** (TRP) is an independent group of international experts in the three diseases and cross-cutting issues such as health systems. It meets regularly to review proposals based on technical criteria and provide funding recommendations to the Board.

**Board** is composed of representatives from donor and recipient governments, civil society, the private sector, private foundations, and communities living with and affected by the diseases.

**Principal Recipient** (PR), is designated by the CCM. The PR receives Global Fund financing directly, and then uses it to implement prevention, care and treatment programs or passes it on to other organizations (sub-recipients) who provide those services.

**Local Fund Agents** (LFAs) monitor implementation. LFAs are responsible for providing recommendations to the Secretariat on the capacity of the entities chosen to manage Global Fund financing.
The fight goes on

Progress

<table>
<thead>
<tr>
<th>Metric</th>
<th>2000</th>
<th>Latest</th>
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<tbody>
<tr>
<td>Sub – Saharan ARV therapy</td>
<td>50,000</td>
<td>6 million</td>
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<tr>
<td>4.5 million treatments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Case Detection</td>
<td>43%</td>
<td>67%</td>
</tr>
<tr>
<td>TB Treatment Success</td>
<td>67%</td>
<td>87%</td>
</tr>
<tr>
<td>9.7 million treatments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LLIN Ownership</td>
<td>5%</td>
<td>53%</td>
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<tr>
<td>310m nets provided</td>
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However

2012

- HIV/AIDS TB Deaths
- Malaria Deaths (2010)

- 2,700,000
- 600,000

Future Funding required and targeted in period

- $87m
- $76m
- HIV/AIDS $58bn
- TB $15bn
- Other $61bn
- Malaria $14bn
- TGF $15bn

Maximising the value from procurement will contribute to the number of lives saved
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
Procurement 4 Impact – our goals

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 recipient countries to exceed 90%.
Direct Spend…Voluntary Pooled Procurement

Current State:

What could improve:

- Poor Penetration (It’s 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 executional
- 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’
Future State

Grant

Country

Suppliers
• Updated and competitive pricing
• Direct relationship with Global Fund
• Volume leveraged price breaks
• Option for inclusion of local vendors

Governance
• Transparent application of QA processes
• Setting of financial rules and constraints
• Dashboard Reporting /$$$/value/lives saved

Logistics
• Regular price / contract review
• Automatically links to product in price build up
• Option for final local delivery

Sourcing

Agency

Receipt

Delivery

Geneva January 2013
What Will Transform

- **Subscription, (spend under control) driven by transparency and ease of application**
- **Control – GF end users will dictate parameters**
- **Greatly reduced Agency Costs**
- **Vendors incentivized to innovate**
- **Creation of product market & supply experts**
- **Ownership of relationships, up and downstream**
- **Greatly improved funds flow ? Cash flow**
- **Simple user designed processes**
- **Comprehensive market intelligence**
- **Frequent price competition**
- **Scalable and can be leveraged**
- **COGS versus Market based costing**
Developing Indirect Procurement

We are:

- Launching a cost optimization program across the organization
- Creating a category matrix, region versus category
- Creating category strategies & improvement plans
- Categorizing into Global categories and introducing category management
- Taking strategic ownership of spend categories outside of the current portfolio
- Building a simple front end user interface

From: Regionally Managed Procurement

To: Globally Leveraged Categories within a Matrix

GF Stakeholders

GF Suppliers

Spend Penetration
i-Fund for The Global Fund

Equipment, Goods and Services team

Health Products Team

The Support Group

GF PSM’s

Suppliers

Partners

Knowledge & Collaboration

Country Ownership & Supply
QUESTIONS ?
ACT and RDT Procurement Facts and Figures
AL Volume (Packs)

Volumes shipped have been trending upwards

Source: PQR as of 03 July 2013
Data extrapolated for year 2012
VPP procurement has reversed this trend

Source: PQR and VPP as of 03 July 2013
MRDTs Volume (Tests)

After significant growth in 2010 the volumes have levelled off

MRDTs (Tests)

<table>
<thead>
<tr>
<th>Year</th>
<th>Volumes (Millions)</th>
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<tbody>
<tr>
<td>2009</td>
<td>15</td>
</tr>
<tr>
<td>2010</td>
<td>55</td>
</tr>
<tr>
<td>2011</td>
<td>60</td>
</tr>
<tr>
<td>2012</td>
<td>60</td>
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Once again VPP purchasing is achieving better performance.
AL (Packs): Market Share 2010-12

Supply is split across 4 manufacturers

- Novartis Pharma: 44%
- Ajanta Pharma: 18%
- Cipla Ltd: 15%
- IPCA Laboratories Ltd: 23%

Source: PQR as of 03 July 2013
AMFm Phase 1

July 2010 – Dec 2012: US$332 million committed and US$283.8 million invoiced

Sanofi 9%

Ajanta 18%

Ipca 22%

Guilin 2%

QCIL 1%

Sigma-Tau 0.1%

Cipla 25%

Novartis 23%

AMFm Phase 1: Value of deliveries
July 2010 - Dec 2012
mRDTs (Tests): Market Share 2010-12

The mRDT market is dominated by three players

- Access Bio: 24%
- Standard Diagnostics: 36%
- Premier Medical: 21%
- Others: 2%
- Orchid Biomedical: 7%
- Span Diagnostics: 4%
- Orgenics: 3%
- ICT Diagnostics: 3%
The new approach in the context of ACTs and RDTs and the implications for suppliers
2014 and beyond…

- AMFm becomes “Private Sector Co-payment Mechanism” and integrated into GF grants
- Any eligible country can allocate GF grant funds to co-payment and set co-payment % and demand levers
- Co-payment system still managed by Secretariat (co-payment requests, invoice payments)
- Potential inclusion of RDTs for private sector
- Global Fund – one source of funding (Public & Private sector); one point of contact; one negotiation and contractual process
## What will change: Core Products

<table>
<thead>
<tr>
<th>Today</th>
<th>12 Months</th>
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<tr>
<td>Reactive procurement based on grant disbursement</td>
<td>Procurement based on forecast demand</td>
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<tr>
<td>Spot tendering through PSA</td>
<td>Long term, multi agency, collaborative contracts</td>
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<tr>
<td>Minimal cross agency leverage</td>
<td>Single negotiation process</td>
</tr>
<tr>
<td>Multiple negotiation processes</td>
<td>‘Remote’ inventory forecasting for VPP</td>
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<tr>
<td>Stock-outs and missed delivery windows</td>
<td>A standardised project based approach.</td>
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<tr>
<td>Lack of standardised processes between Sourcing and PSM</td>
<td>Contractually assured best price promulgated to all PR</td>
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<tr>
<td>Wide discrepancy in prices between VPP and non VPP purchasing</td>
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What does this mean for our Suppliers?

1. We want a new style of relationship that brings links the public and private sector financing

2. We are prepared to enter into longer term contracts with forecast volumes that will allow you to run your businesses more effectively.

3. In return we will require a more open and collaborative style which means working with us in a straightforward, honest fashion.

4. We will adjust our level of business with you dependent on your performance with us and our buying partners.

5. Zero tolerance of non compliance with Global Fund policies
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.

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

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

These changes imply a different way of working together……..and we expect the bulk of our orders to be placed as part of a framework contract.

- Aggregated demand
- New Funding model

TGF

ACT /RDT Suppliers

- Selected Suppliers
- Bulk Volumes
- Target priced 80%
- Collaborative

+ Tenders
- Spot orders 20%
- Benchmarking
- Small volume

PSA First line buyers

- Order execution, QC
- and logistics

PR
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.
Food for Thought
What is it like on the ground?

Perception

Manufacturers develop specifically for the Aid sector and price according to their social responsibility programs

Reality

Most of the drugs we buy are mid to late lifecycle, and we rarely follow the price curve in the way that the private sector does
What is it like on the ground

Perception

We are a customer of choice

Reality

Spot procurement, diverse specifications and poor planning and forecasting capability make us unattractive to many manufacturers
What is it like on the ground?

Perception

Innovation just keeps on coming, there are great pipelines

Reality

We sense a declining interest among the originators as the aid sector leans more towards generics. Declining volumes are eroding profitability for originators.
Academia and Operations

- Write a concept note
- Initiate multiple studies
- Wonder why we did not implement?
QUESTIONS?
Lunch
PMI: ACTs and RDTs

-Sonali Korde, USAID Bureau for Global Health
The President’s Malaria Initiative: ACT and RDT Procurement
President’s Malaria Initiative Background

• **PMI Goal & Strategy:** Achieve Africa-wide impact by halving the burden of malaria in 70% of at-risk populations (450 million people) in sub-Saharan Africa.

• **Where:** 19 focus countries and a regional program in the Greater Mekong Subregion, plus 3 non-focus countries.

• **Interventions:** PMI supports four key interventions to prevent and treat malaria:
  – Indoor residual spraying with insecticides
  – Insecticide-treated mosquito nets
  – Intermittent preventive treatment for pregnant women (IPTp)
  – Diagnosis of malaria and treatment with artemisinin-based combination therapy (ACT)
PMI ACT and RDT Procurement Strategy

• Procurement and technical assistance are closely linked to ensure a comprehensive support program.

• Procurement through procurement agents—JSI/DELIVER Task Order 7/Malaria and UNICEF (case by case).

• Supply Chain strengthening technical assistance through multiple partners at the country level.

• PMI focus and non-focus country have partners to assist with the technical assistance, quantification, planning, distribution.
PMI ACT/RDT Procurement Facts

• Nearly 29 million Rapid Diagnostic Tests procured in FY2012.

• Over 72 million ACTs procured in FY2012.

• PMI is committed to ensuring medicines and RDTs are high quality—all ACTs and RDTs procured are subjected to QA procedures.

• Technical priorities are to scale up case management including diagnosis and treatment. Procurement and supply chain assistance supports the overall goal of access to case management.

• PMI maintains stockpile for ACTs in Amsterdam to mitigate risk of stockouts.

• Consolidates PMI orders for ACTs biannually to ensure supply and manage lead times.
Key Challenges

1. 2013 has been relatively stable in terms of ACT supply. Prior years have witnessed supply interruptions and price fluctuations.
2. Pricing remains key concern.
3. PMI is focused on ensuring availability and access of RDTs and ACTs at lowest peripheral levels—conduct rapid health facility surveys, monitor central level stocks, work with partners e.g. WHO ACT Task Force to respond to stock outs.
UNITAID: ACT Forecasting, API activities, OR RDT Scale up

- Alexandra Cameron, Technical Officer, Market Dynamics
- John Cutler, Malaria Portfolio Manager
Global Fund Meeting of Antimalarial and RDT Suppliers
Geneva, 10 July 2013

Project Updates

Alexandra Cameron, Technical Officer, Market Dynamics
John Cutler, Portfolio Manager, Operations
Agenda

1. ACT Forecasting Service
2. API Market Intelligence
3. Private sector RDT project
ACT Forecasting Service

• Consortium composed of BCG, CHAI and MIT-Zaragoza
• Overseen by a Steering Committee: UNITAID, RBM, WHO, Global Fund and MMV
• Quarterly forecasts of global demand for WHO-prequalified ACTs, and resulting demand for artemisinin
• "Demand" based on available funding, vs. "need"
• Current project is concluding; RFP for Phase 2 in progress
ACT Forecasting

Key feature: triangulation of parallel models
- public channel: disbursement-based model and procurement plan-based model
- private channel: pilot uptake-curve model, and portfolio uptake-curve model

DATA SOURCES
- GF Grants R1-10
- PSM plans
- PMI, World Bank
- AidsData.org
- AMFm summary data
- 2009-9 mkt sting Kenya
- WMR2008
- DHS/MIS survey data
- ACTwatch survey data
- MICOS data
- ACTWatch Tx-seeking Cohen Tx-seeking Cohen grant reprogramming
- Kozelsky (2007)
- Snow (2003, 2005)
- WHO fever (2010)
- Malaria Atlas Project
- Guyatt & Snow Tx-seeking
- DRC ACTWatch study
- Extrapolated data
- Tanzania subsidy pilot
- Kenya subsidy pilot
- Rwanda subsidy pilot
- Senegal subsidy pilot
- Uganda MMV report
- UN population data

MODELING
- Applied models
  - Disbursement-based model
  - Procurement-based model
- Resolved high variance
  - Pilot uptake curve
- Private-sector models
- Vetting of assumptions

ANALYSIS and REPORTING
- Global Forecasts
- Implications and Recommendations
- Q4 2011
- Q1 2012

EXTERNAL RESOURCES
- Steering Committee
- CHAI AMFm Teams
- Country experts
- Other outside experts
ACT Forecasting Phase 2 – building on lessons learnt

- Forecasting of RDTs alongside ACTs
- Estimation of need alongside demand
- Diversification of data inputs, including data from manufacturers
- Additional data inputs from selected countries that represent majority of the market
- Artemisinin demand outside of prequalified ACTs
- Short-term and longer-term estimates
API Market Intelligence

William Davidson Institute, U of Michigan & Howard University

Project Goals:
1. to collect & synthesize information on API and raw material markets;
2. to generate new insights around API markets to support design of market interventions.

Methods: desk research, surveys, key informant interviews, modeling

Information to be collected for all therapeutic areas includes:
• Number of QA API manufacturers
• Aggregate demand and capacity of QA API manufacturers
• Capacity estimates of non-QA API manufacturers
• API & FPP market prices; API cost as a % of FPP price
• Analysis of raw materials costs, process efficiency, technology investments, and supply-demand
API Market Intelligence

Information to be collected for malaria medicines:
- Artemisinin area under cultivation
- Capacity of semi-synthetic vs. agricultural starting material
- Yields of artemisinin to artemether/artesunate conversions
- Annual risk assessment of API/artemisinin situation
- Strategies to stabilize prices and available supply of artemisinin relative to demand

Information to be collected for malaria RDTs:
- Mono-clonal antibody (Ab) manufacturers
- Overall capacity of monoclonal Ab
- Factors (including cost) likely to expand use of RDTs vs. indiscriminate dosing
- Other material inputs
Creating a Private Sector Market for Malaria Diagnostics

**Population Services International (PSI)**
Kenya, Madagascar and Tanzania (direct market approach)

**Malaria Consortium**
Nigeria and Uganda (indirect market approach)

**FIND**
RDT QA & systems to monitor quality in the private sector
Quality case management & lot-testing of RDTs

**WHO**
Country regulatory matters
Guidelines, recommendations, clinical quality control
Why RDTs? Why the private sector?

Clinical management context
- WHO recommendation for confirmatory diagnosis 2010
- Overtreatment with anti-malarials
- Poor management of other causes of fever
- Continued drug pressure and risk of resistance

Care-seeking context
- Up to 40–60% seek care from the private sector
- Policy and guideline gaps for diagnosis in the private sector
- RDTs are scarce and expensive in the private sector
- Low demand for diagnosis and lack of compliance with results
What causes fever?

Diagnoses of 1005 Tanzanian children presenting with fever

- URTI: 35%
- Malaria: 9%
- Pneumonia: 10%
- Other Viral: 10%
- Systemic Infections: 10%
- Typhoid: 3%
- Skin Infection: 1%
- UTI: 5%
- Pneumonia (Rx): 3%
- Bronchiolitis: 3%
- Gastroenteritis: 8%
- Unknown: 3%
- Meningitis: 0%
Challenges to Malaria Diagnosis in the Private Sector

- Regulatory environment for private sector testing
- Uninterrupted supplies of QA ACTs and RDTs
- Maintain quality of care and safety at scale
- Improving adherence with test results
- Management for non-malaria fevers
- Referral systems
- Getting the incentives right for providers and consumers
- Subsidies & relative pricing for diagnosis and treatment

Modified from RBM Case Management Working Group
Interventions for Pilot and Scale Up Phases – 1

• **Increase access to quality diagnosis**
  – Procurement standards
  – Training materials and job-aids
  – Trade promotions
  – RDT quality control (lot-testing)
  – Consumer recognition of quality-assured RDTs

• **Increase demand**
  – Consumer/provider research
  – Raising awareness and creating demand for testing
  – Marketing, promotion, packaging etc.
  – Price and subsidies
Interventions for Pilot and Scale Up Phases – 2

• Improve case management
  – Develop/adapt case management algorithms
  – Provider training
  – Establish standards of care and monitoring compliance
  – Supervision/medical detailing
  – Referral system

• Conducive policy and regulatory environment
  – Review and update regulations
  – Stakeholder engagement
  – Documentation and dissemination of experience
Thank you
FIND: RDT Evaluation Programme

- Sandra Incardona, Project Manager
GLOBAL FUND Meeting
of Antimalarial and RDT suppliers
Geneva, 10th July 2013

The FIND – WHO
Malaria RDT Evaluation Programme,
funded by UNITAID

Current status, impact,
and plans for the future
WHO and FIND strategy for QA of RDT-based diagnosis
Delivering a quality product and effectively using results

**Supply chain management**

**End users**
- Appropriate training and instructions
- Management of positive and negative results
- Monitoring of commodity supply and disease rates

**Manufacture**
- Product development
- Availability of common reference standards

**Stage 1: Product testing**
Evaluate product performance

**Stage 2: Lot testing**
Confirm product quality on arrival in country before dissemination to the field

**Stage 3: QC at point of use (positive control wells)**
Ensure that RDTs have maintained accuracy through transport and storage

**Transport and storage**

- Before purchase
- Before distribution
- Before use
WHO Malaria RDT Product Testing
Rounds 1, 2, 3 & 4 results

Rnd 1 (2008-9) 41 products
Rnd 2 (2009-10) 29 products
Rnd 3 (2010-11) 50 products
(Rnd 4 (2011-12) 46 products)
Round 5 (2013-14): 42 products being tested
(out of >90 applications)

P. falciparum

75% PDS @ 200 p/ul
WHO Malaria RDT Product Testing
Rounds 1, 2, 3 & 4 results

P. vivax

Figure S2: Malaria RDT performance in Phase 2 of Rounds 1–4 against wild type (clinical) samples containing P. vivax at low (200) and high (2000–5000) parasite densities (parasites/μL) and clean-negative samples.

Panel detection score

75% PDS @ 200 p/ul
2000 para/μL
200 para/μL

* Panel detection score - A sample is considered detected only if all RDTs in both lists read by the first technician, at minimum specified reading time, are positive.
* Clean-negative - Blood samples from healthy volunteers with no known current illness or blood abnormality.
Lot Testing

Number of new Malaria RDT lots tested per year

- Product Testing Round 1
- New GF policy: LT mandatory for GF recipients

METHODS MANUAL FOR LABORATORY QUALITY CONTROL TESTING OF MALARIA RAPID DIAGNOSTIC TESTS

Manual of standard operating procedures for: Laboratory quality control testing of malaria rapid diagnostic tests using standard solutions of malaria parasites, and preparation of quality control samples from malaria parasites.

Manuscript: April 2018

World Health Organization and Global Fund to Fight AIDS, Tuberculosis and Malaria

Photo credits: FIND, MTB, AMI, CDC, UCD, KEMRI, IHRDC, IPM

Source: FIND, 2018
RDT QC impact: Improvement in RDT quality in 2008-2010

23 re-submitted products

- Increase in PDS for Pf @ 200 parasites/µl;
  - Mean: 61.3 to 74.7
  - Median: 63.1 to 83.8
- Increase in PDS for Pv @ 200 parasites/µl;
  - Mean: 31.1 to 60.7
  - Median: 30.0 to 62.9
Manufacturing output based on WHO procurement criteria

- 2007: 76.01% (PDS <50% including False Positive), 23.22% (PDS ≥50%)
- 2008: 68.39% (PDS <50% including False Positive), 27.66% (PDS ≥50%)
- 2009: 66.88% (PDS <50% including False Positive), 36.10% (PDS ≥50%), 1.00% (PDS ≥75%)
- 2010: 88.68% (PDS <50% including False Positive), 11.16% (PDS ≥50%), 0.13% (PDS ≥75%)

*PDS: Panel Detection Score
The future: sustainable RDT evaluation and QC based primarily on recombinant proteins

- Use of standardized recombinant antigen panels referenced against existing data using blood samples.
- Revised product testing platform performed in a rolling fashion (rather than annually), supported directly by users’ fees, under the auspices of WHO or another appropriate body.
- Sustainable, country-based lot testing with standardized panels made available to national programmes and manufacturers, in a manufacturer- and user-funded programme.
- Roll-out of PCWs at point of care level.
- Investigate the application of similar comprehensive and sustainable models of QA to other disease programmes.
Quality Control at end user level
Using Positive Control Wells (PCWs)

2013:
Development being completed.
Demonstration studies (with WHO) are ongoing in Uganda and Lao PDR.

FIND; Reametrix (Bangalore, India); HTD (UK), US CDC
RBM HWG: ACTs and RDTs

-Melanie Renshaw, Chief Technical Adviser, ALMA
ACTs and RDTs

Africa gap analysis 2013-2016

Melanie Renshaw (ALMA)

Co-Chair, Roll Back Malaria
Harmonization Working Group
GF Malaria Resources for Africa

- 2007 - Round 7
- 2008 - Round 8
- 2009 - Round 9
- 2010 - Round 10
- 2011
- 2012 - TFM
- 2013 - INFM

$0,000,000,000
- $2,000,000,000
- $1,800,000,000
- $1,600,000,000
- $1,400,000,000
- $1,200,000,000
- $1,000,000,000
- $800,000,000
- $600,000,000
- $400,000,000
- $200,000,000
- $0
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<th>2013</th>
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<th>2015</th>
<th>2016</th>
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<td>Need</td>
<td>358,605,514</td>
<td>324,437,299</td>
<td>288,494,547</td>
<td>241,407,712</td>
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<tr>
<td>Financed</td>
<td>231,201,974</td>
<td>192,287,031</td>
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<td>127,403,540</td>
<td>132,150,268</td>
<td>185,483,817</td>
<td>202,200,384</td>
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ACT Gap Analysis Africa

Bar chart showing the gap analysis for Africa in the years 2013 to 2016. The chart compares the need, financed amounts, and the gap.

- **Need** (blue) increases sharply from 2013 to 2014, stabilizes in 2015, and shows a slight decrease in 2016.
- **Financed** (red) shows a significant increase from 2013 to 2014, with a slight decrease in 2015 and a noticeable decrease in 2016.
- **Gap** (green) indicates the difference between need and financed, with the gap being the highest in 2013 and gradually reducing in subsequent years.
# RDT Gap Analysis Africa

<table>
<thead>
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<th>2014</th>
<th>2015</th>
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<tr>
<td>Need</td>
<td>298,140,192</td>
<td>340,806,281</td>
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<td>Financed</td>
<td>180,604,892</td>
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<td>171,803,414</td>
<td>228,807,315</td>
<td>375,593,117</td>
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RDT Gap Analysis Africa

The bar chart shows the gap analysis for the years 2013 to 2016. The chart compares the need, financed, and gap for each year.

- **Need**: Blue bars show the total need for each year.
- **Financed**: Red bars indicate the financed amount for each year.
- **Gap**: Green bars represent the gap between need and financed amounts for each year.

The chart highlights a significant gap in funding, with a notable increase in the gap from 2013 to 2016.
ACT/RDT Need

![Bar Chart showing the need for ACTs and RDTs from 2013 to 2016.](chart.png)
ACTs: Public/Private Sector
RDTs: Public/Private Sector

![Bar chart showing the comparison between total public and private sector RDTs from 2013 to 2016.](image-url)
PERSPECTIVES FROM PARTNERS

Q&A
Group Discussion & Plenary Presentation

- What worked well under the previous arrangements?
- What can be improved? i.e. What do the Global Fund and partners need to “get right” going forward?

Focus areas by table number:

1. Demand
2. Timing
3. Value
4. Quality
5. Collaboration
6. Innovation
1 – Demand

What has worked well?

• Access to ACTs provided to so many people.
• Global need/demand forecast (to generate funding) was quite accurate/successful.
• Some learning has taken place (some countries – therefore to be extended): from repeated emergency orders, to more planned procurements that cover a longer time-span.

What can be improved?

• RDTs were not rolled out in parallel to ACTs (To what extent were the ACTs used efficiently to treat malaria, or used on other fevers/diseases?)
• Manufacturers lack visibility: a global forecast does not allow them to plan their production, neither does a request… only once the order is really funded and confirmed, they can act on it.
• The actual need (as opposed to the compilation of quantities to be funded per product) is very difficult to quantify – whether for the country, or for donors.
1 – Demand

What can be improved? (2)

• Different organisations come up with different forecasting arithmetics, hence different (access to and compilation of) data. -> need clearer definitions of forecasting, its different aspects/levels (overall need vs. funded vs, orders to be generated, etc.), and how it is done.

• The timeline between a manufacturer receiving a request for quotation and the order being confirmed is too long. -> streamline process, forward commitments.

• Furthermore, it repeatedly happens that goods are stuck with the manufacturer, pending completion of importation-related processes (waivers, provision of other authorizations or documents by the country), or due to warehousing capacity constraints in-country. -> The Global Fund/VPP should take more ownership or at least follow more closely on this process.

• Costs, barriers, slowness related to national registration requirements, (where registration is a requirement) are also barriers.
1 – Demand

What can be improved? (3)

• Payment process with PFSCM slow – whether it is because goods are not yet cleared in-country and hence fully delivered (DAP delivery), or because of requirements such as sending in paper invoices.
• Manufacturers experience too much variation of order level – Place confirmed orders earlier/forward commitments (but confirming the detailed specifications such as exact type of RDT, packing), stagger deliveries so that there are planned production schedules rather than one-off orders.
• Manufacturers do not have enough direct exposure with the Global Fund – only VPP Procurement Services Agent (PFSCM) or countries. There needs to be more interaction.
• If RDTs are to be co-financed and delivered through the private sector, be aware that training and implementation will take time.
1 – Demand

What can be improved? (4)

• Make countries more responsible for their ordering: through a bigger contribution from them. In AMFm Phase 1, countries did not have to support a portion of the freight costs (as all was paid by AMFm), which incentivised costly air shipment. Also, more education of countries for timely forecasting, planning, ordering is needed.

• “Country ownership does not work” – building capacity takes many years.

• A supplier: “If it is the country placing the order [selecting the manufacturer – in reference to the “i-Fund” concept where it was understood that the country would choose their suppliers], then we are not in it/forget it” (corruption etc. issues).

• For now, there are concepts and well-sounding formulations being discussed – the challenge will be to concretely implement, operationalize.
2 – Timing

What has worked well?

- **ACTs**
  - Manufacturers responded to significant demand increase with AMFM (although prices increased and lead-times extended)
  - Private sector is a viable distribution channel for subsidised ACTs
  - More products and manufacturers prequalified
  - Unit price differential depending on lead-time from Novartis has encouraged earlier procurements

- **RDTs**
  - Manufacturers responded to significant demand increase (with falling prices and increased quality)
  - WHO increased recommendations for product performance in procurement
  - Price competition
2 – Timing

What can be improved?
(* = Short term priorities – NB some interdependencies)

• Improved demand forecasts with longer vision and willingness to sacrifice some prevision to reduce the delayed publication experienced so-far*

• Differentiate between global high level need/demand forecasts with vision of 24 months - and more precise committed procurement forecast of 12-18 months*

• Simple processes

• Improve financial flows to enable orders to be confirmed earlier*

• Reduce price volatility (ACTs) and variability (RDTs)*

• Coordinate counterfeit/diversion interventions

• Standardise specifications/variations - RDTs

• Decrease product/packaging volumes (ACTs and RDTs)

• Optimise sea/road freight - improved/earlier planning/procurements (50% savings)*
3 – Value

What has worked well? - VPP / AMFm
• Transparency is improving, on RFPs, who got it, price, why you lost, quantities
  – Helps to plan with production / requests
  – Provides market insights, helps with future planning
• Leverage quantities for high volume countries with prices that can be extended to smaller volume countries
• Local production as part of value in RFPs
• Total landed cost vs. FOB; Recognizing benefit of local manufacturing and lead times also considered
• Quality is very important; Global Fund adheres to quality requirements
• Responsiveness of suppliers is important in terms of value
• Reliability of payment is sometimes more important than volumes

July 2013
Geneva
3 – Value

What can be improved?
• Better quantification and information to have a better idea of what’s coming down the pipeline
• System to track and monitor KPIs and to incentivize manufacturers
• Binding forecasts, confirmed business; Advanced purchase commitment
• Better planning – can ship more for ocean vs. air freight, can reduce cost of shipment
• Standardization of packaging with option to opt out
• Try to reduce administrative burden – AMFm
• VPP is sometimes tough as well, as cumbersome administrative process slows down movement of goods
4 – Quality

What worked?
• Performance testing under QA allowed for competition on performance
• QA policies led to procurement of quality products
• Harmonization led to competition on price
• ACT quality standardized and harmonized

What can be improved?
• Understanding of implications of stringent IUD regulatory requirement – full WHO PQ
• Market behavior not to reduce price and compromise quality [donor requirements and supplier predatory pricing]
• Forecasting was deficient – need detailed rolling forecast for procurement
• Do not go for “winner takes all”
• Risk-based approach to testing for ACTs with PQ’d products
• Avoid single-source situations
5 – Collaboration

Why collaboration?
• improve communication
• sharing information

What has worked well?
• RDTs: Simple process through the VPP compared to public tenders (less documents to provide)

What did not work well?
• RDT manufacturers have limited knowledge of the Global Fund
• No feedback on outcomes of the tenders through VPP (like in the public)
• Lack of visibility on orders/no guarantee/poor planning

What can be improved?
• More regular meeting with RDTs manufacturers
• More active communications are needed
• Collaborate to find innovative solutions
6 – Innovation

Ideas for consideration:
• A Global Fund for innovation?
• Incentivized contracting?
• Financed innovations?
• Incentivize in procurement and supply
• “Risk” innovation and willingness to take risk
6 – Innovation

What has worked well?
• Courageous AMFm
• Followed WHO recommendations
• Adoption of ACTs
• Artemisinin scale-up
• Quality standard implementation
• Good implementer
• ERP process
• Quality above cost
• Transparency
• Evolving

What did not work well?...
• Post AMFm
• Procurement NOT innovative
• Slow
• No predictability
• Volatile
• R&D support
• Data “black hole”
• VPP
• Bureaucratic
• Silo’d

Country Ownership
RECAP AND NEXT STEPS