The Global Fund
To Fight AIDS, Tuberculosis and Malaria

ACTm

Innovation, Evidence and Policy: What AMFm Independent Evaluation Means for the Global Fund

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Outline

1. Proof of Concept: what was AMFm supposed to do?
2. Implementation: what actually happened?
3. TERG review of Independent Evaluation
4. Next steps: what we need to do
5. Lessons Learned

The Concept: Scope of AMFm Phase 1*

What it was

- Innovation in the architecture of financing; this was new
- New approach to development assistance,
- Working with and through all sectors, targeting private sector
- Making the market work for public health
- A proof of concept: how well does the basic design work?

What it was not

- A new or alternative service delivery mechanism
- Substitute for clinics or community health workers
- General primary health care
- General health system strengthening
- The solution to all problems in malaria control

**Source: OA presentation at R4D Institute, November 2010*

What AMFm was supposed to do

Goal 1: Contribute to Malaria Mortality Reduction

Goal 2: Delay Resistance to Artemisinin

Four objectives:

1 – Increasing availability of quality-assured ACTs

- Working through public, private for-profit and private not-for-profit sectors

2 – Increasing affordability of quality-assured ACTs

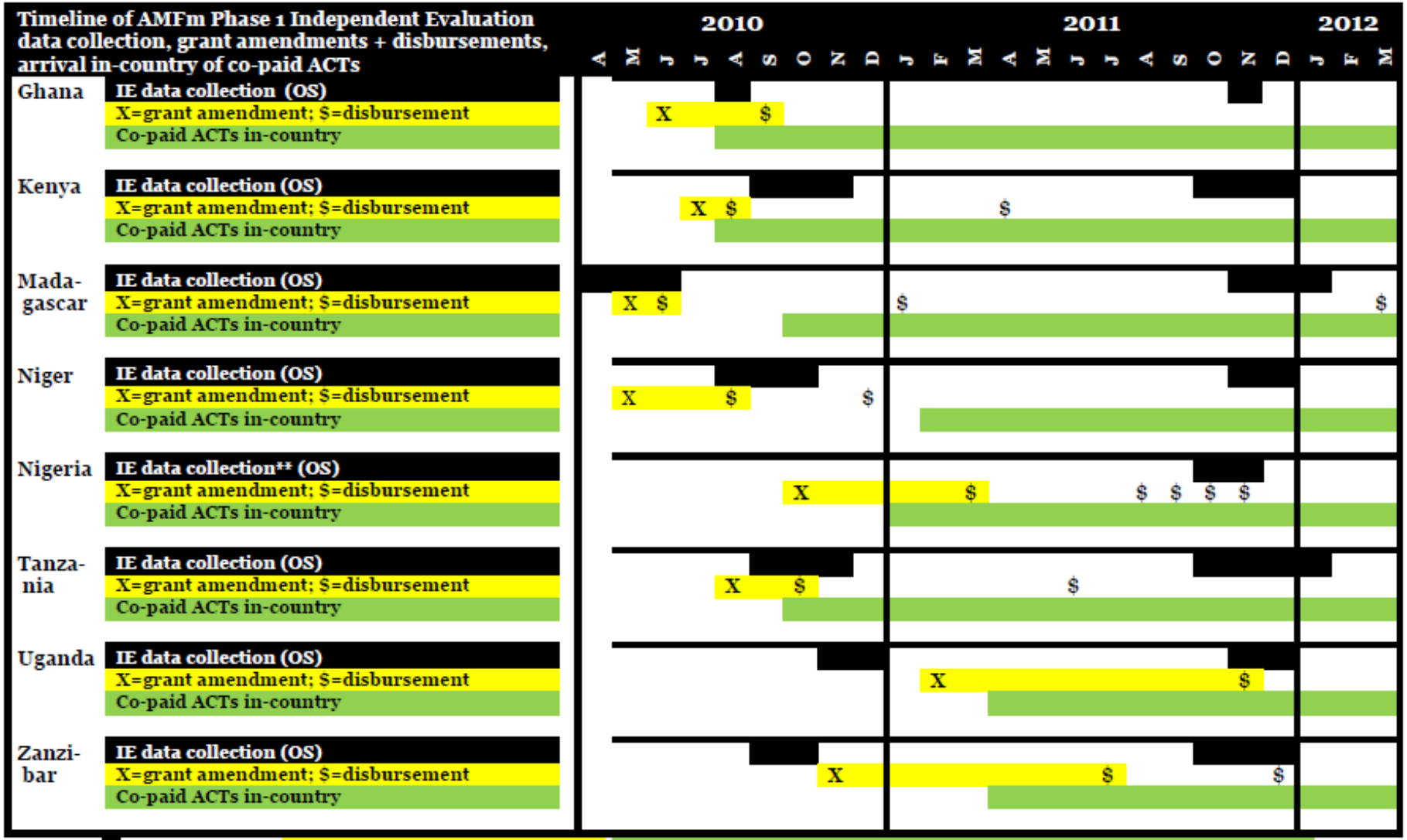
3 – Increasing market share of quality-assured ACTs

- Decrease likelihood of artemisinin resistance by crowding out oral artemisinin monotherapies

4 – Increasing use of quality-assured ACTs

- Including among vulnerable populations

Implementation: AMFm Timelines



Notes: = IE data collection X=grant amendment; $=disbursement Co-paid ACTs in-country (although not necessarily in continuous supply over the entire period)
**Nigeria: Baseline data collection completed Sept-Nov 2009. OS = Outlet survey (main study)

How did AMFm work in practice?

Pillars of the AMFm Model

1 Negotiations with Manufacturers

- To reduce price of ACTs &
- Assure same price to public and private sector first-line buyers

2 Finance co-payments to manufacturers

- To further reduce price to first line buyers

3 Fund "Supporting Interventions"

- To ensure safe and effective ACT scale up

What happened in practice?

- AMFm was disconnected from VPP and Global Fund procurement processes
- AMFm was detached from Global Fund Malaria grants
- AMFm price negotiations with manufacturers limited ability for Global Fund to leverage buying power across the portfolio, including for the public sector

How did AMFm work in practice?

Design changes introduced mid-stream, to manage excessive demand on resources

- Due to a rapid uptake of co-paid ACTs by the private sector in the first year, AMFm was not financially able to continue approving all requests for co-payment received

- Rationing levers were introduced in August 2011 to rationalize and moderate demand**

- This "mid-stream" change represented a shift from a "demand driven" to a "demand shaping" financing facility, the impact on the market is not yet clear

***Demand levers included but not limited to formulation/pack size; pediatric; pipeline; etc.*

The Role of Government

- Prior to AMFm, **many governments' public sector were suspicious** of and had limited experience engaging with the private sector

- **Government buy-in over time was key** in creating an enabling environment, strong political will and support for AMFm in the pilot countries

- **Policy shifts were made to support AMFm goals**:
  - Tax waiver on importation of ACTs
  - Re-classification of ACTs from prescription-only medicines to over the counter (OTC) medicines
  - Importation of ACTs by manufacturers and First-Line Buyers

AMFm / Global Fund Synergies in Nigeria

AMFm in Nigeria

- AMFm introduced in September 2010
- Nigeria achieved mixed results against AMFm success benchmarks;

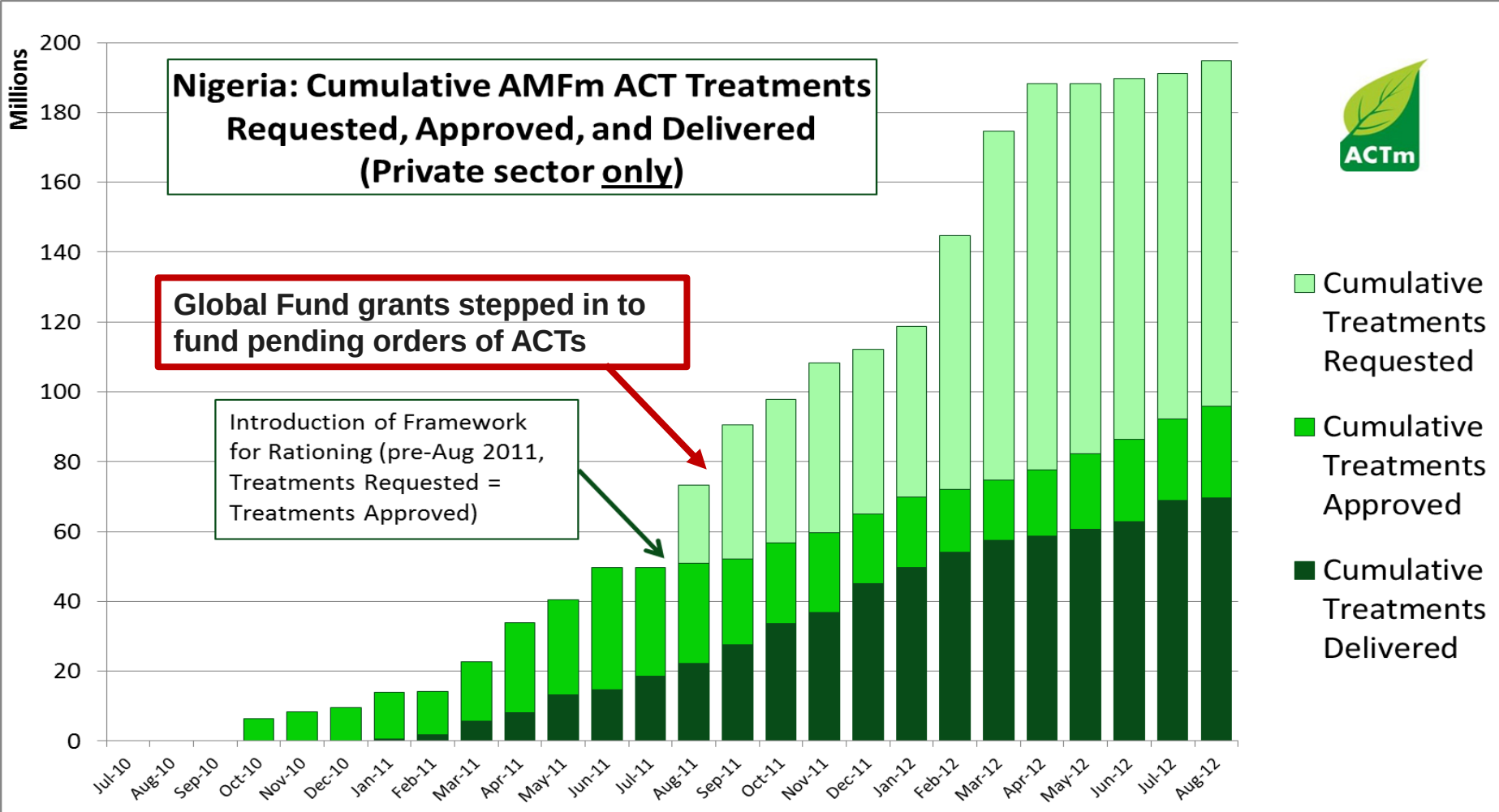
  - QAACT market share increased from 2% → 20%

  - Importation of Artemisinin mono-therapies continued in the 2-year period after regulation

- Private sector plays a dominant role in malaria treatments in Nigeria (>90%)
- Relatively low supply of co-paid ACTs compared to demand
- Most local manufacturers have stopped production of ACTs because they cannot compete with AMFm products

GF Malaria Program in Nigeria

- Delays in AMFm (negotiation, disbursement, procurement and delivery of ACTs) affected grant performance
- Risk and OIG issues led to delays in the implementation of the supporting interventions.
- By August / September 2011, AMFm funds exhausted due to excessive demand.
- Funding for ACTs complemented through Global Fund grant budgets;
- By end 2011, PRs financed pending ACT orders at full price



Nigeria Private Sector (not covered by GF Grant, i.e. not including SFH)

Cumulative Data

Total # AMFm co-paid ACTs requested:	194.7 M treatments
Total # AMFm co-paid ACTs approved:	95.9 M treatments - 49% of total ACTs requested
Total # ACT treatments delivered:	69.2 M treatments - 72% of total ACTs approved

Since August 2011

AMFm co-paid ACTs requested :	145.1 M treatments (11.2 M treatments/month)
AMFm co-paid ACTs approved:	46.3 M treatments (3.6 M treatments/month) - 32% of requests since Aug 2011
AMFm co-paid ACTs delivered (31 July 2012):	50.4 M treatments (4.2 M treatments/month)

Public Health System – 64 M annually

TERG Review of Independent Evaluation

Adequacy of timing of evaluation relative to implementation - no pilot had more than 12 months of "effective implementation*". Timing of evaluation was deemed 'premature'.

System equilibrium – would the effects observed be sustained over time? Risk that observed upstream results may reflect a "honey moon" effect with the market slipping back to another equilibrium over time.

Use amongst poorest and most vulnerable – critical missing piece of evidence to inform policy, as it matters little if the market share and availability of a lower price ACT improves to benchmark levels if those in need do not use it.

Lack of comparison limits interpretation of results – in 2010 TERG envisioned that "*future decisions would be informed by a comparison between the AMFm and other possible means of financing expanded access to affordable antimalarials*"

Value for money – it would be useful to establish efficiency and effectiveness of investments; relative contribution and optimization of interventions in AMFm model

For all three components - manufacturer negotiations; buyer co-payment; and supporting interventions

TERG Observations from Evaluation

- **The private sector was a major player** at endline; role going forward remains critical

- **AMFm model was not a one size fits all** – considerable variations in context and experiences in pilot countries; effects of AMFm difficult to generalize to other national systems

- **RDT was not part of AMFM; availability and use will be crucial going forward -**
  - Given rapid declines in malaria
  - Encourage rational use of ACTs
  - Delay resistance to artemisinin
  - Deal with non-malaria febrile illnesses

What are some of the design flaws?

What was planned, design flaws and assumptions of the experiment

a. Policies or enablers across pilot countries were uneven, and not in place at the same time

b. There was a mixed selection of countries, including where rationale for AMFm was unclear from the start (e.g. Zanzibar)

c. Importance of effectiveness of Global Fund operations and malaria grants in enabling success was underestimated

d. The Board did not allow for adequate time for “effective implementation” of the experiment

e. Provision for a counterfactual was later not required; what could have happened if there was no AMFm?

Next Steps – what we need to do

September Board recognized that abrupt termination of AMFm was not desirable –

- Prevent reversal of gains and mitigate reputational risk to the GF
- Meet contractual commitments between GF and first-line buyers
- Governance mandate lies with the Board, to allow for greater ownership of decision on future of AMFm

September Board Decision (GF/B27/DP4) extends AMFm for 12 months until December 2013 to ensure –

- access to quality-assured ACTs in AMFm countries is not disrupted;
- ACT and API markets are not destabilized; and
- countries have adequate time to take measures to implement outcome of November 2012 Board Decision

Next Steps: Define and cost options for Board Decision in November 2012

Lessons – proof of concept

- From the start, **adequate time** should have been allowed for design and implementation of an experiment, with such complex interventions, before evaluation.

  Different lessons could have emerged over time.

- As the experiment was rolled out, Global Fund should have developed policies to **facilitate smooth implementation**, **enhance synergies** with malaria grants and **leverage** strategic initiatives including VPP.

- **Anticipation of sustainability** should have been built into the experiment at the outset.

- Lack of **champions** and a **clear governance structure**