Global Fund Grants for Malaria: Lessons Learned in the Implementation of ACT Policies in Ghana

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Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), artemisinin-based combination therapies (ACTs), implementation, malaria, grants, lessons learned

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ACRONYMS

ACT	artemisinin-based combination therapies
ADR	adverse drug reaction
AFRO	Regional Office for Africa [World Health Organization]
AIDS	acquired immunodeficiency syndrome
BCC	behavior change communication
CCM	Country-Coordinating Mechanism
CIP	Commodity Import Program
CMS	Central Medical Stores
CP	condition precedent
EDM	[Department of] Essential Drugs and Medicines [World Health Organization]
FDB	Food and Drugs Board
FPM	Fund Portfolio Manager
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	Ghana Health Service
HIV	human immunodeficiency virus
IPT	intermittent preventive treatment
ITN	insecticide-treated nets
LFA	Local Fund Agent
M&E	monitoring and evaluation
MMSS	Malaria Medicines and Supplies Service (hosted by the RBM Partnership Secretariat)
MOH	Ministry of Health
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
NGO	nongovernmental organization
NMCP	National Malaria Control Program
PR	principal recipient
PSM	procurement and supply management
PU	procurement unit [Ghana]
RBM	Roll Back Malaria [Initiative]
RPM Plus	Rational Pharmaceutical Management Plus
SR	subrecipient
STG	standard treatment guidelines
TB	tuberculosis
TAG	Technical Advisory Group [World Health Organization]
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

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EXECUTIVE SUMMARY

Ghana has been awarded funding for malaria from the Global Fund during Rounds 2 and 4. The Round 2 proposal includes activities aimed at malaria prevention and supportive activities for appropriate treatment, including changing the first-line policy. Phase 2 of the Round 2 proposal is already under way. Activities in the Round 4 proposal are aimed at improved prevention and treatment of malaria, including implementing the new treatment policy in all 138 districts in the country; the main beneficiaries are children under five years of age and pregnant women. In both cases, the principal recipient (PR) is the Ghana Health Service (GHS)of the Ministry of Health (MoH) and the subrecipient (SR) is the National Malaria Control Program (NMCP). Artemisinin-based combination therapy (ACT) procurement and implementation was included only in the proposal developed for Round 4; therefore, the activities and processes described, although relevant to both proposals, specifically refer to the implementation of Round 4 proposal activities.

At the time of this study, approximately 90 percent of the funds approved for Phase 1 of the Round 4 grant has been spent on the specific objectives outlined in the proposal. The PR had procured two consignments of prepackaged artesunate-amodiaquine combination tablets, using the Malaria Medicines and Supplies Service (MMSS) of the RBM Roll Back Malaria Partnership in Geneva to negotiate the procurement.

The first consignment of medicines arrived in Ghana in April 2005; however, the medicines could not be distributed for a further six months because training on the new treatment guidelines had not yet begun. During this time, some public health facilities procured a locally manufactured artesunate-amodiaquine combination before the providers in the public sector were trained. Adverse drug reactions in patients to the locally manufactured combination which contained a higher strength of amodiaquine than recommended, resulted in a highly publicized opposition to the new treatment guidelines. As a result, compliance with the new policy has been poor at all levels of the public health system, although training and communication to counter the negative press were undertaken. Behavior change communication strategies are needed to address this concern. Operational research to elucidate the reasons for the noncompliance to the new guidelines should be considered.

In addition, the quantities procured for the implementation of the Global Fund proposal were inadequate. The quantification assumed that resources from the Global Fund would be used to procure medicines for 40 percent of the country's needs for the vulnerable groups—children under five years of age and pregnant women—with the rest being covered by the government of Ghana. However, the government of Ghana failed to carry out any additional procurement of ACTs, with the result that ACTs procured using Global Fund resources were being used to cover the whole country.

Ghana has been able to overcome the gap in resources for procurement by making funds available from other activities and negotiating for additional funds from the Global Fund. Ghana would have benefited from allocating appropriate budgets for implementation, including acquiring external assistance for activities for which capacity may not be adequate, supply chain

management, and monitoring and evaluation (M&E). Budgeting should be done at the proposal planning stage with widespread consultation with the various agencies within government.

One of the main reasons for the relatively smooth procurement in Ghana was that the proposal was developed with the inclusion of a wide variety of stakeholders who continued to play a part in implementation, thus creating a sense of ownership. Furthermore, coordination and collaboration, and the clear understanding of roles and responsibilities among the PR, NMCP, Country Coordinating Mechanisms (CCM), and other implementers have enabled a conflict-free, transparent process with clear lines of accountability.

The PR and SR did not adequately plan for the amount of time necessary to train providers in the new standard treatment guidelines (STGs), leading to distribution delays. Training should begin at least three months before the medicines are dispatched. Training plans need to consider the procurement timelines and must also be correlated with distribution and communication plans. In addition, a clear correlation should exist between the indicators and targets and the rollout of the procurement, supply, and management.

M&E is a large part of grant implementation. Some delays have occurred in reporting of data from the SR to the PR. The PR and SR need to build more capacity in monitoring, reporting, and accounting.

INTRODUCTION

Background

In 2001, the World Health Organization (WHO) recommended that all countries experiencing drug resistance to conventional malaria monotherapies such as chloroquine, amodiaquine, or sulfadoxine-pyrimethamine (SP), should change to ACTs.[1] Of the 43 malaria proposals submitted and approved by the Global Fund during Rounds 1, 2, and 3 (April 2002 to September 2003), however, 11 did not include ACTs as the first-line treatment. An article published in the *Lancet* in January 2004[2] criticized the Global Fund for funding treatments such as chloroquine and SP, which were ineffective in many countries, and called for a more rapid change to effective malaria treatment. Following this criticism, WHO issued a statement to reassert its recommendation, and the Global Fund encouraged and assisted countries that had received funding for the procurement of malaria treatments during the first three rounds to modify their workplans, budgets, and forecasts to change to the more effective ACTs in accordance with WHO recommendations. To make this change, countries needed to reprogram their existing budgets for procurement from Phase 1 of the grant, which covers the first two years of grant implementation, to accommodate the new first-line treatments. The Global Fund agreed to advance the funding for the procurement of ACTs by making available the funds from Phase 2 for the procurement of medicines in Phase 1. This announcement culminated in a September 2004 meeting held in Nairobi, Kenya, to assist countries to plan for the reprogramming of resources from the Global Fund.

At the time of the assessment, the Global Fund had approved malaria grants amounting to 2,584,874,749 U.S. dollars (USD) over five years, budgeting for 109 million insecticide-treated nets (ITNs) and 264 million treatments of ACT. Approximately 47 percent of all Global Fund grants are for the procurement of medicines and commodities. Despite the availability of these resources, only a part of these commodities have been procured so far, and the Global Fund recipients are facing significant problems implementing the programs as outlined in the approved project proposals. The Global Fund recognized that countries were facing similar challenges in implementing their grants for malaria and they would greatly benefit from sharing their lessons learned with other countries in the region. Consequently, the Global Fund requested that the Rational Pharmaceutical Management (RPM) Plus program of Management Sciences for Health, in collaboration with the RBM Partnership, develop descriptive case studies on the procurement and distribution aspects of malaria grant implementation in three countries in West Africa (Nigeria, Ghana, and Guinea-Bissau)—specifically with respect to the implementation of the first-line treatment (ACTs). The Global Fund chose these countries because of their location in the West African region and their status of malaria grant implementation. This report summarizes the findings and lessons learned on the implementation of the Global Fund grant for malaria in Ghana.

[1]World Health Organization (WHO). 2006. Procurement of Artemether/Lumefantrine (Coartem®) through WHO. Geneva: WHO. <http://www.who.int/malaria/cmc_upload/0/000/015/789/CoA_website5.pdf> (accessed Jan. 15, 2007).

[2] Attaran, A., K. I. Barnes, C. Curtis, et al. 2004. Viewpoint: WHO, the Global Fund, and Medical Malpractice in Malaria Treatment. *Lancet* 363(9404):237–40.

Objectives of the Study

The purpose of this study was to describe the implementation of the Global Fund malaria grants in Ghana; identify the bottlenecks that the countries faced at each step of the implementation process; and draw key lessons learned. The case study is intended to be descriptive and focused on the procurement, supply, and distribution aspects of implementing ACTs as the new first-line treatment for malaria in the country. The PRs can use the lessons learned to take remedial action to ensure that future procurement and distribution of ACTs will go more smoothly. In addition, PRs from other countries in the region can use these lessons learned to identify barriers to effective implementation, adapt the recommendations and strategies to tackle similar challenges, and facilitate the implementation of their own grants.

The specific objectives of the study were to—

- Trace the progress and document the key events of implementing the Global Fund grant related to ACTs—from developing the proposal and the procurement and supply management (PSM) plans to distributing ACTs to health facilities
- Identify bottlenecks in the process that contributed to delays
- Describe the steps taken to address these bottlenecks
- Draw lessons learned

Methodology

RPM Plus conducted meetings with the Global Fund and the MMSS of the RBM Secretariat to refine the research questions and the scope of work ands to define the mechanisms for collaboration. RPM Plus developed the concept paper and framework with specific research questions for the study data collection and the tools to guide data collection during the fieldwork. A literature review was then conducted for Ghana, which included documents on malaria, treatment guidelines, MoH and malaria program background documents, and Global Fund–related documentation.

RPM Plus in collaboration with the Global Fund and RBM Partnership Secretariat developed a list of relevant stakeholders in the country who might have information pertaining to the case studies. In October 2006, RPM Plus conducted field trips of 7–10 days in Ghana and held meetings with stakeholders to collect relevant documentation and to identify the various challenges and bottlenecks they had faced when procuring and distributing ACTs as part of the malaria grant.

Summary of the Standard Global Fund Process from Grant Application to Implementation

CCMs, which comprise country-level stakeholders involved in fighting HIV/AIDS, tuberculosis (TB), and malaria, prepare proposals in response to the Global Fund's call for proposals. The Global Fund Secretariat forwards eligible proposals to the Technical Review Panel (TRP) for

review, which recommends them for Global Fund board approval. The board approves grants based on technical merit and availability of funds. Countries that have two proposals rejected can appeal the second decision.

The following is a brief description of the Global Fund process after the grant is approved for readers that are unfamiliar with the process, which is taken from the Global Fund's website[3]—

1. The Secretariat contracts with one LFA per country. The LFA certifies the financial management and administrative capacity of the nominated PR(s). Based on LFA assessment, the PR may require technical assistance to strengthen capacities. Development partners may provide or participate in such capacity-building activities. The strengthening of identified capacity gaps may be included as conditions precedent to disbursement of funds in the grant agreement between the Global Fund and the PR. In addition, the LFA makes an assessment of the procurement capacity and M&E capacity.

2. The Secretariat and PR negotiate grant agreement for the first two years of the grant (Phase 1), which identifies specific, measurable results to be tracked using a set of key indicators.

3. The grant agreement between the Global Fund and the PR is signed. Based on a request from the Secretariat, the World Bank makes initial disbursement to the PR. The PR makes disbursements to SRs for implementation, as called for in the proposal.

4. Program and services begin. As the coordinating body at the country level, the CCM oversees and monitors progress during implementation.

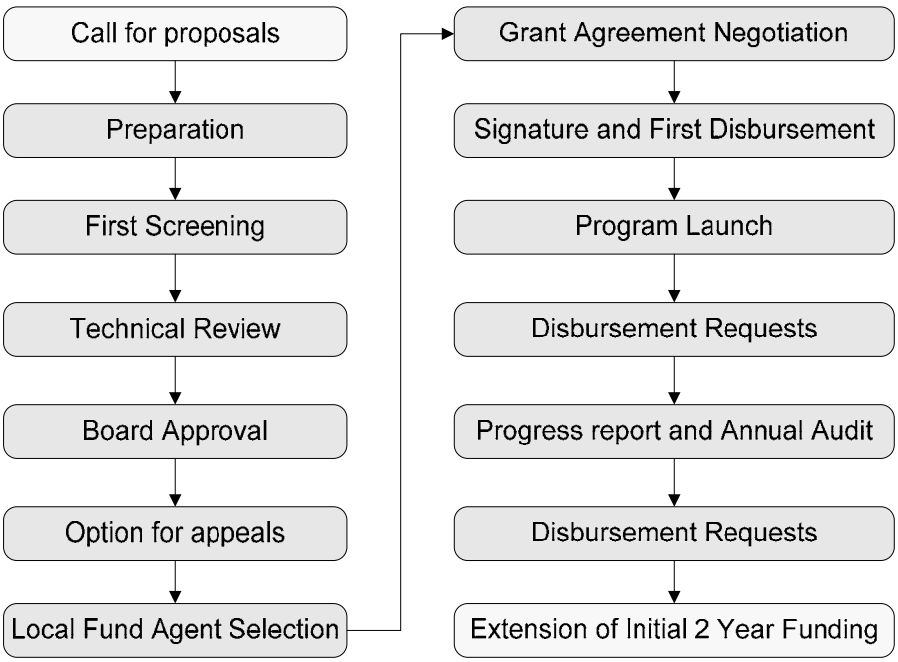
5. The PR submits periodic disbursement requests with updates on programmatic and financial progress. The LFA verifies information submitted and recommends disbursements based on demonstrated progress. Lack of progress triggers a request by Secretariat for corrective action.

6. The PR submits fiscal year a progress report and annual audit of program financial statements to the Secretariat through the LFA.

7. Regular disbursement requests and program updates continue, with future disbursements tied to ongoing progress.

8. The CCM requests funding beyond the initially approved two-year period (Phase 1). The Global Fund approves continued funding based on progress and availability of funds (Phase 2).

[3] See <http://www.theglobalfund.org/en/apply/proposals/>.



Source: <http://www.theglobalfund.org/en/apply/proposals/>.

Figure 1. Global Fund proposal approval and implementation process

CASE STUDY: GHANA

Background

Ghana has a decentralized central government administration system at the local government level with 10 regional coordinating councils and a total of 138 metropolitan, municipal, and district assemblies. Ghana's malaria program falls under the NMCP in the GHS. Since 1999, Ghana has committed itself to the RBM Initiative and developed a strategic framework to guide implementation. Until recently, Ghana used chloroquine as the first-line treatment for malaria. However, following unacceptably high cases of parasite resistance to chloroquine, a policy of artesunate and amodiaquine was adopted in accordance with the WHO recommendations for uncomplicated *Plasmodium falciparum* malaria.

Ghana has been awarded USD 27,410,858 for malaria from the Global Fund during Rounds 2 and 4. Activities in Ghana's Round 2 malaria proposal aim to accelerate access to prevention, care, support, and treatment of malaria for targeted persons in 20 districts. Activities in the Round 4 proposal aim to reduce malaria mortality and morbidity in children under five years of age and pregnant women by 25 percent by 2008 through improved access to prevention and treatment of malaria, including implementing the new treatment policy in all 138 districts in the country. In both cases, the PR is the Ministry of Health (MoH)/GHS, and the SR, the main implementer in GHS, is the NMCP. The LFA is PricewaterhouseCoopers.

ACT procurement and implementation were included only in the proposal developed for Round 4, and therefore the activities and processes described, although relevant to both proposals, specifically refer to the implementation of activities outlined in the Round 4 proposal. Table 3 summarizes the malaria grants in Ghana.

Table 3. Summary of Grant and Other Data for Ghana

Round	Grant Number and Date Signed	PR/ SR	LFA	Total Amount (USD)	Approved Funding (USD)	Amount Disbursed to Date (USD)	Procurement Budget in Agreement (USD)
4	GHN-405 G04-M February 8, 2005	MoH/GHS/ NMCP	Pricewaterhouse-Coopers	18,561,367.00	Phase 1: 18,561,367.00	16,891,410.00	8,613,676.00
Total	**—**			**27,410,858.00**	**27,410,858.00**	**23,469,068.00**	**11,976,366.00**

Proposal Development

Proposal development in Ghana involved key stakeholders with wide ranging expertise contributing to the subsequent ownership of the implementation process. Following a call for proposals by the Global Fund, the CCM invited interested parties to submit relevant concept papers. After receiving the papers, the CCM set up technical teams to develop the concept papers into proposals focusing on specific areas for subsequent approval by the CCM. The technical teams were made up of the program managers, select CCM members, and MoH experts. Global Fund partners and bilateral agencies in-country (for example, the United Nations Children's Fund [UNICEF], WHO, the U.S. Agency for International Development [USAID], MoH/GHS, Noguchi Memorial Institute for Medical Research, and other nongovernmental organizations [NGOs]) offered technical support to the process. Civil society institutions, such as NGOs and church mission hospitals, were not involved at this stage.

Procurement and supply chain management were not covered in sufficient detail until the PSM plans were developed for the Round 4 proposal. Before the proposals were finally approved, the Global Fund's Technical Review Panel requested some clarifications, but none related to procurement or supply chain management.

Selection of the PR

The MoH/GHS was selected as the PR for both the Round 2 and 4 proposals based on its experience in the three Global Fund diseases and existing capacity for program and financial management and implementation including procurement. Recent discussions have raised the possibility of having a civil society representative as an additional PR to complement the MoH/GHS.

LFA Assessment of PR Capabilities Related to PSM

The LFA assessed the PR's PSM capabilities for the Round 4 proposal in January 2005 and concluded that the PR's capacities and systems fully satisfied the minimum requirements for procurement of ACTs. However, the LFA felt that capacity gaps existed in forecasting, as evidenced by the inconsistencies in the quantities of ACTs required in the original grant application, the PSM plan/questionnaire, the PSM narrative plan, and the final version of the budget submitted to the Global Fund. The PR subsequently said the quantities of ACTs to be procured as part of the Global Fund grant had to be reduced because of limited funds. The LFA found that these discrepancies could be overcome by a quantification of the shortfall in funding by the PR and an assessment of options to fill this gap. Distribution, management, and coordination were identified as other areas of weakness. Specifically, the PR needed to clarify how ACTs would be integrated into the distribution system and to what extent cost-recovery or exemption mechanisms would be implemented in the public system. In addition, the LFA recommended that the timing of district-level implementation and training be harmonized.

The budgets were critically reviewed at the negotiation stage, and because the Global Fund has few provisions for contingencies, adjustments were made in areas such as vehicles and training to introduce cost-saving procedures. The grant agreement for the Round 4 proposal contained no conditions precedent to be satisfied before future disbursements could be made.

Role of the CCM

The Ghana CCM is largely independent of the government and comprises a wide-ranging technical membership that appears to have contributed to its acceptance by other implementing partners.

The Global Fund through the grants funds the activities of the CCM; however, this level of funding is thought to be inadequate by the CCM. The financial constraint on the CCM, which has a secretariat of two staff members, adversely affects its oversight role.

The CCM monitors activities quarterly. A permanent M&E team was created to integrate the monitoring for malaria and HIV/AIDS. Comprising technical personnel, representatives from the CCM, and independent monitors, the M&E team also has a finance committee that monitors financial records and verifies the PR's financial reports before they are presented to the main CCM assembly.

PSM Plan Development

Before implementation of the Global Fund proposals, the MoH had a general procurement plan for all medicines procured by the public sector. The MoH developed a PSM plan for the Round 4 proposal for malaria. The main problem with the PSM plan was that the MoH's Directorate of Procurement and Supplies and other implementers were not directly involved in the initial processes, which resulted in procurement and implementation milestones that did not correlate with available budgets, and disbursements and timelines that did not consider procurement lead times. In addition, the steps, processes, and timelines outlined in the PSM plan were not detailed enough to be useful during the implementation phase. Personnel from the MoH procurement unit have since participated in several subregional, regional, and other training workshops and seminars on different aspects of PSM.

Policy Issues

After unacceptable parasite resistance to chloroquine, the MoH set up a task force to review the evidence and the treatment protocols for malaria. Although various consensus-building meetings were held, many practitioners perceived that chloroquine was still effective, which resulted in later challenges with provider adherence to the new STGs. Furthermore, manufacturers alleged that they had not been properly involved and informed of the policy change process, so chloroquine was still widely available in the market. WHO and Global Fund recommendations that countries change their first-line treatments and reprogram existing funds to procure ACTs

accelerated Ghana's decision to change treatment protocols. The policy change was, therefore, greatly influenced by the desire to access Global Fund financing.

The revised STGs for malaria were published in December 2004, and the official change in the treatment policy to the artesunate-amodiaquine combination occurred in January 2005, but the actual implementation started in October 2005 when disbursements for the Round 4 grant began. The legal status of ACTs was changed from a prescription-only medicine to an over-the-counter medicine to enable their distribution and use at all levels of health care delivery.

Meanwhile, the Ghana National Drug Program (GNDP), the national drug regulatory authority, had registered a locally manufactured compressed dosage form of artesunate 200 milligrams (mg) and amodiaquine 600 mg that was being marketed and sold in the private sector, mainly in private clinics. It is unclear whether this product had received any quality testing by the GNDP. At the initial stages of implementing the new ACT policy, some public health facilities procured this artesunate-amodiaquine combination with the higher amodiaquine content than recommended in the WHO treatment guidelines for malaria directly from the local manufacturers. At this time the providers in the public sector had not been trained in the new STGs and the NMCP had not launched its communications campaign about the policy change. Adverse drug reactions (ADRs) to the amodiaquine in this locally manufactured combination resulted in highly publicized negative national opposition to the new treatment guidelines. Consequently, compliance with the new policy has been poor at all levels of the public health system.

Furthermore, adherence in the teaching hospitals has been poor because the hospitals consider the program to be a GHS program. Data from the field indicated that at the end of June 2006, 17.5 percent of the total target population had been treated with the new antimalarial medicines compared with the target of 60 percent that was set at the beginning of implementation; therefore, only 30 percent of the target was reached. Actions to counter the negative press included setting up a policy implementation review committee to make relevant recommendations to address the issue and withdrawing the locally manufactured products from the public and private sector markets. At the time of this assessment, the reports of ADRs had ebbed considerably, and many facilities were implementing the new STGs.

Quantification of Antimalarial Medicines and Supply Needs

The CCM and PR created a PSM task team responsible for PSM functions including quantification. The quantification of the ACTs to be procured using the Global Fund monies was based on public sector malaria morbidity data. WHO and UNICEF provided some technical support, and malaria program staff attended regional trainings on quantification organized by partners.

The LFA assessment of PSM capacity had identified forecasting as an area with critical weaknesses. The LFA concluded that disparities existed in quantities of ACTs stated in the various documents submitted to the Global Fund; the PR reduced the quantities to be procured using Global Fund resources because of limited funds available. The LFA had recommended that

the PR quantify the shortfall and explore other options, such as negotiating additional funding from the Global Fund, reallocating funds from the Round 4 malaria grant budget, obtaining funding from other health partners, or supplementing funding from the Government of Ghana. It was decided that the Government of Ghana would procure 40 percent of the public sector requirement of artesunate-amodiaquine with the remaining 60 percent being procured using Global Fund resources. The government, however, did not follow through with the procurement using its own resources, resulting in widespread stock-outs of artesunate-amodiaquine within a few months of implementation. The first procurement of 3.2 million doses using Global Fund resources did not cover consumption for six months as planned. Therefore, the quantification had to be redone, and a second procurement had to be carried out sooner than initially planned.

At present, no efficient systems are in place to validate the forecasts by monitoring consumption of ACTs; therefore, accurate quantification continues to be challenging. This problem is being addressed by using a supervision checklist to collect data on quantities of ACTs dispensed from the facilities.

Grant Signing, Receipt of the Funds, and Disbursements

The start date for the implementation of the Round 2 proposal was September 1, 2003, and for Round 4, March 1, 2005. Generally, procurement-related funds are released between two and three months after signing the grants, but in Ghana the first disbursement for Round 4 procurement occurred less than one week after signing.

The PR's accounts department collates the requests for funds through the various implementers of the Global Fund grant. This request for disbursement is then sent to the Global Fund through the LFA. Requests normally take 10 to 14 days to process at the Global Fund level, and the payment takes about 2 to 3 days to clear after it has been deposited. No significant delays in disbursements were reported.

Procurement, Receipt of Goods, and Custom Clearance

The Directorate of Procurement and Supplies is responsible for procurement activities in Ghana. A new procurement bill in 2005 that intended to provide better transparency and efficiency actually increased the average time required to satisfy all requirements to eight months. To avoid the delays associated with competitive tenders and other new processes, the PR contracted MMSS to procure the ACTs.

All requests to MMSS were made through the WHO country office. The Procurement Unit of the PR indicates the specifications and the quantities of artesunate-amodiaquine needed. MMSS then obtains quotations for the ACTs. In Ghana, local manufacturers lobbied intensely to bid for the supply of the artesunate-amodiaquine combination. However, because they were not WHO prequalified or GMP certified—a requirement under Global Fund standards of quality assurance—they were not considered.

The Ghana MoH has strict guidelines and standard operating procedures for product receipt and storage. In Ghana, tax exemptions are granted by the Ministry of Foreign Affairs for donated medicines and medical equipment as well as for medicines classified as "program medicines." In the case of ACTs, WHO obtained the letter of exemptions to forward to the customs department for endorsement. A mutual understanding between WHO and the governmental agencies facilitated entry of the ACTs by allowing the goods to be cleared before the final documents for the exemptions were made available to the port authorities. The Ghana Supply Company, a government-owned agency and the clearing agent for WHO, cleared the ACTs within 48 and 72 hours of receipt and delivered them to the Central Medical Stores for distribution. Although no duties are paid on the ACTs procured through WHO, the PR had to pay for local port processing, administrative charges, goods clearance, workspace, staff, and utility bills. Some of these costs directly pertaining to the procurement of ACTs should have been built into the proposal but were not.

At the time this study was conducted, MMSS had carried out two procurements of pre-packaged artesunate-amodiaquine from Ipca and Sanofi-Aventis in accordance with the Global Fund approved list of products. In general, apart from the inadequate quantification that led to stock-outs during the early stages of implementation, Ghana has not had any real problems in procuring ACTs. Delays of about three months were experienced in sending funds after receipt of the pro forma invoices for both orders, which were attributed to the PR's need to reconcile quantities and communicate with the Global Fund on the direct transfer of funds. In addition, some delays occurred in approving and signing procurement requests—these delays have now been reduced to about four weeks at most. Both orders were dispatched almost exactly at the expected time that was initially communicated by the supplier through MMSS to the PR.

Payment to suppliers was made from grant funds deposited in Ghana. Later, the PR requested the Global Fund to send the funds directly to the supplier, who then forwarded the delivery schedule directly to the PR. This procedure avoided losses from converting currency caused by foreign exchange fluctuations.

In Ghana, using the MMSS mechanism to procure artesunate-amodiaquine contributed to favorable pricing despite the handling fees and short procurement lead times. Countries need to balance the efficiency and cost savings from the price of the medicines against the potentially higher costs of handling charges and insurance of this mechanism. Delegating procurement and shipment clearance to outside professionals also yielded good results. Involving well-established and experienced procurement agencies, such as Crown Agents, worked well for some components of the malaria grant. Crown Agents is responsible for financial reports, payments to suppliers, and freighting. The contractors' track records of transparency and supplier confidence have freed the PR from arduous documentation and allowed the PR to concentrate on program implementation. The procurement contractors also helped in forecasting and defining specifications for products.

Training and Communication

The NMCP organized training for health providers in the public sector on the new STGs as part of the implementation of the Global Fund grant. Training began in July/August 2005; three months after the first consignment of ACTs arrived, and continued to January 2006. The training activities and targets did not immediately precede the delivery of the ACTs in-country, and insufficient planning led to a miscalculation of the time needed to train all the cadres of health providers throughout the country. Meanwhile, the medicines were kept in the central and district storage facilities before distribution began in October 2005. ACTs were allocated to each health facility only after the providers in that facility had been trained. By February 2006, 110 percent of the public sector training target had been achieved. Private medical practitioners and private midwives were also trained on the new medicine policy. The training for the private sector practitioners, which began in January 2006, was coordinated by the private sector in collaboration with NMCP. As of the end of June 2006, more than 5,000 community-based agents had been trained in the private sector.

The CMS also conducts in-service training for staff and for those deployed as service personnel in areas such as stock management, inventory, and handling. No national-level training has been conducted on pharmaceutical supply management for pharmacists or procurement and logistics management personnel.

During the training period, the government launched a communications campaign to prepare for rolling out new medicines to the facilities. This campaign included information, education, and communication (IEC) messages through radio, television, and print materials for health providers. The media advertisements were, however, put on hold after negative publicity in the press followed a spate of adverse events associated with the locally manufactured medicines, as mentioned earlier.

Distribution and Storage

The NMCP developed Ghana's distribution plan for the artesunate-amodiaquine tablets procured under the October 2005 Global Fund malaria grant in conjunction with the training plan of the health providers so that distribution would begin only after training had been conducted in those facilities. The ACTs were stored in the central and district storage facilities for almost four months until the training began. The NMCP developed a distribution list that included the quantities for distribution to the 10 regions in the country based on case prevalence in the regions' facilities, the military and police hospitals, and two teaching hospitals. Products were accompanied by issue vouchers; ledgers, inventory cards, and stock valuation are also monitored to ensure that the exact amount and type of products dispatched from the medical stores are received at the facilities. A new method encompassing scheduled deliveries from the regional stores down to the facility levels was being implemented at the time this report was written. The CMS will finance these deliveries without any additional price markup.

Challenges faced in the distribution and storage of the ACTs were (a) inadequate storage space in the smaller facilities, (b) inadequate capacity for quantification, and (c) delayed distribution

caused by the quick arrival of the medicines and the delayed training and communication strategy.

M&E: Program Indicators and Milestones, Action Plans, and Budget

The NMCP has recently appointed additional staff to be in charge of implementation in three zones in Ghana (a total of 10 regions). The staff carries out extensive monitoring that covers regional, district, subdistrict, and facility- and NGO-level activities. This arrangement has enhanced the timely identification and solution of problems. Data collection is primarily undertaken by the zonal officers, but this practice has been cumbersome and costly because of travel expenses. To improve the quality of data collection, regional and district malaria focal persons across Ghana were trained to routinely monitor activities from the facility to the regional level. Although data collection skills have been improved, better coordination and incentives are required to achieve data completeness and timeliness of reporting. Some districts are still not reporting regularly, and some health facilities in some districts fail to report at all.

The LFA receives quarterly reports from the PR, reviews and approves the reports, forwards them to the Global Fund, and requests the subsequent funding for the PR. No funding requests have ever been refused outright. Initially, reporting was difficult because of the paucity of data officers to consolidate data for all the regions. This issue was addressed by adding more data officers. The PR was spending a large proportion of time on reporting for the Global Fund but is computerizing the reporting formats to make more time for program demands. The LFA is also conducting an analysis of the PR's monitoring tools and assessing how the PR takes action when the reports indicate a need for intervention. In addition, the LFA has recommended that the PR install and implement accounting software. At times, the LFA must visit the SR when answers recorded at the PR level are not satisfactory.

The indicators and milestones related to procurement of medicines and goods were fairly well defined and maintained as outlined in the original proposal. An impact assessment has not yet been carried out, but the external monitoring of the grant implementation for malaria in Ghana by the LFA and the Global Fund has shown a strong adherence to the grant's original milestones.

Treatment targets were slow to be achieved mainly because provider adherence was poor and training targets were not closely correlated with distribution targets. Nevertheless, initial analyses indicate some improvements in mortality due to malaria in the general population. One of the main reasons that the targets are being met is because funds from other programs were available to cover many of the general PSM activities. However, the resources earmarked for grant implementation M&E were too small.

Management and Coordination

Coordination between the PR and SR has facilitated the implementation of the malaria grant in Ghana. Regular meetings are held between the PR and SR that include discussion of the funds

available for the implementation of activities under the Global Fund proposals and help make the process more transparent.

LESSONS LEARNED

The case study identified the various bottlenecks faced in Ghana when implementing their Global Fund malaria grant. Ghana experienced few challenges during the procurement process; the ACTs arrived in the country with minimal lead time. Most of the limitations experienced in Ghana can be attributed to precipitated preparatory stages of implementation including planning for complementary activities, such as training and supply chain management. In addition, there was inadequate quantification and problems with provider acceptance and adherence to the treatment policy.

Lessons learned from the Ghana experience in implementing their Global Fund grant for malaria are discussed below:

General

Resource mobilization for critical activities not already planned may alleviate serious implementation bottlenecks.

Ghana was able to overcome the shortfall in resources for procurement by making funds available from other activities and negotiating with the Global Fund. Countries with serious shortfalls in funds for critical activities may consider if funds can be released from other activities and engage the Global Fund in discussions on reallocating funds, adjusting workplans, and also the possibility of forward funding for urgent needs.

Effective Coordination among Stakeholders

MOUs or other contractual mechanisms among PRs, SRs, and other implementers may help establish or create greater accountability.

Applicants for Global Fund grants must ensure compliance with the Global Fund requirements, which stress the need to develop clear mechanisms for accountability between the PR, CCM, and implementing partners. Although Ghana did not have any MOUs between the PR and SR, they have able to operate efficiently due to other contractual arrangements that existed in the public sector.

Incorporating potential stakeholders including those in the private sector early in the process promotes ownership and subsequent acceptance and adherence to the policy.

Key stakeholders within the MoH and external partners with specific strengths were involved at all stages of proposal development and program implementation, which had a significant positive impact on Ghana's grant implementation. Ensuring that the main stakeholders from all levels of implementation (including the peripheral levels of the health system, such as district and facilities) are involved in some aspect of proposal development and in defining activities and

milestones may promote ownership and accountability. Pharmaceutical manufacturers may have the potential to form a strong lobby group and impact the acceptance of the new treatment. In Ghana, the manufacturers were not involved in the process and this may have contributed to their direct distribution of the locally manufactured product directly to some health facilities.

Appointing a PR that is involved in the process from proposal development with the CCM may avoid potential discord during implementation.

The PR, the GHS/MoH, worked with the CCM with little conflict starting from the proposal development stage and continuing through grant implementation. This may have facilitated a congenial context for implementation activities.

Creating mechanisms for coordination and collaboration among PR, SR, and other implementers assists in the implementation process.

The CCM in Ghana has also maintained an increased level of involvement and ownership which has facilitated its oversight role. The PR, SR, and the CCM enjoy open channels of communication and mutual respect.

Decentralizing resources can enable a more rapid implementation process.

Ghana's decentralization of the implementation funds enabled flexibility in its grant implementation.

Delegating specific functions while maintaining oversight has the potential to liberate the PR for other macro-level activities.

Ghana's delegation of certain procurement functions, such as shipment clearance, forecasting, and product specifications, to external agencies has freed the PR from arduous documentation, allowing it to concentrate on its main tasks related to program implementation.

Experience of the Principal Recipient

Selecting PRs on the basis of stricter criteria that measure their capacity and ability may promote great credibility and smoother implementation.

In Ghana, the PR enjoys a high status and is recognized as a technical coordinating body. Furthermore, the GHS/MoH had established credibility through its existing relationships, its channels of communication with the SR and other implementing partners, and its chains of accountability within the public health sector. It therefore did not have to invest time and resources in building capacity or in establishing these relationships.

Insuring that PRs have experience and capacity in procurement and supplies management reduces bottlenecks in these processes.

In Ghana, the PR was experienced in all areas of implementing malaria treatment policies and had access to procurement and supply chain management networks and external assistance that facilitated the planning and processes of implementation.

Procurement and Distribution Planning

Developing implementation, procurement, distribution, training, and M&E plans soon after the proposal is approved and before implementation begins facilitates appropriate planned implementation.

One of the biggest strengths in Ghana was that the PR began planning for implementation using a coordinated approach involving a variety of stakeholders very early in the process. This enabled a rapid endorsement of the new recommended treatment and the order placed quickly for the ACTs. The main challenge in implementing the Global Fund grant in Ghana was a lack of sufficient planning for complementary activities such as training leading to subsequent delays in implementation.

The following written plans are crucial to a successful rollout of ACTs—

- An **implementation plan** should describe each step, timelines for each step, roles and responsibilities for each partner, and budgets. Before the start of implementation, transitional committees should outline the documentation needs and appropriate budgets at each stage of the implementation process. Working groups for specialty areas can be convened to address specific issues.

- A **procurement plan** should outline each stage of the procurement process, the roles and responsibilities of all the stakeholders in the procurement process, and an inventory of any documentation that may be needed with specific timelines attached to each activity.

- A **distribution plan** should lay out the distribution steps and describe the roles and responsibilities of the various partners involved in distribution. The plan should list the quantities to be distributed to different districts, and it should include a detailed budget and source of resources for getting the commodities to the facility level.

- A **training plan** should include clear timelines for activities. A training strategy to introduce new standard treatment guidelines should be planned to coincide with the product's arrival in the country.

- A **M&E plan** should outline targets and milestones, and list activities, roles and responsibilities, data needs and sources, frequency of data collection, and supervisory

schedules. A logical relationship should exist between the indicators and targets proposed in the M&E plan and the rollout of the PSM plan.

The PR and SR developed an implementation plan in collaboration with other partners. However, the timing of the training was not considered and the time taken to train was underestimated.

The appointment of technical working groups facilitates planning for implementation.

The CCM appointed technical committees within its structure with members co-opted on the basis of expertise to develop appropriate plans with activities and timelines. This has appeared to facilitate ownership of the process.

Including provisions for technical assistance and capacity building in key areas ensures budgets are available with minimal time lag for obtaining such assistance.

Technical assistance was not adequately built into or budgeted for the Ghana proposal. Although Ghana was able to access technical assistance for some activities through additional donor funding and existing mechanisms for accessing such technical assistance, entities involved in developing proposals ought to consider the country's capacity and make provisions for obtaining external assistance as needed and plan early for technical assistance in areas where capacity is weak. Including capacity building in key areas such as M&E, quality assurance, and systems strengthening to complement the implementation activities within the proposals ensures that adequate budgets are available for these actions.

Quantification and budgeting adequately for the medicines while developing mechanisms to ensure that governments follow through on their budget commitments facilitates the availability of an uninterrupted supply of medicines.

The funds allocated to procure ACTs in Ghana's Round 4 grant were not adequate because of the assumption that the Government of Ghana would scale up the purchase of more ACTs, which did not happen. Appropriate budgets need to be allocated at the proposal planning stage with widespread consultation with the various agencies within government.

Budgeting adequately for complementary activities, such as customs clearance, distribution, and M&E ensures budgets are available for these activities with minimal lead times.

The proposal budget did not sufficiently account for the implementation costs, especially for activities occurring after the medicines arrived in the country, such as warehousing and distribution. Ghana has no waivers for port clearance, value-added taxes, national health insurance levies, and some other charges, even for donated products, so these funds must be budgeted for at the proposal stage to avoid delay of the goods at the ports. The proposal budget may also include resources for activities such as customs clearance and for administrative costs,

such as work space, human resources, utilities, and data collection and reporting.

PSM Plan Development

There was inadequate emphasis placed on the PSM plan development; the plan lacked details, including specific timelines with clear-cut roles and responsibilities. In addition, the milestones and targets were neither aligned with fund disbursement nor realistic, which made reporting difficult. In Ghana, the PSM plans were developed by the SR in consultation and collaboration with institutions and external partners in the country. Although the plans lacked essential details, they were at least developed by parties that understood the country's PSM system.

Procurement

Direct disbursement by the Global Fund to the suppliers reduced procurement lead times.

In Ghana, the procurement process was fairly smooth, facilitated in part by the Global Fund sending a direct disbursement to WHO for the ACT procurement. Besides simplifying the logistics, the direct payment also circumvented losses from converting currency caused by foreign exchange fluctuations. The first consignment of ACTs arrived in Ghana four weeks after placing the order.

Planning, placing orders early, and rapid payment reduces lead times.

Ghana placed an order for artesunate-amodiaquine and paid for it in full shortly after the grant agreement was signed thereby facilitating a procurement lead time of about one month.

Clearly the selection and ordering of an ACT that is in abundant supply also facilitated the short procurement lead time; countries need to consider the implication of choosing a single-source first-line treatment versus a multiple source product.

Using external procurement agencies reduces lead times.

Ghana used Roll Back Malaria's MMSS to liaise with ACT suppliers, which led to favorable pricing and short procurement lead times for quality assured artesunate-amodiaquine in Ghana. Countries need to balance the efficiency and cost savings on the price of the medicines of this mechanism against potentially higher costs incurred from handling charges and insurance.

Supply Chain Management

Involving existing institutions involved in the country's pharmaceutical management, and using the existing distribution agency facilitates adequate buy-in and use of existing systems.

Using its existing pharmaceutical supply chain facilitated Ghana's procurement and distribution of ACTs to the facility level.

Clear standard operating procedures with forms and documents needed for recording facilitates inventory management, monitoring, and re-ordering of supplies.

In Ghana, standard forms and templates were disseminated to the facilities with the medicines to enable providers to track inventory.

Establishing systems to ensure that substandard products are not widely available to circulate in the market may minimize adverse drug reactions.

Poor quality ACTs produced by local manufacturers in Ghana compromised providers' and patients' confidence in the safety of the new treatment. Countries should therefore address the quality of the locally produced and imported medicines as part of a broader quality assurance system, which may include testing samples before registration and not granting registration for products that do not meet quality standards. Not registering products that do not comply with standard dosage schedules or quality standards may reduce the likelihood of them being procured and widely distributed

Establishing an ADR monitoring system may promote the early detection and removal of the product and restores provider and consumer confidence in the therapy

Ghana was able to institute a recall for the substandard artesunate-amodiaquine after the ADRs were detected; however, this did not occur until there had been a public outcry. Establishing a simple ADR monitoring system particularly for new products may promote the early detection and removal of the product and avoid adherence issues.

Involving practitioners in collecting data on ADRs lets them assess for themselves whether the data justify concerns over ADRs. In addition, countries should consider investing in a system for monitoring ADRs, particularly when introducing new medicines, and develop plans to respond quickly to potential problems.

Establishing a simple post-marketing system may detect substandard medicines early.

CCMs and PRs may consider including in their proposal the means to implement a simple postmarketing surveillance system to detect poor quality medicines on the market.

Collecting appropriate consumption data improves future forecasting.

Although locally manufactured ACTs cannot be procured under the Global Fund grant, in the event that health facilities use their own funds to procure them, adding the amounts procured to the inventory system may help to ensure realistic data on consumption for future forecasting.

Improving capacity for quantification helps to reduce stock-outs.

Inadequate capacity for quantification was one reason for the shortage of ACTs. Capacity should be built in-country to accurately forecast needs of antimalarials, and technical assistance should be sought in this area.

One of the challenges in distribution in Ghana was inadequate storage in the smaller facilities. Storage capacity should be assessed early in the planning process. In the event of inadequate storage at peripheral areas, smaller quantities should be delivered to the facilities with replenishment at regular intervals from the district level.

Training and Communication

Coordinating training to begin before medicines arrive in country and end before distribution begins facilitates minimal time lag for distribution while ensuring that health providers have effective recall of issues at distribution.

Training schedules need to be correlated with medicines' procurement and distribution so that health care providers are familiar with the new treatment guidelines before they receive the medicines in the health centers. Training should begin at least three months before the medicines are dispatched. Training too early will result in providers forgetting the information, and training too late will lead to long lag times for distribution, decreased acceptance of the new treatment, and confusion. If procurement is delayed, training should also be delayed. Planning needs to consider that nationwide training may take some months to complete; in the case of Ghana, it took six months. In Ghana, training began after the ACTs had already arrived in the central storage facility, which delayed distribution of the medicines. Insufficient planning also led to Ghana underestimating the time needed to train all the cadres of health providers throughout the country, which resulted in a delay in meeting the training targets. Distribution and training plans were coordinated to ensure that training of health providers was carried out before the distribution occurs.

Training all health system cadres in key pharmaceutical management functions improves the supply chain management of the commodities.

Training in storage and inventory management should be carried out at all levels of the health care system and include all cadres of staff.

Mechanisms to improve treatment adherence and acceptance improves patient outcomes.

Although Ghana revised its communication strategy to address the ADR concerns arising from the higher content of amodiaquine in the artesunate-amodiaquine combination, at the time of this assessment, providers were still not fully adhering to standard treatment guidelines.

An additional challenge in Ghana was that stakeholders at the teaching hospitals perceived the new treatment policy as applying only to the Ghana Health Service and not them. Broad communication messages may not be enough to target key stakeholders, and behavior change communication strategies may need to be developed.

Program Monitoring, Evaluation, and Reporting

Aligning milestones and targets with activities and fund disbursement facilitates the continual availability of funds for planned activities.

Overall, a clear framework which identifies specific, relevant, measurable and achievable results with a clear and logical fit among the grant's targets and milestones, the disbursement of funds, and the planned activities with synchronized timing may help to ensure that funds are available for the activities and facilitate the meeting of the targets. Good malaria expertise is required in order to develop and include the right indicators together with an understanding of the system's capacity to respond to increases in demand.

Recruiting staff to collect and analyze data helps with efficiency and long-term cost effectiveness.

Reporting in Ghana has benefited from the recruitment of officers in various technical areas and has helped free the PR from cumbersome monitoring and reporting—for example, field officers who report to the malaria control coordinator, and finance and administration staff who report to the PR finance director.

Assigning roles and responsibilities for reporting may assist in overall monitoring.

Monitoring to track, document, and address trends in program implementation must be carried out routinely, and a comprehensive framework that delineates the roles and responsibilities of those involved in monitoring and supervising implementation may affect overall implementation of the grant.

Developing a database for reporting and monitoring may save time and improve implementation.

Strengthening the system for collecting, analyzing, and reporting the results of monitoring activities at the state level will be a major factor in generating accurate country data. In Ghana, the PR spent a large proportion of total time on reporting for the Global Fund. After the situation was assessed at a training workshop, the PR has computerized the reporting formats to make more time for program demands.

Strengthening M&E systems may positively impact overall health systems.

The Global Fund's required linkage between reports on key indicators and disbursement has forced countries to improve their information systems, which has had a positive impact on overall health systems; however, countries would benefit from continuing to build capacity for supervision and monitoring. However, the PR and SR need to strengthen the system for collecting, analyzing, and reporting the results of monitoring activities at the district level. These results will be a major factor in submitting early and more dependable country data from the malaria control program.

CONCLUSION

Countries will benefit from familiarizing themselves with Global Fund procedures and processes and creating mechanisms for accountability within their own programs. The grant process—from proposal development to planning to implementation—should include key stakeholders to promote ownership of the process and minimize opposition. PRs and SRs need to agree on their respective roles and responsibilities and develop mechanisms for collaboration. Appointing PRs with the experience and capacity to implement large projects may limit the time spent on capacity building rather than on the final targets and health outcomes; PRs may consider delegating key responsibilities to expert institutions and decentralizing implementation activities while focusing on overarching activities.

Early planning which may include written documentation outlining activities with timeline estimates, and any needs for external technical assistance may facilitate the implementation process. However, while having detailed written plans is helpful, mechanisms need to be created to ensure that agreed-upon plans are implemented and that commitments are fulfilled. Plans also need to address the coordination of components such as policy changes, procurement, training, and communication to ensure that the preparatory steps are completed before medicines begin to be distributed to the facilities. Overall, a clear framework with realistic indicators is needed. In addition, a rational fit among the grant's targets and milestones, the disbursement of funds, and the planned activities with synchronized timing may help to ensure that funds are available for the activities and facilitate the meeting of the targets.

This case study has evolved since the assessment was conducted and therefore all recommendations may not currently apply to the specific cases. Nevertheless, the lessons learned offer valuable insights into the challenges that affected the implementation in Ghana. It must be noted that some of the challenges experienced such as delays in policy change and developing treatment protocols are peculiar to the introduction, transition, and implementation of ACTs with which many PRs, malaria control programs, and other implementers had little experience. These lessons may not be relevant to Global Fund recipients that are not implementing new limited source therapies. However, many of the identified issues such as the capacity to manage the procurement and distribution processes, inadequate information systems, and inadequate planning and quality assurance systems are valid for malaria grants for most PRs of other countries but also for other products and commodities.

ANNEX 1. PEOPLE CONSULTED OR INTERVIEWED IN NIGERIA DURING THE STUDY

Name	Organization/Position
Mr. Louis Agbe	CCM Chairman
Ms. Rosina Ampadu	Accountant MOH
Ms. Edith Andrews	EDM WHO
Mr. Samuel Asiedu Agyei	CCM Member (representing private sector)
Mr. Samuel Boateng	Director of Procurement and Supplies MOH
Dr. (Mrs.) Constance Bart-Plange	Program Manager National Malaria Control Program
Mr. Faustus Dasaah	CCM Administrator
Dr. Pradeep K. Goel	Infectious Disease Advisor; USAID Member of CCM
Mrs. Martha Gyansa-Lutterodt	Assistant Program Manager Ghana National Drugs Program, MOH
Mr. Peter Gyimah	Head Central Medical Stores, Tema
Mr. Samuel Hanson	Logistic Assistant WHO (procurement agents for the ACTs)
Rev. Prof. Adukwei Hesse	Consultant; former CCM Chairman
Dr. Ebenezer Incoom	UNICEF
Mr. Daniel Ekow Mensah	Former CCM Member
Mr. Benard Moro	Project Manager Crown Agents
Ms. BethAnne Moskov	Team Leader, Health USAID
Mr. Alex Nartey	Director of Finance MOH
Mr. Daniel Norgbedzie	CCM Executive Secretary
Mr. Benson Okundi	Director of Assurance PricewaterhouseCoopers; LFA, Ghana
Mr. Derick Oppong-Agyare	Quality Assurance, PricewaterhouseCoopers Ghana (LFA)
Mrs. Matilda Owusu-Ansah	HIV/AIDS Advisor DFID
Ms. Dorothy Rozga	UNICEF Country Representative
Mr. A. Manu Sarpong	PR Administrator MOH
Mr. Sylvester Segbeya	Program Officer National Malaria Control Program
Ms. Elena Trajkovska	Supply Officer UNICEF
Dr. Mark Young	Project Officer Health & Nutrition UNICEF