

Global Fund Grants for Malaria:

Lessons Learned in the Implementation of ACT Policies in Ghana, Nigeria, and Guinea- Bissau

Management Sciences for Health
is a nonprofit organization
strengthening health programs worldwide.



USAID
FROM THE AMERICAN PEOPLE

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

Rima Shretta
Catherine Adegoke
Peter Segbor
Melissa Thumm

August 2007

Global Fund Grants for Malaria: Lessons Learned in the Implementation of ACT Policies in Ghana, Nigeria, and Guinea-Bissau

Rima Shretta
Catherine Adegoke
Peter Segbor
Melissa Thumm

August 2007



Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmpplus@msh.org

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

This report may be reproduced if credit is given to RPM Plus. Please use the following citation.

Shretta, R., C. Adegoke, P. Segbor, and M. Thumm. 2007. *Global Fund Grants for Malaria: Lessons Learned in the Implementation of ACT Policies in Nigeria, Ghana, and Guinea-Bissau*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Key Words

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

Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
Web: www.msh.org/rpmplus

CONTENTS

ACRONYMS	v
ACKNOWLEDGMENTS	vii
EXECUTIVE SUMMARY	ix
Nigeria.....	ix
Ghana	x
Guinea-Bissau.....	xi
General Conclusions	xi
INTRODUCTION	1
Background.....	1
Objectives and Rationale of the Study.....	2
Methodology.....	2
Summary of the Standard Global Fund Process from Grant Application to Implementation	3
CASE STUDY: NIGERIA	5
Background.....	5
Proposal Development.....	6
Selection of the PR.....	6
LFA Assessment of PR Capabilities Related to Procurement, Supply, and Management	7
CCM Role	8
PSM Plan Development.....	8
Policy Issues.....	9
Quantification of Antimalarial Medicine Needs.....	10
Grant Signing, Receipt of the Funds, and Disbursements	10
Procurement	11
Training.....	13
Distribution and Storage	14
M&E: Program Indicators and Milestones, Action Plans, and Budget	15
Management and Coordination.....	16
CASE STUDY: GHANA	18
Background.....	18
Proposal Development.....	19
Selection of the PR.....	19
LFA Assessment of PR Capabilities Related to PSM	19
Role of the CCM.....	20
PSM Plan Development.....	20
Policy Issues.....	20
Quantification of Antimalarial Medicines and Supply Needs	21
Grant Signing, Receipt of the Funds, and Disbursements	22
Procurement, Receipt of Goods, and Custom Clearance.....	22
Training and Communication	23

Distribution and Storage	24
M&E: Program Indicators and Milestones, Action Plans, and Budget	25
Management and Coordination.....	25
CASE STUDY: GUINEA-BISSAU	26
Background.....	26
Proposal Development	27
Selection of the PR.....	27
LFA Assessment of PR Capabilities Related to PSM Capacities.....	28
Role of CCM.....	28
PSM Plan Development.....	29
Policy Issues.....	29
Quantification of Antimalarial Medicines and Supply Needs	30
Grant Signing, Receipt of Funds, and Disbursement.....	30
Procurement	30
Receipt of Goods and Customs Clearance.....	31
Training.....	32
Distribution and Storage	32
M&E: Program Indicators and Milestones, Action Plan, and Budget.....	33
Management and Coordination.....	33
SUMMARY OF FINDINGS and LESSONS LEARNED	34
Coordination among Stakeholders.....	34
Experience of the Principal Recipient.....	36
Procurement and Distribution Planning.....	37
PSM Plan Development.....	39
Procurement	39
Supply Chain Management.....	41
Program Monitoring, Evaluation, and Reporting	43
CONCLUSION.....	46
ANNEX 1. PEOPLE CONSULTED OR INTERVIEWED IN THE STUDY.....	53
Nigeria.....	53
Ghana	54
Guinea-Bissau	55
REFERENCES	57
Nigeria.....	57
Ghana	59
Guinea-Bissau.....	60

ACRONYMS

ACT	artemisinin-based combination therapies
ADR	adverse drug reaction
AFRO	Regional Office for Africa [World Health Organization]
AIDS	acquired immunodeficiency syndrome
CCM	Country Coordinating Mechanism
CECOME	Central de Compra de Medicamentos [Central Office for Purchasing of Medicines, Guinea-Bissau]
CMS	Central Medical Stores
FDS	Food and Drugs Service [Nigeria]
FMoH	Federal Ministry of Health [Nigeria]
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	Ghana Health Service
GMP	Good Manufacturing Practices
IEC	information, education, and communication
IPT	intermittent preventive treatment
ITN	insecticide-treated nets
LFA	local fund agent
LGA	local government area [Nigeria]
M&E	monitoring and evaluation
mg	milligram
MMSS	Malaria Medicines and Supplies Service (hosted by the RBM Partnership Secretariat)
MoH	Ministry of Health
MOU	Memorandum of Understanding
NAFDAC	National Agency for Food and Drug Administration and Control [Nigeria]
NGO	nongovernmental organization
NMCP	National Malaria Control Program
PNDS	National Health Development Plan [Plano Nacional de Desenvolvimento Sanitário; Guinea-Bissau]
PR	principal recipient
PSM	procurement and supply management
RBM	Roll Back Malaria [Initiative]
RPM Plus	Rational Pharmaceutical Management Plus
SP	sulfadoxine-pyrimethamine
SR	subrecipient
STGs	standard treatment guidelines

TB	tuberculosis
TRP	Technical Review Panel
UNDP	United Nations Development Programme
UNICEF	United Nations Children’s Fund
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization
YGC	Yakubu Gowon Centre for National Unity and International Cooperation [Nigeria]

ACKNOWLEDGMENTS

The fieldwork for this study was carried out by Rima Shretta, Catherine Adegoke, Peter Segnbor and Melissa Thumm while the report was written by Rima Shretta with inputs from the other authors. The authors wish to express their thanks to the following contributors from the Global Fund: Mabingue Ngom, Team Leader, West and Central Africa, and the Global Fund Portfolio Managers for Ghana, Nigeria, and Guinea Bissau — Blerta Maliqi, Mark Willis and Cyrille Dubois, respectively.

Thanks to all the key informants in Nigeria, Ghana, and Guinea-Bissau for the immense amounts of time they spent providing details for this report. The authors' thanks also go to Roselyne Souvannakane of the Global Fund and the Roll Back Malaria Partnership Secretariat particularly Dr Awa Coll Seck, Executive Director and Maryse Dugue, formerly of Malaria Medicines and Supplies Service of the RBM Partnership Secretariat for the information provided and for their inputs into the concept paper and data collection tools. Thanks also to Helena Walkowiak, Maria Miralles, David Lee, Martha Embrey, Patricia Paredes, Laurie Hall, Laura Glassman, DeeDee Clendenning, and Malick Diara.

EXECUTIVE SUMMARY

The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has approved malaria grants amounting to 2,584,874,749 U.S. dollars (USD) over five years, budgeting for more than 264 million treatments of artemisinin-based combination therapies (ACTs). Despite the availability of these resources, however, Global Fund recipients are facing significant challenges in using the allocated funds for procurement and in making the products available at the service delivery points as planned in the original proposals.

This report describes and analyzes the processes contributing to the implementation of ACTs under the Global Fund malaria grants in three countries—Ghana, Guinea-Bissau, and Nigeria—with a particular focus on procurement and supply chain management. Document reviews and in-depth interviews were conducted with grant stakeholders in all three countries between August and November 2006. In addition, discussions were held with the Fund Portfolio Managers of the Global Fund as well as other partners involved with procurement processes. The findings intend to assist principal recipients (PRs) in the three case study countries to apply the lessons learned to future challenges. In addition, other countries' PRs can benefit from the analyses of malaria grant procurement and supply chain management in the case study countries to (1) identify potential barriers and ensure that remedial actions are taken promptly for effective implementation, and (2) adapt recommendations and strategies used to address similar challenges in their countries to help implement their own grants.

The Global Fund selected countries based on their geographic location in the West African region and their varied status in implementing the malaria grants; Ghana procured the ACTs rapidly after the grant agreement was signed, Nigeria faced considerable bottlenecks at the procurement stage, while Guinea-Bissau had not begun the process of procurement at the time this assessment was requested and conducted. Both Nigeria and Ghana were awarded Global Fund grants for malaria during Rounds 2 and 4 while Guinea-Bissau was the recipient of a Global Fund grant during Round 4. Guinea-Bissau also received approval of its Round 6 malaria Global Fund grant application; however, this approval was announced after the fieldwork for this case study was completed and therefore is not included in the report.

Nigeria

The Round 2 grant agreement was signed in October 2004, just two months before the Round 4 agreement was signed due to delays in responding to clarifications requested by the Global Fund Technical Review Panel (TRP) for the Round 2 proposal, delays in appointing the PR, and the reprogramming of funds for the procurement of ACTs. Coartem[®] was officially adopted as the first-line therapy for treating uncomplicated malaria in February 2005, and procurement of ACTs using Global Fund resources began in May 2005. However, Coartem did not begin to arrive in the country until March 2006, nearly 15 months after the grant agreements had been signed. The reasons for this included—

- A global shortage of Coartem

- Limited procurement experience of the PR, Yakubu Gowon Centre for National Unity and International Cooperation (YGC); as a result, Crown Agents was contracted to manage the procurement issues, but limited understanding of the World Health Organization's (WHO) procurement process and failure to meet WHO requirements, such as advance payment and insurance requirements, resulted in delays
- The PR's limited knowledge of the documentation needed for importation, country duty waivers for customs, and the time taken to obtain these papers
- Overall poor planning and coordination between the PR and implementing partners
- Inadequate follow-up of processes and procedures

No distribution plan for the medicines was developed by the PR and SR until the shipment was about to arrive. Crown Agents was hurriedly contracted to distribute the product—who in turn subcontracted to a local firm. Although distribution was completed within four days of customs clearance, the lack of distribution plan resulted in quantities distributed that did not agree with the delivery notes in several states, and stock purchased using Global Fund resources was reportedly found in the private sector. Although the PR provided funds to the states to distribute the ACTs to the local government area (LGA) level for the first consignment of ACTs, no plans existed on how subsequent supplies would reach the facilities. Mechanisms to reorder Coartem once the initial stock was consumed were not established. Furthermore, because of the late arrival of the medicines, the PR and subrecipient (SR), the National Malaria Control Program, distributed the ACTs to non-Global Fund states to avoid expiration without having a plan for how or who will replenish the ACT stocks. Although the federal government was expected to provide treatment for the non-Global Fund states and for the population over five years of age, this commitment was not met. In the Global Fund states, this failure caused providers, under pressure from patients, to prescribe and dispense multiple pediatric packs for treating older children and adults, thereby using up the product faster than expected and confusing measurement of the actual consumption by specific age groups.

Ghana

In Ghana, the procurement process was fairly smooth, facilitated in part by the Global Fund's direct disbursement to WHO to procure ACTs. The first consignment of ACTs arrived in Ghana in April 2005, four months after the grant was signed and four weeks after placing the order. Because of delays in training health care providers on the new treatment guidelines, the ACTs could not be distributed for another six months and remained in storage. During this time, some public health facilities procured an artesunate-amodiaquine combination that is locally-manufactured and registered in the country, but that had higher quantities of amodiaquine than recommended by WHO. Furthermore, the product was not produced under Good Manufacturing Practices (GMP) standards, was not quality certified, and the factory has not been prequalified by WHO. The use of this product resulted in adverse drug reactions (ADRs) to the amodiaquine component, which led to poor acceptance of the new treatment policy at all levels of the public health system despite the efforts on training and communication to counter the negative press.

Inaccurate estimation of needs for implementing the Global Fund proposal and the failure of the government to procure ACTs for the 60 percent of the country not covered by the Global Fund grant resulted in the inadequate stock procurement, stock-outs, and the need for a subsequent emergency order of additional ACTs using funds from the Global Fund.

Guinea-Bissau

Guinea-Bissau did not officially endorse the change in the first-line treatment policy to artemether-lumefantrine until October 2006, a delay mostly caused by lengthy in-country processes and consensus building. In addition, competing priorities, poor planning, and limited human resources contributed to some of the challenges in implementing the new policy. Although resources from the Global Fund were not originally planned for procurement of ACTs during Phase 1 of the Round 4 malaria grant, funds could have been made available upon the submission to the Global Fund and approval of an implementation plan for the transition to ACTs. A final implementation plan was not submitted, however, for several reasons—

- Limited capacity for international procurement in country: although the United Nations Development Programme (UNDP) was chosen as PR to circumvent the limited capacity in the public sector, the UNDP country office has limited experience with procurement, quantification, and general pharmaceutical and supply management
- Little coordination and cooperation existed between the PR and the implementing partners
- Delays in mobilizing consultants to develop the implementation plan
- Partners' lack of knowledge that ACTs could be procured before Phase 2 of the grant began—therefore, it was assumed that there was no urgency to instituting the processes to complete the implementation plan to enable ACT procurement

The weak Country Coordinating Mechanism (CCM) and poor coordination between the PR and SRs also led to other problems, including delays in reporting on activities and budgets.

General Conclusions

Although each country experienced a unique set of issues, some general conclusions can be drawn about the lessons learned. Some of the challenges can be attributed to in-country processes, and a weak articulation of the roles and responsibilities of the various stakeholders involved. In Nigeria and Guinea-Bissau, coordination among key stakeholders, including the CCM, PR, SR, and other implementing partners, was poor and contributed significantly to delays in implementation. In all three countries, to varying extents, country key stakeholders in implementation were either not involved at all or not involved early enough in the process. The CCM needs to ensure that the main stakeholders from all levels of implementation (including the peripheral levels of the health system, such as states, districts, and facilities) work together to

develop the proposal, in developing targets and milestones, and in developing plans for implementation to ensure appropriate buy-in to the process.

Many of the delays in implementation were caused by a poor general understanding of some of the Global Fund processes. Although the Global Fund has developed guidelines for CCMs that elucidate the roles and responsibilities of the PR and CCM, and the grant agreements recommend that formal contracts be developed to ensure clear mechanisms for accountability among the implementing partners, these are not fully understood at the country level. Countries will benefit from familiarizing themselves with Global Fund procedures and processes and creating mechanisms for accountability within their own programs. Furthermore, operating funds for the CCM may be budgeted at the proposal stage to avoid future conflicts.

All three case studies demonstrate the need for CCMs to corroborate the level of expertise and technical capacity before nominating a PR, including that the processes it uses for procurement, logistics, and monitoring are effective. PR capacity building is a key activity in new projects, and if capacity is poor, time and budgets needs to be built into proposals and implementation plans for this purpose.

In all three countries, the planning for procurement and supply management (PSM) was inadequate leading to poor coordination of the implementation process. Even though the countries had either hired consultants or obtained external assistance to develop the written plans, in general they were lacking in detail, particularly in assigning specific timelines and clear-cut roles and responsibilities for completing activities. Furthermore, activities did not adequately match the corresponding targets and milestones.

The following written plans are crucial to successfully implementing ACTs—

- An plan that outlines each implementation step, timelines for each step, roles and responsibilities for each partner, and budgets
- A procurement plan outlining each stage of the process, and the roles and responsibilities of all stakeholders in the procurement process with specific timelines attached to each activity
- A distribution plan that lays out the distribution steps and elucidates the roles and responsibilities of the various partners involved in distribution and the quantities to be distributed to the various districts
- Plans for improving inventory management of the GF-funded products, including levels in which health facilities and storage facilities need to inform and reorder from province or central level
- A training plan with clear timelines for activities
- A monitoring and evaluation (M&E) plan with activities, roles and responsibilities, data needs and sources, frequency of data collection, and proposed supervisory schedules: a

clear relation and logical fit should exist between the indicators and targets proposed in the M&E and the rollout of the PSM plan

All three countries experienced challenges related to the capacity and systems for M&E, human resources capacity, and general investment in systems. Although PRs have found the Global Fund reporting requirements to be time consuming, countries have been forced to address and streamline their M&E systems to the benefit of the entire health system.

Many of the cases have evolved since the studies were conducted and therefore all recommendations may not currently apply to the specific cases. Nevertheless, the lessons learned from these case studies offer valuable insights into the challenges that affected the implementation of Global Fund malaria grants in Ghana, Guinea-Bissau, and Nigeria and about Global Fund procedures and policies. It must be noted that some of the challenges experienced in the three countries, such as delays in developing treatment protocols and training staff and producer capacity bottlenecks, were peculiar to the introduction, transition, and implementation of ACTs. 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, bureaucratic importation and customs procedures, inadequate information systems, and inadequate planning are valid for malaria grants for most PRs of other countries but also for other products and commodities.

Figure 1 illustrates the ideal situation in proposal development, grant approval, and implementation from the country-level perspective.

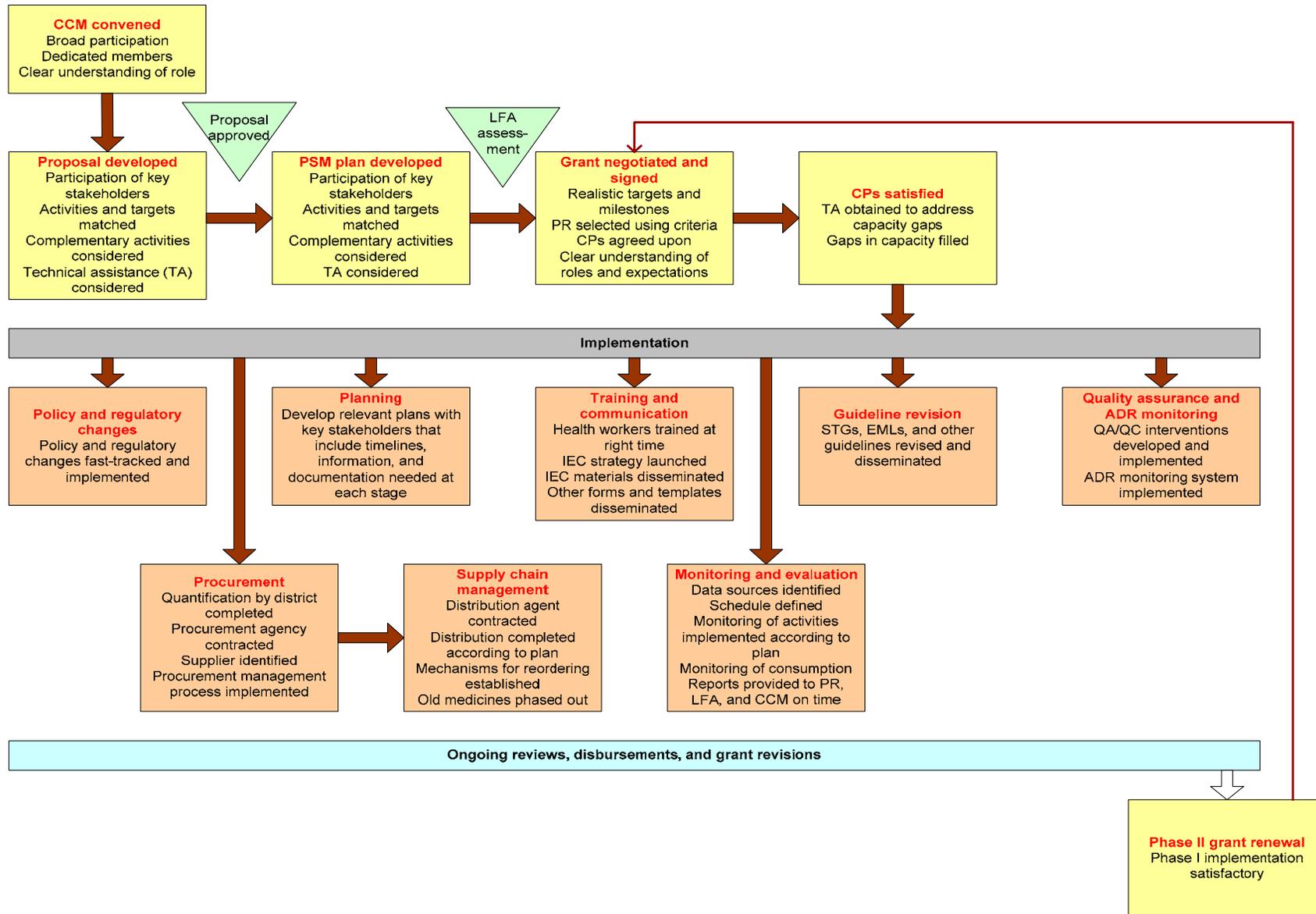


Figure 1. Process at country level in Global Fund proposal development and Implementation

INTRODUCTION

Background

In 2001, WHO recommended that all countries experiencing drug resistance to conventional malaria monotherapies such as chloroquine, amodiaquine, or sulfadoxine-pyrimethamine (SP), should change to artemisinin-based combination therapies.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 2004² 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 assessments in 2006, the Global Fund had approved malaria grants amounting to USD 2,584,874,749 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 funding, Global Fund recipients are facing significant problems implementing the programs as outlined in the approved project proposals and only part of the commodities needed have been procured so far. The Global Fund recognized that countries facing similar challenges in implementing their grants for malaria would greatly benefit from lessons learned from other countries in the region. Consequently, the Global Fund requested that the Management Sciences for Health Rational Pharmaceutical Management (RPM) Plus Program, in collaboration with the Roll Back Malaria (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 on 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.

¹ WHO (World Health Organization). 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 January 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 and Rationale of the Study

The study objectives were to describe the implementation of the Global Fund malaria grants in Ghana, Guinea-Bissau, and Nigeria; to identify the bottlenecks that the countries faced at each step of the implementation process; and to draw key lessons learned. The case studies are descriptive and focused on the procurement, supply, and distribution aspects of implementing ACTs as the new first-line treatment for malaria in the countries. While rational medicine use is key to the success of the malaria grants, assessment of this concern is beyond the scope of these studies. The three study countries' principal recipients (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 experiences 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 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, Supply, and Management (PSM) plans to distributing ACTs to health facilities
- Identify bottlenecks in the processes that contributed to delays
- Describe the steps taken to address these bottlenecks
- Draw lessons learned about how the three countries implemented their grants

Methodology

Each case study focused on tracing key events of the implementation process, from the development of PSM plans, receipt of funds, mobilization of key stakeholders for the procurement process, to the ultimate distribution of the medicines to the relevant end points. The case studies are intended to be descriptive, documenting the process of ACT policy change as part of the implementation of the Global Fund malaria grant, specific challenges faced, reasons for delays (if any), and actions that were taken to alleviate the challenges identified.

RPM Plus conducted meetings with the Global Fund and the Malaria Medicines and Supplies Service (MMSS) of the RBM Secretariat to refine the research questions and the scope of work and 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 document review was conducted for each country that covers malaria treatment guidelines, ministry of health and malaria program background documents, and Global Fund–related documentation.

In collaboration with the Global Fund and RBM Partnership Secretariat, RPM Plus developed a list of relevant stakeholders in each country who might provide information pertaining to the cases studied. In October and November 2006, RPM Plus conducted country visits of 7–10 days each in Nigeria, Ghana, and Guinea-Bissau, and met with stakeholders to collect relevant

documentation and to identify the various challenges and bottlenecks they had faced when procuring and distributing ACTs.

This report summarizes the findings and lessons learned, draws similarities and differences among the three case studies, discusses their implications for future programming, and presents conclusions.

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.

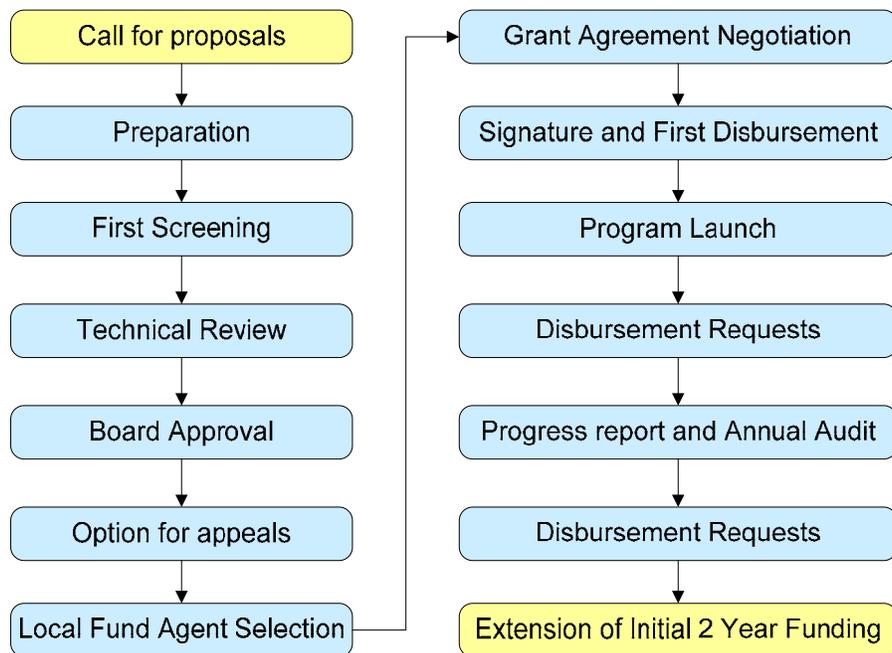
The following is a brief description of the Global Fund process after the grant is approved taken from the Global Fund's website³ for readers that are unfamiliar with the process—

1. The Secretariat contracts in each country with an LFA, an audit company, which certifies the financial management and administrative capacity of the nominated PR or PRs. Based on the 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 the M&E capacity of the PR.
2. The GF Secretariat and the PR negotiate the grant agreement for the first two years (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 subrecipients (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 updates on programmatic and financial progress with disbursement requests. The LFA verifies information submitted and recommends

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

disbursements based on demonstrated progress. Lack of progress triggers a request by the Secretariat for corrective action.

6. The PR submits a fiscal year 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).



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

Figure 2. Global Fund proposal approval and implementation process

CASE STUDY: NIGERIA

Background

Nigeria has a population of 140 million. The country has a pyramidal, decentralized administrative structure and is divided into 36 states plus the Federal Capital Territory. The states are further divided into 774 local government areas. The federal government level is responsible for developing policies and standards, the states offer technical coordination of programs and are involved in training, while the LGAs actually implement programs at the service delivery level.

The malaria program falls under the National Malaria Control Program (NMCP), which hosts the RBM Secretariat. Nigeria has a broad-based RBM partnership made up the Federal Ministry of Health (FMoH), multi- and bilateral organizations, the private sector, nongovernmental organizations (NGOs), community-based organizations, and regulatory bodies. High-level political commitment and support has been expressed for the RBM initiative in Nigeria, and a global malaria summit was held in Abuja in March 2000.

Nigeria has been awarded two Global Fund malaria grants—in Rounds 2 and 4. The Round 2 proposal covers a population of 4.4 million children under age five and 870,000 pregnant women in 12 states. Activities on this round focus on scaling up the coverage of existing strategies, including providing ITNs for pregnant women and children under age five, prepackaged treatments for children under age five, and intermittent preventive treatment (IPT) for pregnant women. Training of health personnel was one of the key strategies of this round. The Round 4 proposal focuses on home-based management, prompt and effective treatment, and on monitoring drug resistance.

When the Round 2 proposal was developed, chloroquine was the first-line treatment. However, before the grant agreement was signed, the Global Fund announced that countries needed to change their first-line treatments to ACTs, a more-effective treatment, in accordance with WHO recommendations, and reprogram their budgets for procurement to accommodate the new first-line treatments. In response, the PRs in collaboration with the NMCP adjusted their budgets and reprogrammed their funds to procure ACTs using funds earmarked from Phase 2. The Global Fund made these funds available for procuring medicines during Phase 1. The CCM expected that funds from the federal government would be used to procure ACTs for the remaining states not covered by the Global Fund grants and for the population over five years of age in all 26 states. The official endorsement of the new treatment, artemether-lumefantrine (Coartem), occurred in May 2005.

The CCM nominated the Yakubu Gowon Centre for National Unity and International Cooperation (YGC) to serve as the PR for both grants. The NMCP of the FMoH was nominated as the SR for the malaria grants. KPMG Professional Services was contracted as the LFA.

Table 1. Summary of Grant and Other Data for Nigeria

Round	Grant Number and Date Signed	Total Amount Awarded (USD)	Approved Funding: Phase 1 (USD)	Amount Disbursed to Date (USD)	Procurement Budget in Agreement (USD)	Current Procurement Expenditure (USD)
2	NGA-202-G04-M-00 October 22, 2004	44,314,691.00	20,994,149.00	14,597,437.75 ^a	2,880,000.00	3,081,186.00
4	NGA-404-G05-M December 3, 2004	86,122,000.00	20,467,000.00	7,145,340.64	15,120,000.00	8,399,211.56
Total	—	130,436,691.00	41,461,149.00	21,742,778.39	18,000,000.00	11,480,397.56

Proposal Development

The process of proposal development varied between rounds. For Round 2, the CCM placed an advertisement in the local print media requesting interested organizations and individuals to submit proposals. The CCM created a technical committee to review applications that was chaired by the WHO Country Representative and included representatives of national disease programs, members of academia, and others, as appropriate. Consensus meetings with a broader range of stakeholders identified and addressed gaps in the proposal. Consultants from outside the CCM were engaged to prepare the proposal for Round 4, which involved similar consensus building.

In both the rounds, PSM was inadequately covered at the proposal stage, partly because the information requested in the proposal forms did not cover important areas of PSM that the country needed to consider and partly because key stakeholders, such as the Food and Drugs Service (FDS), National Agency for Food and Drug Administration and Control (NAFDAC), the Central Medical Stores (CMS), or WHO's Department of Essential Drugs and Medicines in the country, were not involved in proposal development for either Round 2 or 4. An overarching problem was that there was no procurement expertise among the CCM members or the technical committee appointed to review the proposals.

Before the proposals were finally approved, the Global Fund TRP requested some clarifications, but these did not involve procurement or implementation capacity. Because of delays in responding to the queries, nearly six months passed before the TRP was satisfied and the Round 2 proposal approved which partially contributed to the delay in signing the grant agreement. TRP clarifications of Round 4 proposal took three months.

Selection of the PR

The CCM appointed both the PR and SR. The PR was recruited through an advertisement inviting interested and qualified groups to respond. The selection criteria included—

- A nongovernmental body unbiased and uninfluenced by government
- Ability or proof of efficient financial management
- Experience in project management
- Experience in project implementation in target diseases
- Experience with international agencies
- Project experience in important public health diseases, especially the three target diseases (HIV/AIDS, malaria, and TB)
- Ability to provide good procurement services and efficient facility management

Interviewees reported that YGC, an organization that was created by a former Nigerian head of state, General Yakubu Gowon, was chosen as PR because of its credibility, and its previous experience in implementing a vertical Guinea worm control program in Nigeria based on donated goods. YGC was also an indigenous organization that had implemented a small portion of the HIV/AIDS Global Fund grant for civil societies.

In retrospect, many of the interviewed stakeholders felt that YGC lacked experience in managing and implementing a program of the magnitude of the Global Fund grant and should have been asked to demonstrate more evidence of procurement, supply, and distribution management capacity. Although these gaps in capacity were identified and acknowledged during the Round 2 proposal commencement, YGC was again selected as the PR for the Round 4 proposal. The new CCM appointed in June 2006 has proposed that a second PR and other SRs be engaged to address some of the capacity gaps.

LFA Assessment of PR Capabilities Related to Procurement, Supply, and Management

The LFA, KPMG Professional Services, assessed the PR's capabilities related to PSM in August 2004. This assessment evaluated Nigeria's organizations that have some PSM capabilities, including the CMS, which currently carries out some storage and distribution of medicines. KPMG concluded that the CMS did not have enough storage or distribution capacity to handle the goods expected to arrive under the Global Fund grant and recommended that the PR subcontract the warehousing and distribution functions from other organizations. Because of its lack of experience with this activity, the PR asked Crown Agents for assistance in floating a tender for this subcontract.

Both grant agreements had conditions precedent to be addressed before future disbursements could be made. The conditions related to the development of M&E and internal audit plans, the establishment of an external auditor and audit plan, and the recruitment of a program director. Other requirements for fund disbursement were developing a procurement plan and the

contracting with a distribution agent, both of which were satisfied. Concerns about PR capacity for PSM were identified quite early in the grant implementation, however, and the PR failed to take adequate and immediate action to bridge those gaps.

CCM Role

There appeared to be a somewhat strained relationship between the PR and the CCM. The PR did not adequately understand or recognize the oversight role of the CCM, and the CCM felt it did not have any power over the PR or the implementation process of the Global Fund grants. Nor did the CCM have any mechanism to enforce the PR's accountability or to make recommendations to the PR on how challenges might be addressed.

The CCM did not have an operating budget for meetings. In general, the Global Fund expects the country government, the donors, or the PR to fund the CCM's functions. If the CCM can show that other donors cannot support it, the CCM can access up to USD 50,000 from the Global Fund grant. However, in the case of Nigeria, neither the CCM nor the PR clearly understood those different mechanisms to obtain funding, and so, the CCM expected the PR to fund it. As a consequence, the relationship between the two entities was strained during the early stages of grant implementation. At present, the Global Fund is planning to support the CCM with a maximum of USD 30,000, after which the CCM must find another source of funding to conduct its activities.

In June 2006, based on recommendations of the Global Fund, the CCM underwent major changes in both leadership and membership. These changes were prompted in part by the potential threat of losing the malaria grants because of poor performance in grant implementation. The new CCM is based on constituency membership, as opposed to individual membership, and an electoral process. The phasing out of the old CCM and phasing in of the new CCM has been challenging, with some documentation lost during the process. Plans are under way to develop a Memorandum of Understanding (MOU) between the CCM and the PR to establish roles and responsibilities and a process for better accountability of the PR to the CCM. Some discussions have also taken place about having a second PR with clear responsibilities assigned to each PR. The CCM also plans to develop MOUs between the federal and the state levels to establish a process and lines of accountability in implementation, which does not currently exist because of the decentralized structure of the federal and state levels.

PSM Plan Development

The Global Fund did not require a PSM plan for Round 2 proposals. However, for the Round 4 proposal, the Global Fund advised the PR to contract with a consultant to help develop a PSM plan; in August 2005, YGC approached Crown Agents for assistance in this area. One PSM plan for both rounds of the malaria proposal covered ITNs, SP, and Coartem. Crown Agents used information that was provided by the PR and SR and other stakeholders identified by the SR to develop the plan. The procurement method outlined was based on World Bank procedures, and

the forecasts of commodities needed were provided by the SR (NMCP). The PSM plan was then forwarded to the Global Fund, which approved the plan.

Policy Issues

Several policy changes and issues delayed the procurement of ACTs and affected Nigeria's implementation of the Global Fund malaria grant.

According to Global Fund requirements, Coartem could not be procured until the national treatment policy had been changed. By December 2004, following medicine resistance monitoring studies in Nigeria, a consensus existed on the choice of artemether-lumefantrine as the first-line treatment, and the National Council on Health had given artemether-lumefantrine a preliminary endorsement by the Minister of Health. However, not until six months later, in May 2005, was the ACT policy officially endorsed by the National Council on Health and signed by the appropriate authorities. Part of the delay was caused by bureaucratic procedures and concerns with selecting a single-source product as the first-line treatment. Furthermore, the subsidized price of artemether-lumefantrine was available only to the public sector. As a result, although artemether-lumefantrine was chosen as the first-line treatment, artemether-amodiaquine was chosen as an affordable ACT alternative for the private sector.

Other policy issues that contributed to the implementation challenges included—

- Delay in obtaining a local customs duty waiver from the Customs Department. The application for this waiver was made in January 2005, but it was not received until December 19, 2005—almost a full year later.
- Port reforms that necessitated a change in procedures: the new policy in January 2006 stated that instead of pre-shipment inspection, destination inspection will be required. For this, Nigerian authorities required a number of forms that were not obtained in advance, before the Coartem could be received at the port of arrival
- Nigeria requires that imported product be insured by a Nigerian insurance company. The Coartem procured through WHO also had to be insured by WHO to follow WHO regulations, and communication to resolve these issues contributed to some delays.
- Delays in obtaining a waiver from NAFDAC to allow the product to be cleared while NAFDAC processes the results of product quality testing. All medicinal products entering Nigeria are subjected to quality testing by NAFDAC.

Quantification of Antimalarial Medicine Needs

The proposal requested support from the Global Fund for 25 to 30 percent of the national needs for malaria treatment for children under five years.⁴ However, neither of the expert institutions with the capacity for forecasting needs for procurement—the CMS or the FDS—were involved in this process. WHO headquarters was requested to estimate the amount of ACTs for the Global Fund grant. Because there is no data on medicine consumption or malaria cases consistently reported to any central level, the number of malaria episodes used for the calculations followed the WHO global figures for all stable high transmission areas. Among the assumptions used was that 40 percent of the cases will go to the public health facilities. Given that the estimates were not based on accurate country-level data, there was no direction on the quantities of ACTs needed for each state. As a result, the PR and SR had to provide gross estimates during distribution that did not seem to be related to need (as described below).

Grant Signing, Receipt of the Funds, and Disbursements

The Round 2 proposal was approved in January 2003, but it was not signed until October 21, 2004. The delay had several causes; during this time, the Global Fund recommended that countries reprogram the funds that were earmarked for chloroquine procurement to accommodate ACTs which involved significant consensus building, quantification of needs, re-budgeting and planning. Other reasons for the delay included delays in responding to clarifications requested by the TRP and a change in the originally nominated PR, German Technical Cooperation Agency, to YGC on the recommendation of the Global Fund due to possible conflicts of interest arising from the German Agency also being a donor.

The Round 4 proposal was approved in June 2004 and signed on December 3, 2004. The grant agreements for the Rounds 2 and 4 proposals were, therefore, signed within two months of each other (October and December 2004) with start dates within a month of each other (December 2004 and January 2005, respectively). The first disbursement of funds for Round 4 arrived in Abuja within one week of signing the grant agreement.

The time taken for disbursement after requests were made was about four months. Much of delay this stemmed from late and incomplete submission of quarterly reports by the PR to the LFA necessitating numerous iterations of the report between the PR and the LFA before submission to the Global Fund. However, some of the delay was due to time lags in the LFA's submission of these reports to the Global Fund. This problem has been attributed to KPMG's policy of sending reports to U.S. headquarters for approval before forwarding them to the Global Fund. These delays have contributed, in turn, to some delays in fund disbursement.

During the early stages of grant implementation, disbursements for procurement by the Global Fund were made to the PR for Round 2. However, as a result of delays in payment by the PR to the supplier for procurement orders, and losses incurred through currency conversions to pay for orders of Coartem, for Round 4, procedures were revised and the disbursements specifically

⁴ After the reduction in the price of Coartem by Novartis in 2006, the number of doses to be procured using the same amount of funds was increased.

earmarked for procurement of Coartem were banked in the United Kingdom for release to the Crown Agents account after YGC approval.

Procurement

Following Global Fund approval of the malaria PSM plan, Crown Agents was hired in November 2004 as the procurement agent for purchasing all medical products, including antimalarials, under the Global Fund grant to Nigeria. This date coincided with the Minister of Health's approval of the change in first-line treatment to Coartem. Crown Agents contacted WHO in December 2004 to agree on arrangements for purchasing Coartem for Nigeria. At that time, all Coartem orders and procurement had to go through WHO's procurement department to receive the subsidized price from Novartis, the manufacturer. Later, the Coartem procurement agreement with Novartis was shifted from WHO to the MMSS of the RBM Partnership Secretariat.

Several factors, both external and in-country, contributed to delays and bottlenecks in the first procurement—

External Factors

- Novartis indicated that it would not be able to meet the demand for Coartem and that countries that had not already placed orders could expect longer procurement lag times, leading to an additional nine months added to the procurement process for the first shipment.

In-country Factors

- Neither Crown Agents nor YGC were aware that the application for the subsidized price of Coartem had to be approved by WHO's technical advisory committee on Coartem, which was next scheduled to meet in March 2005.
- A lack of understanding of WHO's procurement process resulted in not meeting WHO requirements: YGC made only a partial payment for the initial order to WHO. When WHO transferred responsibility to MMSS, neither Crown Agents nor YGC realized that full payment was also required before MMSS could place any order with Novartis. The transfer for the balance of the funds was not made until July 2005. At that point, MMSS informed Crown Agents to expect a November 2005 delivery.
- In November 2005, part of the Coartem order was ready to ship and was originally scheduled to arrive in Nigeria on December 5, 2005, but the shipment was delayed because YGC had not obtained the duty waiver despite having applied for it nearly a year earlier. YGC was under the impression that the supporting letter obtained from President's office in September 2005 requesting the duty waiver was sufficient documentation. An official duty waiver document obtained in December 2005 was

further deemed to be insufficient because it lacked a signature by the Customs Department. The final documentation was not obtained until February 2006.

- Delays in YGC application for documents for importation: YGC did not apply for the required documentation (Form M) until January 2005. Approval was obtained in February 2006 and WHO shipped the first order of Coartem to Abuja in March 2006.
- Nigerian authorities required that the goods be insured by a Nigerian company despite insurance being paid to the WHO Procurement Department—this resulted in the insurance being paid twice. In addition, some delays resulted from the communication between Crown Agents and MMSS to try and resolve this issue.

The delays in the duty and customs requirements effectively stalled the shipment of the ACTs by an additional 5 months for a total delay of 14 months. The reasons for these delays were slow in-country processing of the required documentation for importation of the Coartem shipments, a lack of effective follow-up by the PR, poor planning on the part of the PR, a poor understanding of the regulatory requirements for importation and the necessary documentation required for the process, and a lack of understanding of the implications of changing regulations and policies.

Several actions were taken to address these challenges. Depositing YGC funds in the Crown Agents Bank in the United Kingdom helped alleviate some payment issues. Subsequently, the Global Fund arranged to pay the ACTs supplier directly, cutting down any payment lags.

Because of the experience with the previous procurement, subsequent shipments had fewer challenges. In February 2006, a second order for 2,914,560 treatment courses of Coartem was placed with Novartis through MMSS for a total of USD 3,781,566.72. It was shipped to Abuja on May 20, 2006, and YGC subcontracted a customs clearance agency directly.

Subsequently, discussions between Novartis and Crown Agents resulted in direct procurement of Coartem from Novartis, which eliminated the 3 percent fee that MMSS (on behalf of WHO's Procurement Division) charged for handling and advance payment. In addition, direct procurement from Novartis is expected to eliminate the administrative delays at WHO and give Crown Agents direct access to cost, delivery, and shipping information from the supplier and eliminating the insurance requirement by WHO.⁵

On July 31, 2006, a third order was placed directly with Novartis, the first consignment of which arrived on August 23, 2006, less than a month later. However, the balance of the shipment was withheld because of delays in obtaining additional disbursements from the Global Fund mainly due to issues with performance and their reluctance to release large sums to a grant that may not be renewed for phase 2. These decisions were based in part on consumption patterns and expiration dates of the medicines already procured as well as the extent that the grant was meeting the defined targets.

⁵ Until 2006, all procurements of Coartem had to go through MMSS or UNICEF to obtain the subsidized price. In 2006, Novartis allowed direct procurement by select procurement agencies. MMSS continues to act as a broker for ACT procurement to other countries

Although many of these delays were outside the direct responsibility of the PR, many could have been avoided by the PR's appropriate planning and early recognition of its lack of experience in the area of procurement, and by obtaining outside assistance in this area.

Table 2. Significant Dates in the Process of Coartem Procurement in Nigeria

Date	Event
November 2004	Change in first-line treatment to Coartem is approved by Minister of Health
November 2004	Crown Agents is contracted by YGC (the PR) as the procurement agent
January 2005	Application for a duty waiver is made
February 21, 2005	WHO "Submission Form 4" is forwarded to MMSS for action
March 17/18, 2005	The WHO Technical Advisory Group meeting is held
April 15, 2005	A pro forma invoice is issued to Crown Agents; Delivery: September/October 2005
May 31, 2005	MMSS receives partial payment (USD 1,680,000)
July 1, 2005	Balance of funds is transferred to MMSS. MMSS informs Crown Agents of a November 2005 delivery
November 4, 2005	MMSS sends communication that the order would be delivered on December 5, 2005
November 24, 2005	Crown Agents is asked to assist with customs clearance and inland distribution
December 19, 2005	The Ministry of Finance signs the duty waiver
January 19, 2006	YGC submits the Form M for Coartem importation
February 6, 2006	The submitted Form M is rejected because the pro forma invoice from WHO is more than six months old
February 27, 2006	Documentation (Form M) is approved
February 28, 2006	WHO is instructed to arrange the shipment of Coartem
March 15, 2006	WHO ships first order of Coartem to Abuja

Training

The main themes of training were malaria case management and prevention (IPT) and M&E. Training modules were developed with technical assistance from WHO and approved by the FMoH, after which training plans and schedules, which employed a cascade training approach, were developed. Training began in March 2005 with a national facilitator's workshop. At the time of this case study, all implementers had been trained down to the facility level and community level, and all training targets had been met.

One of the main challenges, however, was the frequent movement of staff. All staff that were trained in Lagos have since been redeployed outside the city. Henceforth, the intention is to have in-service training curricula and review training programs for medical students and nurses. In addition, apart from one series of training in stores management, during which standard forms and templates were developed to assist distribution and management of ACTs, pharmaceutical management was not sufficiently addressed in the training. The NMCP had expected that the

ACTs would arrive soon after the orders were placed and proceeded to plan for and implement the health workers training in the public health system on the new treatment guidelines. However, the training occurred too soon relative to the arrival of the ACTs.

Distribution and Storage

The LFA carried out an assessment of existing logistics systems in the country and determined that the CMS did not have the capacity to store, transport, or distribute the Coartem. As a result, YGC rented two stores in Abuja to store ACTs. These stores had no shelves, pallets, fans, security, or air-conditioning—important factors if Coartem was to be stored in these facilities for a prolonged period of time. It is unclear whether the PR's storage facilities or storage at the state level were assessed by the LFA. The recommendation of the LFA was to contract a distribution agent to deliver the ACTs to the state level, and that the state level distribute to the lower levels, thereby eliminating the need for storage at the state level.

What appears to have been overlooked are the details beyond delivering the medicines to the state store. The ACTs arrived in the YGC store in Abuja and were then dispatched to the various tertiary and federal facilities and the states. YGC carried out distribution using two vehicles with assistance from NMCP staff. At the state level, the RBM managers of the NMCP distributed the Coartem to the LGAs. However, this procedure was a short-term answer to the problem at hand; parallel systems were created with little consideration for creating a sustainable long-term solution. These issues will still need to be resolved to ensure efficient future distribution.

Inventory management practices were poor. No systems were created to manage the Coartem inventory and to reorder and replenish supplies. Micro-planning forms and templates developed earlier in collaboration with FDS for the movement and control of medicines at the state, LGA, and facility levels, and to be used during the national training on store management, were not delivered to the state level. Therefore, little tracking on consumption is being done at the facility level, and when stocks run out, no established mechanism exists for reordering, resulting in facilities experiencing stock-outs. Furthermore, supervisors have no way to track which age groups are consuming the medicines unless patient medical records are accessed or to determine at what level of the distribution chain stocks are leaking from.

A major issue was that Coartem procured with Global Fund resources was reported to have been found in the private, for-profit sector. Records showed that the state medical stores received all medicines distributed by the PR; however, it is unclear what level leakages may have occurred. While some leakage can be expected in a program of this scale over time, in Nigeria this seemed to be soon after the distribution of the first ACT shipment. The PR in response has identified the cases of leakages independently and was in the process of investigating them at the time of this assessment. Interventions to improve the inventory and tracking systems had however, still not been developed.

Many of the challenges can be attributed to a lack of knowledge of the standard procedures to ensure appropriate storage, distribution, and management of pharmaceuticals, particularly ACTs. Inadequate planning caused a crisis management approach to implementation and short-term solutions were sought for bottlenecks without planning for sustainable systems. Many of the interviewees believed, in retrospect, that the cost of the logistics for distribution and inventory management was grossly underestimated in the figure negotiated between the Global Fund and the PR. Little consideration was given to supportive supervision for the providers at the peripheral levels, and trained personnel appeared to be replaced continuously.

Another example of proper contract definition is shown in the misunderstanding between Crown Agents and the PR, mainly about their respective roles and how distribution would be paid for. Furthermore, the ACTs were being managed by YGC, which is relatively inexperienced in pharmaceutical management. The FDS developed micro-management forms at the time of training, but subsequently, neither the CMS nor the FDS were involved during much of the implementation process. Efforts are now being made to involve the CMS and to inform all partners when the goods arrive, so that every partner will have copies of the arrival and distribution lists.

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

The indicators and milestones were first developed for the proposals and then outlined in the grant agreements signed by the PR. At the time of the fieldwork for this study, the development of an M&E plan was a standard condition precedent to the second disbursement of funds for the grant agreements. With the assistance of Crown Agents and HealthFocus International, this plan was developed soon after receiving the first disbursement for the Round 2 grant.

However, neither the NMCP nor other implementing partners were directly involved, meaning that procurement time lags and capacity building were not built into the action plans. Furthermore, although the plan outlined how the data would be collected, processed, and used, it lacked some specific PSM indicators and milestones. In addition, the proposed activities within the M&E plan do not appear to have sufficient financial backing in the detailed Global Fund workplans and budgets. Several stakeholders believed that the targets set were too ambitious, and the lag time for capacity building and program development was not considered in the time frame set for achieving the milestones. As mentioned above, the fact that no procurement expertise was sought for either grant preparation explains these issues.

Key M&E activities carried out by the PR to date include submission of quarterly performance reports for the two grants using approved indicators and reporting format. This report is submitted to the CCM and LFA. To strengthen its M&E capability, the PR has recently been restructured and recruited three additional M&E staff. The primary source of information for PR reporting is the SR. For ongoing data recording, the NMCP has installed a manual database in a computer that can be accessed by the YGC data manager. The database currently captures information on monthly commodity distribution, IPT, and case management but not on actual consumption; the database is not linked with any other health information system. Information on training activities and meetings is stored separately. The PR has also established its own

vertical reporting system that primarily gathers data from the NMCP reporting tools, personnel, and databases.

Implementation of M&E activities for both Round 2 and Round 4 grants has not proceeded as stated in the M&E plan. Certain states frequently do not submit the required Global Fund data within the required time frame. In addition, some of the information received from the SR is incomplete and not validated by the central level because of a lack of mechanisms to ensure the quality of the field data. As a result, the LFA has sometimes questioned the accuracy of the data and the quality of the PR's reports.

Management and Coordination

YGC has a newly expanded structure with key positions in place to implement the two grants. This structure was too new at the time of this study to assess whether the situation had improved as a result of these changes.

At the NMCP, the poor staffing situation is being further compounded by a high attrition rate at the national and state levels. This problem has resulted in inconsistent malaria program management skills from state to state, which has negatively affected reporting and grant implementation in the weaker states.

Communication and coordination between the PR and SR are not optimal. The SR identified a person to liaise between the two organizations; however, this person has not improved the situation. No other mechanism has been established for joint planning, information sharing, or follow-up of program implementation. The SR does not submit timely reports to the PR, which has resulted in the PR's having to go independently to the field to gather data on implementation progress. The PR and SR have developed parallel implementation plans, suggesting considerable weakness in joint planning. Furthermore, neither plan is strictly followed to guide program implementation. Planning and implementation is done on an ad hoc and activity-specific basis, mostly in response to a crisis. The Global Fund-approved workplan is not translated into quarterly or monthly workplans for implementation. These weaknesses have led to duplications of efforts and confusion in the roles and responsibilities of SR and PR. Although the expected role of an SR is project implementation and oversight of implementation by other subpartners, the PR sometimes undertakes direct implementation—for example, delivering ACTs to tertiary institutions and collecting data directly from the field.

States are major recipients of commodities and cash from the grant, yet the states did not sign any MOU for the health products received and, therefore, cannot easily be held accountable. Ultimately, however, the SR is accountable for implementation carried out by the states. At the state level, multiple actors are involved in implementation without a common coordinating mechanism. For example, medicines at the state level are received at the state medical store under the director of pharmaceutical services, but the facilities are under the director of public health, leading to poor coordination, poor service delivery, and low accountability for product use.

Little collaboration or consultation took place with bodies in the country routinely involved with pharmaceuticals, such as the FDS, CMS, and NAFDAC, with the result that implementation has been inefficient. The FDS has a “contact person” at the NMCP to serve as a liaison for information sharing between the two organizations. In reality, these mechanisms have not been adequately used, and the intended collaboration has not occurred.

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 Ghana Health Service (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 aimed to accelerate access to prevention, care, support, and treatment of malaria for targeted persons in 20 districts. Activities in the Round 4 proposal aimed 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	Total Amount (USD)	Approved Funding (USD)	Amount Disbursed to Date (USD)	Procurement Budget in Agreement (USD)	Current Procurement Expenditure (USD)
	GHN-405 G04-M		Phase 1: 18,561,367.00			
4	February 8, 2005	18,561,367.00		16,891,410.00	8,613,676.00	6,574,207.39
Total	—	27,410,858.00	27,410,858.00	23,469,068.00	11,976,366.00	9,081,034.05

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. Upon the receipt of the concept papers, the CCM set up technical teams for the various diseases to develop them 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 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 standard treatment guidelines (STGs). Furthermore, manufacturers alleged that they had not been properly involved and informed of the policy change process, so chloroquine is 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), which is 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 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 they 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 malaria morbidity data from the public sector. 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 a critically weak area. 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

In general, GF 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 start date for the implementation of the Round 4 proposal was March 1, 2005.

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 the 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 PR procurement unit 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.

In Ghana, tax exemptions are granted by the Ministry of Foreign Affairs for donated medicines, medical equipment and 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 CMS 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 they were not.

At the time this study was conducted, MMSS had carried out two procurements of pre-packaged artesunate-amodiaquine from Ipca Laboratories 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. Sending funds was delayed about three months after receipt of the pro forma invoices for both orders—this was 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. In the case of both orders, 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 the case of 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 its main tasks related to 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 miscalculating 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 Ghana MoH has strict guidelines and standard operating procedures for product receipt and storage. The NMCP developed Ghana's distribution plan for the artesunate-amodiaquine tablets procured under the Global Fund October 2005 malaria grant in conjunction with the training plan of the health providers, so that distribution would begin only after training in those facilities had been conducted. 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 various regions in the country based on case prevalence in the facilities in the 10 regions, the military and police hospitals, and two teaching hospitals. This list was used in the initial push of ACTs to the regions and facilities. 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 inadequate storage space in the smaller facilities, inadequate capacity for quantification, and 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). This 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 make sure complete data is received on time. 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 total 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 M&E of grant implementation were too small.

Management and Coordination

Coordination between the PR and SR has facilitated the implementation of the malaria grant in Ghana. The PR and SR hold regular meetings together that include discussion of the funds available for the implementation of activities under the Global Fund proposals and help make the process more transparent.

CASE STUDY: GUINEA-BISSAU

Background

Guinea-Bissau's public health system is divided into three levels: central, regional, and local. The system includes 114 health centers, five regional hospitals, one national referral hospital, and several specialized referral institutions. Rural areas are served primarily by small mobile health units and community health workers. The NMCP at the central level is responsible for developing policies and strategies related to malaria control and coordinating, monitoring, and evaluating malaria activities throughout the health system.

Guinea-Bissau has been awarded a total of USD 3,613,397 from the Global Fund during Round 4 for malaria. Activities under the Round 4 grant are aimed at—

- Increasing the availability of adequate and acceptable treatment within 24 hours after the appearance of symptoms from 5 to 60 percent of probable or confirmed cases of malaria by the end of 2009
- Increasing the use of ITNs from 5 to 60 percent for children under five years of age and from 9 to 60 percent among pregnant women by the end of 2009
- Increasing the use of IPT by pregnant women to at least 60 percent by the end of 2009.

After the fieldwork for this study was completed in November 2006, the Global Fund announced that Guinea-Bissau was among the successful countries for the malaria proposal submitted during Round 6. The Round 6 proposal focused primarily on the national rollout of ACTs to areas not covered in Phase 2 of Round 4. The processes described in this paper are limited to the Round 4 proposal.

Table 4. Summary of Grant and Other Data for Guinea-Bissau

Round	Grant Number and Date Signed	Total Amount (USD)	Approved Funding Phase 1 (USD)	Amount Disbursed to Date (USD)	Procurement Budget in Agreement (USD)	Current Procurement Expenditure (USD)
4	GNB-404-G03-M November 24, 2004	3,613,397.00	1,885,791.00	1,688,828.00 (February 2007)	774,256 (741,136 for year 1; 8,280 per year for years 2–5)	295,561.29 (for quinine and SP)
6	Not signed	12,816,656.00	Not signed	Not signed	Not applicable	Not applicable
Total		16,430,053.00				

Proposal Development

The institutions and organizations involved in the proposal development for Round 4 were the NMCP, WHO, UNICEF, the World Bank, the National Institute for Studies and Research, and health committees (community members), as well as various NGOs working in malaria in Guinea-Bissau. The proposal listed UNICEF (primary) and WHO as the subcontracted bodies responsible for PSM, including supervision of and support to the national and regional depots of the Central de Compra de Medicamentos (CECOME, or Central Office for Purchasing Medicines), the autonomous entity responsible for storage and distribution. However, the PSM plan submitted before grant signing stated that UNDP would be responsible for procuring health products.

Because Guinea-Bissau's first-line treatment was still chloroquine at the time of proposal development and submission, the proposal did not include procurement of ACTs, despite the fact that the proposal was signed after the Global Fund and WHO recommended that countries change their first-line treatments to ACTs and reprogram funds to cover their procurement. The reasons for this decision are unclear, but one may have been because the Global Fund proposal did not include procurement of any first-line treatment.

PSM was not a significant consideration during the Round 4 proposal development for several reasons, namely—

- UNDP was already established as a competent PR with PSM capacities under other grants.
- UNICEF and WHO were to be subcontracted for procurement and distribution.
- CECOME was already being strengthened through other grants and with support from the World Bank.
- The program was continuing with chloroquine, a medicine the country already had the experience and capacity to manage.

As a result, PSM capacity building was not included in the original proposal or grant agreement for Phase 1, and no funds were allocated for this functional area.

Selection of the PR

UNDP was selected as the PR for all Global Fund grants (TB, HIV/AIDS, and malaria) because the CCM believed that neither the MoH nor any other national institution was strong enough to manage the grants in Guinea-Bissau's post-conflict environment. Furthermore, at the time the Round 4 malaria proposal was submitted in early 2004, UNDP was already the PR for the Round 3 TB grant.

The Round 4, Phase 1, malaria grant agreement contained the condition that the CCM would identify a local institution to succeed UNDP as PR and that UNDP would design a plan for developing the local institution's capacity. This condition, however, has not been met. The institution most likely to succeed UNDP as the PR is the MoH, specifically the National Health Development Plan (PNDS). At the time of this writing, the CCM was in the process of selecting a new PR for Phase 2 of the Round 4 grant as well as for the Round 6 grant. The plan under consideration is to transfer PR responsibilities from UNDP to PNDS over the course of one year, during which time UNDP would focus on building the local institution's capacity to manage the grant. This transfer of responsibilities had not occurred at the time of this assessment. The general belief was that changing the PR on the grant would not cause any delays in the procurement of ACTs, which at the country level was expected to take place after Phase 2 funding was approved. No PR has been named in the Round 6 proposal.

LFA Assessment of PR Capabilities Related to PSM Capacities

The location of the LFA, PricewaterhouseCoopers, in Abidjan, Côte d'Ivoire, has led to some delays in data transmission and some communication issues. The LFA assessed UNDP capacity for PSM capacities, and no conditions were placed on UNDP for future disbursement related to PSM. The LFA also assessed CECOME's capacity for storage and distribution, which was found to be inadequate.

Role of CCM

Guinea-Bissau has a single CCM that is responsible for all of the current Global Fund grants. The 17 members are multisectoral and include representatives from government and NGOs. The Minister of Health serves as president of the CCM, and the WHO representative in Guinea-Bissau serves as vice president.

The malaria proposal assigned the following functions and responsibilities to the CCM—

- Validation of proposals submitted to the Global Fund
- Advocacy for the mobilization of resources needed to implement activities
- Coordination of the project activities
- Follow-up of the execution of the proposal

The CCM was to have quarterly meetings to review progress and an annual meeting to evaluate grant implementation and rectify ineffective implementation strategies. In practice, the CCM has not adequately fulfilled its responsibilities or performed its intended duties. Several of the interviewees attributed the body's ineffectiveness to a poor understanding of its responsibilities, its operational procedures, and the inconsistency of member participation in meetings. Furthermore, many of the positions are held by high-ranking officials who are not regularly involved with program implementation activities. WHO has begun addressing some of the CCM's deficiencies and building its capacity to better manage the grants by developing a manual to clearly outline all operational procedures and responsibilities.

PSM Plan Development

A draft PSM plan was developed for the Round 4 malaria proposal by a consultant, submitted to the Global Fund, and approved before the grant agreement was signed. The PSM responsibilities outlined in the PSM plan were largely assigned to UNDP. This arrangement differed from the grant proposal, which proposed subcontracting to UNICEF and WHO. This PSM plan for the malaria grant was, however, general and not specific to malaria. Activities were loosely outlined without specific details or timelines.

As previously discussed, ACTs were not in the grant proposal, and therefore, not in the original PSM plan. After the treatment policy was changed from chloroquine to artemether-lumefantrine, the NMCP requested assistance from WHO to develop a new PSM plan. A seven-month time lag occurred between adoption of the new treatment policy in June 2005 and completion of the PSM plan. Both UNDP (the PR) and WHO attributed this delay to a cholera outbreak that took resources away from other MoH programs and services, and difficulties in identifying and scheduling an appropriate consultant to do the work. The new plan was developed in collaboration with national stakeholders, including the NMCP, the national professional officer for malaria at WHO, CECOME, UNDP, Directorate of Hygiene and Epidemiology, General Direction of Public Health Management, Directorate of Pharmacy Services, Directorate of the National Public Health Laboratory, UNICEF, and Plan Guinea-Bissau (an NGO); however, this plan has not been implemented because no ACTs have been procured.

Guinea-Bissau expects to develop a shared PSM plan for ACTs for Phase 2 of Round 4 and the Round 6 grant, given their common focus on procurement and implementation of ACTs. Technical assistance is expected to be needed.

Policy Issues

The Directorate of Pharmacy Services is the drug regulatory authority responsible for the legislative aspects of the new treatment policy, which includes registering the new medicine and adding it to the essential medicines lists. Before these processes could begin, the national commission of drugs had to finalize and adopt the national pharmaceutical policy document, which would then enable the procurement process to start. The first-line treatment was therefore changed from chloroquine to a combination of artemether and lumefantrine (Coartem) in July 2005, and was validated and approved in mid-October 2006. Although this process took almost two years after the grant agreement was signed, respondents at the country level did not perceive the policy change process to be unduly lengthy, and the PR, NMCP, and other implementers in Guinea-Bissau did not attribute the delay in ACT procurement to those events.

STGs, which fall under the purview of the NMCP, have not yet been revised to include artemether-lumefantrine as first-line treatment. Respondents thought that the STGs did not need to be revised until the Coartem had been ordered, which according to the PR and NMCP would not occur until sometime after the beginning of Phase 2. The NMCP wanted to wait to develop STGs until it had assurance of adequate global quantities of Coartem, although no implementation plan for the transition had been developed, no order for Coartem had been

placed, and by 2006, no global shortage of Coartem existed and the basis for the concern was unclear.

The Global Fund expected that new treatment guidelines (and other essential preparations for ACT rollout, including an implementation plan) would be a condition of funding in Phase 2.

Quantification of Antimalarial Medicines and Supply Needs

A consultant from WHO's Regional Office for Africa (WHO/AFRO) carried out a quantification exercise for the entire country as part of the PSM plan development at the request of the NMCP. The quality of data used for quantification was not reliable because of the post-conflict situation and difficulties in obtaining malaria data from all the regions. The morbidity method was used for estimating antimalarial needs. Four regions were selected for implementation⁶ on the basis of final estimates in the quantification and costing exercise, which indicated that nationwide introduction of ACTs in Guinea-Bissau would be impossible with the grant funds available for Phase 2 of Round 4 (pending approval).

Grant Signing, Receipt of Funds, and Disbursement

The grant agreement for the Round 4 proposal was signed on November 24, 2004. The grant agreement for Phase 1 stipulated the standard conditions precedent, including the submission of an M&E and auditing plan for the second disbursement of funds and a procurement plan. Under "Special Terms and Conditions for this Agreement," the Global Fund also required that the PR submit its guidelines for selecting and monitoring SRs and a plan for developing the capacity of the national entity selected by the CCM to succeed UNDP as PR.

The Global Fund expects that the grant will be extended to Phase 2 with some conditions and changes, including the submission of the final implementation plan and the completion of all preparatory activities for the rollout of ACTs before the use of funds for procurement. Some cuts in the total funding for Phase 2 are expected because of reductions in the cost of Coartem; low absorption of funds during Phase 1 (much of this was caused by problems with the PR and partner relations); concerns about CECOME's distribution capacity; and the approval of the Round 6 grant proposal (Phase 2 did not account for approval of Round 6 proposal).

Procurement

UNDP is responsible for most aspects of procurement, as outlined and assigned in the first PSM plan. Before becoming PR for the Global Fund malaria grant in Guinea-Bissau, UNDP had not done any malaria procurements in the country. There have been some in-country discussions which have raised the issue of replacing UNDP with UNICEF as the agency responsible for

⁶ Although these four regions were listed by multiple sources, the Round 6 proposal states that funds from Round 4 were sufficient to cover only two regions.

procurement. Either way, CECOME would continue to be responsible for storage and distribution.

Past experience indicates that procurement lead times are long because of supplier transportation problems to Guinea-Bissau. These challenges do not appear to have been considered at the proposal stage or when the PSM plan for Phase 1 was developed.

Some breakdown in understanding appeared to occur regarding accessing Global Fund resources for procurement of ACTs. The PR approached the Global Fund with concerns over chloroquine resistance and the possibility of accessing additional resources to procure ACTs. The Global Fund asked the PR to submit an implementation plan that described the transition to ACTs. In April 2006, the PR, with assistance from a WHO/AFRO consultant and in collaboration with international and national malaria stakeholders, developed the draft plan. It included expected results, indicators, activities, responsible agency, costs, and timeline for each program area. In July 2006, the Global Fund requested more detailed information on each of the activities and specific tasks outlined; however, a final plan had not been submitted at the time of this assessment.

None of the stakeholders interviewed—from the PR to WHO and the MoH—mentioned the need to finalize the implementation plan as a prerequisite for accessing Global Fund resources for ACTs during Phase 1. Rather, they believed that additional funds for ACT procurement would not be available from the Global Fund until Phase 2; therefore, stakeholders had little urgency about instituting the processes to complete the transition plan to enable ACT procurement.

In the meantime, the PR and partners in-country began efforts to identify external sources of funding for ACT procurement to cover the gap in funding. These have been largely unsuccessful except for USD 500,000 obtained from the World Bank, which was not enough to implement ACTs on a wide scale. In addition, some in-country discussions took place on freeing funds for ACT procurement from certain Global Fund proposal activities, but those funds also failed to materialize.

Receipt of Goods and Customs Clearance

As of this writing, ACTs had not yet been procured, so the following information applies to proposed procedures and UNDP's general experience with receipt of goods and customs clearance for the other Global Fund grants and other malaria commodities in Guinea-Bissau. Guinea-Bissau imposes no customs duty for medicines procured under the Global Fund grant.

UNDP and WHO reported that the delivery of goods from suppliers is consistently delayed: few companies dock in the port because it is expensive; goods delivered by air arrive sooner, but only in small quantities; in addition, customs corruption at the ports means that additional funds are expected for faster clearance. Because the procedures for clearing customs have not been clearly or consistently articulated or enforced, UNDP has had problems providing the necessary paperwork to get Global Fund commodities through customs efficiently. CECOME is responsible for obtaining all the documentation before the arrival of the goods; however, the

process is often delayed. Private agents are hired for customs clearance—a standard procedure in Guinea-Bissau. Some respondents noted that these agents were expensive and added another layer of bureaucracy that causes additional delays.

Training

Warehouse personnel have not been trained in pharmaceutical management and health care workers have not been trained in the new treatment policy. The PR does not want to begin training until receiving a commitment of Coartem supply. No training plan has been developed. In addition, the process of revising the STGs needs to begin immediately.

Distribution and Storage

At the time of this assessment, ACTs had not been procured yet, so the following information applies to proposed procedures and UNDP's and CECOME's general experience with storage and distribution of other Global Fund commodities.

At all levels, UNDP has encountered problems related to the lack of physical space for the storage of Global Fund commodities. Some overflow stock has been stored at other sites in Bissau, and the UNDP was looking for another storage space.

When Global Fund commodities clear customs, they are supposed to go to the CECOME central warehouse; however, the limited physical space for storing commodities at CECOME has been a major problem that was not thoroughly considered at the proposal development stage. Some believed that the space problems were largely caused by CECOME's poor planning, and others noted that UNDP had not adequately communicated with CECOME about the quantities ordered and the expected delivery dates.

The conditions at CECOME's current central warehouse are considered good; the regional warehouses meet the minimum requirements. CECOME recently received new equipment, primarily refrigerators for maintaining a cold chain, as part of a Global Fund grant for HIV/AIDS.

The World Bank is supporting construction of a new CECOME central warehouse and physical capacity is expected to be sufficient. The target completion date is November 2007.

Interviewees held conflicting opinions on CECOME's capacity for storing and distributing Global Fund commodities. Some stakeholders felt that CECOME had more expertise than UNDP in pharmaceutical management and procurement, and thus could not only support UNDP but also play a more significant role in the PSM process. Other respondents claimed that CECOME was not reliable. While, these statements were not verified as part of this assessment, if indeed true, these challenges are likely to affect ACT implementation if they are not addressed before ACTs are procured.

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

Guinea-Bissau has a national medical information system that is managed by the MoH's Hygiene and Epidemiology Authority. Medical data are collected in the health centers each month, processed and compiled regionally, and then sent to the Epidemiology Service, which issues an annual national medical statistics report. A national program follow-up and evaluation network will eventually be integrated into the information system. Nevertheless, reports from the LFA suggest that, in general, UNDP has had difficulties collecting the information needed to report on indicators for Phase 1.

The program indicators related to treatment of uncomplicated malaria in the original proposal are not relevant to the implementation of ACTs because, as discussed, ACTs were not adopted until after the proposal was approved and the grant signed. The implementation plan for ACTs, however, does define program indicators.

Management and Coordination

Management and coordination of the procurement, storage, and distribution of commodities have been affected by the limited in-country experience with procurement, quantification, and general pharmaceutical and supply management. This situation, combined with a severe shortage of human resources in the NMCP, has created a dependence on international consultants to perform some tasks related to these technical areas. With only two people working at central level, the NMCP has limited capacity to implement and manage the program.

Poor coordination and communication between the PR and CECOME appear to be creating problems related to the storage and distribution of other commodities procured through Global Fund grants. Certain organizations claimed the PR did not openly and adequately communicate with CECOME on plans, orders, and supplies, which prevented CECOME from planning accordingly. Although roles and responsibilities were delineated and documented in the PSM plan at the beginning of the grant, the collaboration between UNDP and CECOME has not functioned well and may need to be redefined for Phase 2 of Round 4 and Phase 1 of Round 6.

The relationship between the PR and the SRs has also been a problem. UNDP believed that the SRs did not adequately understand or appreciate the procedures for receiving funds. UNDP has had problems getting the SRs to provide information and reports on their activities and spending.

SUMMARY OF FINDINGS AND LESSONS LEARNED

The case studies identified the various bottlenecks that the three countries faced when implementing their Global Fund malaria grants—

- In Ghana, there were challenges related to quantification, provider acceptance, and adherence to the treatment policy; and planning for complementary activities, such as training and supply chain management.
- In Guinea-Bissau, the challenges centered on the policy change processes, the development of a transition plan to ACTs, and coordination between the PR and other implementers in the country.
- In Nigeria, many of the challenges and delays centered on procurement and planning for procurement, mainly because of the PR's lack of capacity and experience in those areas. In addition, Nigeria experienced problems in the distribution and re-ordering of supplies.

Some challenges experienced by all three countries can be attributed to in-country bureaucracy. Other delays in implementation were caused by the poor PSM capacity of the PR and SR, unclear roles and responsibilities of the various stakeholders, and most importantly, a lack of planning and coordination of the implementation process. In addition, all three countries were challenged by inadequate systems for M&E, limited human resources capacity, and poor investment in overall health systems.

While each country experienced unique issues, many of the challenges were similar, and their cumulative lessons learned are discussed below.

Coordination among Stakeholders

Key Lessons Learned

- Clearly articulated stakeholder roles and responsibilities may lead to smoother implementation
- Memorandums of Understanding (MOUs) or other contractual mechanisms among PRs and SRs may help establish/create greater accountability
- Review of the Global Fund guidelines on country coordinating mechanisms (CCMs) may assist stakeholders to better understand roles and responsibilities
- Incorporating potential stakeholders including those in the private sector early in the process promotes ownership and subsequent acceptance and adherence to the policy
- Creating mechanisms for coordination and collaboration among PR, SR, and other implementers assists the implementation process
- Delegating specific functions while maintaining oversight has the potential to liberate the PR for other critical activities
- Decentralizing resources for implementation can enable a more rapid implementation process

The CCM, PR, and SR are entities created primarily to satisfy Global Fund requirements, although the organizations or institutions that make up these entities may have previously existed under other umbrellas. All three countries had some difficulty determining and defining roles and responsibilities of the CCM, PR, SR, and other partners.

The Global Fund guidelines on CCMs recommend that their role is to ensure oversight of grant implementation, but the CCM is unable to operate efficiently unless the CCM, PR, SRs, and other implementers develop and adopt clear structures and modes of operation. Encouraging the CCM to develop the necessary tools to perform these oversight functions and to define fixed periods (the first period not exceeding the first three months of implementation) to meet and review the progress of each grant may help it accomplish its role. In Guinea-Bissau, the CCM had not fulfilled its responsibilities of oversight and monitoring, and periodic absences of members adversely affected its functioning. In Nigeria, the CCM also faced challenges caused by limited operating funds, in part because the CCM and the government assumed that the PR would provide these resources as part of the Global Fund grant. However, the Global Fund expects governments or other country partners to fund CCMs, but when this funding does not occur, the Global Fund may authorize the CCM to use up to USD 50,000 from the grant to cover operations for up to two years. This arrangement has created tension between the CCM and the PR who sees the CCM as taking resources from the program.

By contrast, the CCM in Ghana enjoys a high status and is recognized as a technical coordinating body. The CCM in Ghana has also maintained an increased level of involvement and ownership, partly because the PR, the Ghana Health Service of the Ministry of Health (GHS/MoH), worked with the CCM with little conflict starting from the proposal development stage and continuing through grant implementation. Neither YGC in Nigeria nor UNDP in Guinea Bissau were actively involved in the proposal development, nor retained a strong association with the CCM after the grants were signed. This dissociation in Nigeria led to some discord between the CCM and PR, and the perception was that the CCM's authority waned when the grant agreements were signed. As one interviewee said, "the principal recipient takes the grant and runs with it." This friction seemed more pronounced when the PR had been appointed *after* approval of the proposal. In addition, in Nigeria, key institutions within the public sector such as the Food and Drugs Service, the Central Medical Stores, the National Agency for Food and Drug Administration and Control, and others were excluded from the earlier stages of Global Fund grant process. Whereas an implementation committee existed in Nigeria, it did not regularly meet nor was it involved or consulted in planning or making decisions. Guinea-Bissau had limited participation of groups outside of the public sector and little access to external technical assistance. Ensuring that the main stakeholders from all levels of implementation (including the peripheral levels of the health system, such as states, districts, and facilities) are involved in some aspect of proposal development and in defining activities and milestones may promote ownership and accountability. In addition, civil society and the private sector may be encouraged to play a bigger role in the proposal's development to ensure that the proportion of the population that seeks treatment in the private sector has access to malaria medicines and interventions in the three countries.

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. However, these guidelines had not been utilized effectively at the country level, nor had any of the three countries established written contracts among the implementing partners. In Ghana, it appeared that there was a verbal understanding of the roles of the PR, SR and other partners which worked well. In addition, 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. The PR and SR there enjoy open channels of communication and mutual respect, while in Guinea-Bissau, the Central Office for Purchasing Medicines (CECOME), was often unaware of quantities ordered and delivery schedules of Global Fund medicines.

Creating a mechanism to actively engage key implementing partners in the procurement, distribution, and rational use of antimalarial medicines and commodities, with all the stakeholders playing clearly specified roles, has the potential to improve collaboration. For example, Ghana's delegation of duties to the SRs and nongovernmental organizations and its decentralization of implementation funds enabled flexibility in its grant implementation. MOUs among the partners can create accountability by specifying the individual and interconnecting roles and responsibilities, and what recourse is available if responsibilities are not met.

Experience of the Principal Recipient

Key Lessons Learned

- Selecting PRs on the basis of stricter criteria that measure their capacity and ability may promote great credibility and smoother implementation
- Assuring that PRs have experience and capacity in procurement and supplies management reduces bottlenecks in these processes

The choice of the PR seems to have significantly affected the speed and efficiency with which Global Fund malaria grants were implemented in Ghana, Guinea-Bissau, and Nigeria. 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 helped the implementation planning and process. 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. In Nigeria, the PR, although highly credible, had no previous experience in implementing malaria programs and had little capacity in procurement and supply chain management. The PR was not familiar with importation documentation or with the processes needed to implement health programs in the public sector. In Guinea-Bissau, UNDP was chosen as the initial PR because the country capacity was so limited. However, the UNDP country office had little experience in managing malaria programs and did not have the credibility that a familiar local entity would have had. Furthermore, part of UNDP's role was to build capacity within the PNDS to become the PR; however, at the end of Phase 1 of the grant, this process had not yet begun mainly due to UNDP's and others' skepticism on the capacity of PNDS to fulfill

this role. Furthermore, it is unclear whether UNDP has the human resources to build the PNDS capacity

Before proposing a PR for a Global Fund grant, the CCM should consider an extensive assessment of the PR's abilities and capacities. PRs must show evidence of their own ability or their ability to access experts that can procure, supply, and distribute medicines or commodities to health facilities. The PRs' experience and knowledge of country policies and of formal and informal importation practices including the ability to immediately and efficiently address any conditions in the grant agreements or any local funding agent's recommendations on capacity gaps may assist in the implementation process.

Procurement and Distribution Planning

Key Lessons Learned

- Developing implementation, procurement, distribution, training, and M&E plans soon after the proposal is approved and before implementation begins may facilitate appropriately planned implementation
- Including provisions for technical assistance and capacity building in key areas ensures budgets are available with minimal time lag for obtaining such assistance
- Clarifying country procurement procedures, preparing needed documents, and budgeting adequately for complementary activities, such as customs clearance and distribution, ensures budgets are available for these activities with minimal lead times
- Involving existing institutions involved in the country's pharmaceutical management, and using the existing distribution agency as a central information system may facilitate adequate buy-in and utilization of existing systems

One of the biggest determinants of failure in implementing the Global Fund grants in all three countries was a lack of sufficient planning that led to a crisis-management approach to implementation. Ghana did create an implementation committee with working groups charged with shepherding specific components of implementation, which helped the planning process and facilitated follow up. Nigeria also created an implementation committee, but it is nonfunctioning.

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

- An implementation plan that describes each implementation 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 that outlines 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 that lays out the 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 that includes 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 that outlines 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.

Technical assistance was not adequately built into or budgeted for the three proposals. Entities involved in developing proposals ought to consider the country's capacity and make provisions for accessing 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. The Global Fund does not expect countries to show that they have the ability to complete all activities on their own, and indeed, it encourages countries to mobilize support for activities for which they have limited local skills or expertise.

None of the proposal budgets sufficiently accounted for the implementation costs, especially for activities occurring after the medicines arrive in the country, such as warehousing and distribution. Ghana was not able to obtain waivers for customs clearance and had to obtain these funds from other activities within the proposal. The absence of funding for these key steps could potentially cause delays while additional funds are mobilized within the country. The proposal budget should also include resources for activities such as customs clearance and for administrative costs, such as work space, human resources, and utilities.

Processes for changing policies need to be mapped out early, including analyzing and presenting the evidence to support the change. Any documents and letters that may need to be written can be prepared early, and adequate time allotted to effectively communicate the policy change may facilitate the process. All the stages in treatment policy change from alerts on antimicrobial resistance to the results of pharmaceutical efficacy tests need to be communicated to health care practitioners and other stakeholders in the public and private sectors, such as pharmaceutical manufacturers, before advocacy activities begin to ensure acceptance of the change. An information, education, and communication strategy on the ACT policy change is important to promote public awareness and acceptance.

PSM Plan Development

None of the three countries placed adequate emphasis on PSM plan development; the plans 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. On the other hand, external consultants developed the PSM plans in Nigeria and Guinea Bissau. A delay in lining up the consultant in Guinea-Bissau resulted in a lag of about seven months between adoption of the new treatment policy and completion of the PSM plan, which subsequently contributed to the delays in procuring ACTs. In Nigeria, key PSM stakeholders, such as the Food and Drugs Service and the central medical stores (CMS) were not involved nor consulted in developing the PSM plan, which was needed to reflect the country context. While the Global Fund encourages external assistance to address capacity gaps, remaining engaged in the PSM planning may assist the PR and SR in implementing a plan with which they are familiar.

Procurement

Key Lessons Learned

- Understanding the procedures of suppliers, procurement agents, and others involved in the procurement process, including the payment terms may reduce lead times
- 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 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. Clearly the selection and ordering of an ACT which was not in short supply also facilitated the short procurement lead time.

In contrast, the procurement process in Nigeria for the first order of ACTs was characterized by challenges and delays at each step caused by several factors, including a lack of understanding of the WHO procurement process and failure to meet WHO requirements for payment and insurance. For example, WHO requires full payment before placing an order with Novartis, which was not understood in Nigeria. As a result, YGC did not forward the payment balance until two months after the first payment, which pushed Nigeria further down the list for Novartis's already limited supply of Coartem. In addition, YGC and Crown Agents were unaware that the application for the subsidized price of Coartem must be approved by a WHO Technical Advisory Group, which delayed the process an additional month. Furthermore, delays in the duty and customs requirements stalled the shipment of ACTs by an additional five months.

Several steps were taken to alleviate some of these challenges in Nigeria—

- Crown Agents began procuring Coartem directly from Novartis. This arrangement eliminated the three percent procurement fee that WHO charged and bypassed the advance payment requirement. In addition, direct procurement was expected to eliminate the administrative delays at WHO and give Crown Agents access to cost, delivery, and shipping information directly from the supplier.
- The deposit of YGC funds in Crown Agents' bank in the United Kingdom facilitated payment for the Coartem and reduced losses due to currency fluctuations.
- The Global Fund arranged for direct payment to the ACT supplier at the request of the PR, which reduced payment delays

The procurement process needs to anticipate common and specific problems that countries could face. For example, none of the countries quantified pharmaceuticals to adequately meet the needs of the proposal, which led to both excess stock and shortages, so countries need to enlist external technical assistance to quantify their needs to avoid these problems. In addition, the PR should determine needed documentation and fees and the procedure to obtain waivers. Also, countries need to explore mechanisms to speed up the lead time needed to process procurement requests, but they should build any unavoidable delays into the procurement planning process. Countries need to plan well in advance for the documentation, space, equipment, and personnel needed to import medicines.

Both Ghana and Nigeria used Roll Back Malaria's Malaria Medicines and Supplies Service (MMSS) to liaise with ACT suppliers, which led to favorable pricing and short procurement lead times for quality assured artesunate-amodiaquine in Ghana. However, this mechanism was less rewarding in Nigeria, and led to the payment of higher costs for handling and insurance as laws in Nigeria state that insurance has to be handled by a Nigerian insurance company. Nigeria also used Crown Agents as their country-level agent to coordinate the procurement process. While delegating the procurement to an agent with a track record of transparency and supplier confidence has freed the Nigerian PR from certain procurement tasks, it also added an extra layer of communication, which may have contributed to some delays. Countries need to balance experience and efficiency against the potentially higher costs of external agents.

Guinea Bissau has not procured ACTs and no planning activities in preparation for procurement had been carried out largely due to misunderstanding of the need for an implementation plan in order to access Global Fund resources. Both the PR and implementers in the country believed that additional funds for ACT procurement would not be available from the Global Fund until Phase 2. The reasons for the breakdown are unclear.

In Ghana, locally manufactured medicines will always remain a source of supply to public and private health facilities; however, poor quality ACTs produced by local manufacturers compromised the confidence of providers and patients in the safety of the new treatment. Countries should therefore address the quality of the locally produced medicines as part of a broader quality assurance system, which may include testing samples before registration and inspecting the manufacturing facility. In addition, governments may consider including in their

proposal the means to implement a simple postmarketing surveillance system to detect poor-quality medicines on the market.

Supply Chain Management

Ghana used its existing pharmaceutical supply chain that facilitated the procurement and distribution of ACTs to the facility level. In addition, standard forms and templates were disseminated to the facilities with the medicines to enable providers to track inventory. In contrast, Nigeria created a parallel distribution system, and poor planning meant that Crown Agents was hurriedly contracted as the distribution agent before the ACTs arrived in the country. Crown Agents, in turn, subcontracted with local transport company to deliver ACTs to the state level. There was no distribution plan developed by the PR and SR outlining the quantities and delivery schedules for each state, the transportation to be used, or the roles and responsibilities of each partner. Although distribution was completed within four days of the arrival of the ACTs, problems encountered included the delivery of incorrect quantities as well as leakage of Global Fund-procured ACTs into the private sector.⁷

Distribution is a key area in which countries may be able to take advantage of existing stakeholder technical expertise; however, none of the existing expertise, e.g., FDS and CMS in pharmaceutical management in Nigeria was involved in the distribution process. Although the Nigerian CMS did not have the capacity to distribute ACTs and was therefore excluded from the planning processes, CMS personnel were aware of country procurement procedures and had available standard documentation for tracking and monitoring of supplies, abilities that could have been useful if consultation had occurred. Whether or not it is serving as the distributor, the country's existing distribution agency may be invited to act as a central information system by documenting all receipts and keeping appropriate distribution, consumption, and stock records.

Both Nigeria and Ghana grossly underestimated the costs of distribution. Although the PR in Nigeria provided funds to the state level to distribute the initial shipment of medicines and commodities to the primary (local government area) level, no provisions were made to distribute subsequent shipments. To avoid these challenges during subsequent shipments, the PR and SR distributed Coartem to the tertiary and secondary (state) levels, and NMCP officers at the state level were responsible for lower-level distribution, which provided a short-term, but ultimately unsustainable solution. Furthermore, there were no systems created to track inventory or to reorder stock at the state and facility level, and as a result, some facilities had excess stock in danger of expiring, while others were already experiencing stock-outs.

⁷ While some leakage can be expected in a program of this scale over time, in Nigeria this seemed to be soon after the distribution of the first ACT shipment. The PR in response has identified the cases of leakages independently and was in the process of investigating them at the time of this assessment.

Training and Communication

Key Lessons Learned

- Coordinating training to begin before medicines arrive in country and end before distribution begins helps minimize time lag for distribution while ensuring effective recall of issues by the health care providers
- Training all health system cadres in key pharmaceutical management functions may improve the supply chain management of the commodities
- Avoiding registering products that do not comply with standard dosage schedules or quality standards may reduce the likelihood of their procurement and wide distribution and prevent adverse drug reactions
- Developing mechanism to address the quality of the locally produced medicines as part of a broader quality assurance system may facilitate instilling consumer confidence in the new treatment, particularly if it is being manufactured locally.

A comprehensive training plan provides a framework on which to base program achievements and to keep implementation plans within time and budget targets. The content and scope of training activities should cover all aspects of implementation; from training health care providers (prescribers and dispensers) in the new standard treatment guidelines, training those involved in handling medicines in pharmaceutical management and those involved in reporting in data collection and monitoring. A regular review of training activities should ensure that they are inclusive and continuing to meet program needs. Differences in practices have been observed among those who have been trained, which emphasizes the need for refresher training and regular supervision. In addition, although Nigeria and Ghana allocated extensive funds for the training of health care providers that took place, follow-up training is needed to cover new topics and new personnel. Finally, training in storage and inventory management should be carried out at all levels of the health care system and include all cadres of staff.

Training schedules need to be correlated with procurement and distribution of the medicines, so that health care providers are familiar with the new treatment guidelines before they receive the medicines in the health centers. In addition, training should occur shortly before the medicines arrive; providers may forget training that occurs too early, and training too late may encourage irrational prescribing, because providers will not have received any information on how the new medicines are used. If procurement is delayed, training should also be delayed. In Nigeria, training was carried out before the medicines arrived; whereas, 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. In contrast, Nigeria exceeded its training targets, but, training was carried out too early relative to the arrival of the ACTs. In both countries, the poor timing led to challenges with provider adherence to and rational use of the new therapy.

Mechanisms to improve treatment adherence to the national treatment guidelines and issues of rational medicine use are fundamental to the success of the new policy. When some health facilities in Ghana procured locally produced artesunate-amodiaquine that contained a higher content of the amodiaquine and was not WHO prequalified or certified under Good

Manufacturing Practices, reports of ADRs related to these products compromised the acceptance of the new treatment policy among providers and the public. Although Ghana revised its communication strategy to address those concerns, at the time of this assessment, providers were still not fully adhering to standard treatment guidelines.

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. An additional challenge in Ghana was that stakeholders at the teaching hospitals perceived the new treatment policy as belonging to the Ghana Health Service and not applying to 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

Key Lessons Learned

- Expertise in evaluating target-setting and developing a clear framework which identifies specific, relevant, measurable and achievable results improves the likelihood that targets are effectively met
- Aligning milestones and targets with activities and fund disbursement facilitates the continuous availability of funds for planned activities
- Coordinating the system for monitoring for malaria with other diseases may assist in efficient utilization of resources for similar activities and avoids duplication recording
- Recruiting staff to collect and analyze data helps with efficiency and long-term cost effectiveness
- Standardizing reporting systems avoids overburdening the system with multiple streams of data and reporting mechanisms

All three countries were challenged by a comprehensive evaluation of the targets thereby affecting the ability of the grants to reach the targets that were outlined in the original proposal. Concerns were expressed by various actors that the targets were either too ambitious or too low. The basis for performance based funding is the negotiation of a clear framework which identifies specific, relevant, measurable and achievable results. Therefore 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.

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 is crucial. Strengthening the system for collecting, analyzing, and reporting the results of monitoring activities at the district level will be a major factor in generating accurate country data. A strong M&E system also helps to track medicine availability and identify imminent stock-outs. Leakage of ACTs into the private sector, for example, was an important issue that the Food and Drugs Service and National Agency for Food and Drug Administration and Control in Nigeria could have improved by using an inventory tracking network.

All three countries were challenged by inadequate systems for M&E and underestimated the resources required for this function. All the PRs regularly had problems getting timely reports from the SRs at the field level. In Nigeria, the National Malaria Control Program, the key implementing organization, was not involved in developing the M&E framework, so their reporting to the PR and therefore to the Global Fund was weak. Because program reporting delays affect the disbursement of funds, a mechanism is needed to ensure that any delay in submitting reports to the Global Fund (from PR to local fund agent [LFA] to the Global Fund) is minimal. Fortunately, 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.

Reporting in Ghana has benefited from the recruitment of officers in various technical areas and has facilitated freeing the PR from cumbersome monitoring and reporting—for example, field officers who report to the malaria control coordinator, and staff in finance and administration, who report to the PR finance director. In addition, both Nigeria and Ghana have developed a central database for M&E which the PR and SR can regularly access.

Table 5 summarizes the key actions needed for ACT implementation from proposal development to implementation and summarizes the key challenges identified in the three cases studies. The figure in Annex 1 illustrates the ideal situation in proposal development, grant approval, and implementation from the country-level perspective.

CONCLUSION

While each country had unique issues, many of their challenges were similar, and PRs can benefit from the experiences in other countries. Implementing countries can apply these lessons learned to their own programs to help them identify and address similar challenges early to avoid bottlenecks in implementation.

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. Systems to ensure quality assurance in supply chain management should be integrated early and include mechanisms for monitoring and evaluation. Operational research may be built into the proposal stage to inform the processes of implementation. 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.

Many of the cases have evolved since the studies were conducted and therefore all recommendations may not currently apply to the specific cases. Nevertheless, the lessons learned from these case studies offer valuable insights into the challenges that affected the implementation of Global Fund malaria grants in Ghana, Guinea-Bissau, and Nigeria and about Global Fund procedures and policies. It must be noted that some of the challenges experienced in the three countries, such as delays in developing treatment protocols and training staff and producer capacity bottlenecks, were 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, bureaucratic importation and customs procedures, inadequate information systems, and inadequate planning are valid for malaria grants for most PRs of other countries but also for other products and commodities.

Table 5. Key Actions Needed and Potential Bottlenecks from Proposal Development to Implementation

Grant Stage	Key Actions	Stakeholders	Challenges
CCM appointment	<ul style="list-style-type: none"> • Appoint broad-based CCM, involving key stakeholders including drug regulatory authority and mix of technical and political institutions • Establish membership by constituency • Ensure partners are committed to CCM and participate regularly in meetings • Appoint CCM chair and co-chairs • Develop regular schedule of meetings • Develop working groups and implementation committee with appropriate terms of reference • Appoint PR and SR with capacity to carry out activities • Ensure CCM understands its roles • Plan for funds for CCM operations • Develop mode of working 	CCM	<ul style="list-style-type: none"> • Appointment process not transparent • Key stakeholders not involved or informed • Membership based solely on political criteria rather than technical need • Members not committed to process and meetings • CCM does not understand roles • CCM does not plan for funds for its survival from various sources
Proposal development	<ul style="list-style-type: none"> • Map and analyze the roles of the relevant stakeholders • Involve key stakeholders that will be involved in implementation • Consider activities to be supported by government and other partners and identify gaps to be filled by Global Fund • Consider and budget for external assistance • Identify and budget for complementary activities (e.g., distribution, M&E) • Ensure that potential PRs and SRs understand their roles • If consultant hired, maintain involvement and understanding of all aspects of plan • Give PSM appropriate importance • Identify realistic activities and targets in the proposal 	<ul style="list-style-type: none"> • CCM • Technical bodies in country • Technical partners 	<ul style="list-style-type: none"> • Key stakeholders not involved or informed • Funds for external assistance and complementary activities not identified and budgeted • Potential PRs and SRs do not understand roles • Consultant hired to develop proposal without involvement and understanding of implementers of the plan • PSM issues are not given appropriate importance • Activities and targets in the proposal are not realistic • Implementation of activities in proposal are not given adequate importance • Lack of procurement capacity

Grant Stage	Key Actions	Stakeholders	Challenges
Proposal approval	CCM/PR promptly respond to queries and conditions of TRP	<ul style="list-style-type: none"> • Global Fund (TRP and Board) • CCM 	<ul style="list-style-type: none"> • TRP does not query key operational aspects of proposal • Queries not responded to adequately in sufficient time
LFA assessment	<ul style="list-style-type: none"> • Assesses PR on financial management, program management, and PSM • Gaps identified and recommendations made • Conditions identified 	<ul style="list-style-type: none"> • LFA • PR • CCM 	<ul style="list-style-type: none"> • LFA does not sufficiently identify gaps in PSM, and disbursements are not adequately linked to satisfying conditions • Recommendations are not adequately communicated to PR
PSM plan developed and submitted	<ul style="list-style-type: none"> • Develop PSM plan through broad consultation with key stakeholders • Coordinate targets and milestones in PSM with key activities and funds • Carry out quantification for national and district level (ensure quantification or parallel procurement efforts are coordinated) • If consultant used to prepare plan, maintain implementers' involvement and understanding of all aspects of plan 	<ul style="list-style-type: none"> • PR • CCM • Technical partners • Consultant 	<ul style="list-style-type: none"> • PR does not understand or have capacity for PSM plan development • PR does not have access to consultants for developing the plan • Consultant hired to develop plan without plan implementers' involvement and understanding • Indicators and targets are not realistic or coordinated with activities and fund disbursement • Key stakeholders are not involved
Grant negotiation, signing, and fund disbursement	<ul style="list-style-type: none"> • Agree on realistic targets and milestones • Identify and agree upon conditions precedent based on LFA assessments • Negotiate and sign grant • PR mobilizes immediately to satisfy conditions precedent 	<ul style="list-style-type: none"> • Global Fund • PR 	<ul style="list-style-type: none"> • PR does not fully understand process • PR delays satisfaction of conditions precedent

Grant Stage	Key Actions	Stakeholders	Challenges
Policy and regulatory issues	<ul style="list-style-type: none"> Alert policy makers to the need for policy change Fast-track any policy or regulatory processes as needed, including registration of medicines Consider changing regulatory status of medicine to over the counter Evaluate whether any regulatory process will affect implementation and develop mechanisms to address this issue Promulgate appropriate regulations 	<ul style="list-style-type: none"> CCM Policy makers Drug regulatory authority 	<ul style="list-style-type: none"> Slow in-country processes for policy change Changing policies may affect planning for implementation Slow registration process for medicines
Planning	<ul style="list-style-type: none"> Develop plans in collaboration with appropriate stakeholders— <ul style="list-style-type: none"> Implementation plan Procurement plan Training plan Distribution and storage plan Phase-out plan for old medicine (determine pipeline, adjust future procurements, and develop mechanisms for phasing out) M&E plan Develop list of documentation needed at each stage of plans Identify roles and responsibilities of stakeholders Define timelines for activities Ensure PRs and SRs and other implementers and partners understand roles and responsibilities Establish mechanisms for accountability Develop MOUs 	<ul style="list-style-type: none"> PR SR Other implementers Partners CCM 	<ul style="list-style-type: none"> Plans not developed or developed inappropriately Lack of understanding and mapping of key steps and documentation needed Stakeholders are not involved PRs and SRs and other implementers and partners do not understand roles and responsibilities Mechanisms for accountability are not established (e.g., MOUs developed) Poor communication among CCM, PR, and SRs
Training and communication	<ul style="list-style-type: none"> Revise and disseminate new guidelines, including standard treatment guidelines and essential medicines lists Carry out training workshops just before medicines arrive in-country according to training plan Train on pharmaceutical management and inventory management Disseminate treatment guidelines and forms and documentation needed for recording Train on quantification for pull system Launch communication strategy Develop and disseminate behavior change communication strategies 	<ul style="list-style-type: none"> PR SR Other implementers 	<ul style="list-style-type: none"> Training and communication not coordinated with arrival and distribution of goods Training plan not implemented appropriately Constant change in staff Lack of capacity for training in all issues Poor communication among CCM, PR, and SRs

Grant Stage	Key Actions	Stakeholders	Challenges
	and information, education, and communication (IEC) messages (coordinate widespread communication with distribution)		
Procurement	<ul style="list-style-type: none"> • Identify procurement agent if necessary • Identify supplier through procurement agent or tender system • Obtain appropriate procurement, import, and other documents, including any waivers • Initiate and manage procurement processes • Procure medicines and commodities • Make timely payment • Contract clearing agent 	<ul style="list-style-type: none"> • PR • SR • Other implementers (CMS, procurement system) 	<ul style="list-style-type: none"> • Lack of capacity in procurement • Unclear understanding of process and procedures, including documentation, waivers needed • Poor communication between procurement agent and PR • Miscalculation of amounts needed
Quality assurance/quality control	<ul style="list-style-type: none"> • Establish mechanisms for quality control of incoming medicines • Establish mechanisms for quality assurance of each implementation step (including supervision) • Coordinate surveillance systems 	<ul style="list-style-type: none"> • PR • SR • Other implementers (drug regulatory authority) 	<ul style="list-style-type: none"> • Lack of capacity for quality assurance/quality control • Regulatory body not involved in process
Distribution	<ul style="list-style-type: none"> • Contract distribution agent if needed before goods arrive in the country • Test quality of procured medicines • Provide distribution list and delivery schedule to distributor • Clear medicines and store in central warehouse until ready for distribution • Distribute medicines to district stores and health facilities according to distribution plan • Distribute documentation for recording inventory and stocks • Establish mechanisms for reordering; develop and distribute appropriate documentation • Establish mechanisms for quality assurance of distribution processes • Develop systems for tracking consumption • Phase out old medicines • Develop/review transportation • Develop/review strategies for preventing leakage to private sector • Develop/review systems to ensure management of shelf life 	<ul style="list-style-type: none"> • PR • SR • Other implementers (CMS, distribution system) 	<ul style="list-style-type: none"> • Poor communication among PR and SRs • No systems for inventory management, tracking consumption, and reordering • Poor distribution capacity • Lack of planning for distribution • Poor transport capacity • Inadequate storage • Stock-outs caused by miscalculation of amounts needed • No mechanisms for quality assurance of distribution processes
Rational use by patient/caretaker	<ul style="list-style-type: none"> • Disseminate IEC messages • Develop supervisory system for monitoring provider adherence 	<ul style="list-style-type: none"> • PR • SR • Providers 	<ul style="list-style-type: none"> • Inadequate IEC • Inadequate quality assurance, including

Grant Stage	Key Actions	Stakeholders	Challenges
	<ul style="list-style-type: none"> • Develop system for monitoring patient use 	<ul style="list-style-type: none"> • Patients 	<p>supervision</p> <ul style="list-style-type: none"> • No systems for monitoring rational use
Reporting and M&E	<ul style="list-style-type: none"> • Identify data needs and sources • Build capacity for M&E (human and information technology) • Develop and implement systems and schedules for routine and accurate data collection • Enter data into database and store in central location easily accessible by PR and SR • Ensure SR reports on key indicators to PR promptly each month • Convene quarterly meetings of PR, SRs, and CCM • Provide quarterly reports from PR to CCM • Provide quarterly reports from PR to LFA • Conduct periodic supervisory visits by PR to validate accuracy of data 	<ul style="list-style-type: none"> • PR • SRs • Other implementers • LFA • CCM • Global Fund 	<ul style="list-style-type: none"> • Poor systems for monitoring • Poor data collection • Inadequate planning for reporting to chain of accountability • No central storage of data • No mechanisms for validating accuracy of data

ANNEX 1. PEOPLE CONSULTED OR INTERVIEWED IN THE STUDY

Nigeria

Name	Organization/Position
Mrs. Gloria Abumere	RBM focal person Food and Drugs Service Federal Ministry of Health
Dr. Akua Addo-Kwateng	Health Team Leader USAID/Nigeria
Mr. O. G. Amosun	Deputy Director (Manufacturing and Distribution) Food and Drugs Service Federal Ministry of Health
Dr. M. Belhocine	WHO Representative to Nigeria WHO
Mr. Ali Bukar	Monitoring and Evaluation Officer Yakubu Gowon Centre
Mr. Kenneth Chukwuemeka	Country Director Crown Agents Nigeria Limited
Dr. Polly Dunford	Director Office of Health, HIV/AIDS and Education USAID/Nigeria
Dr. Isaac Egboja	Program Coordinator Yakubu Gowon Centre
Dr. Bayo S. Fatunmbi	National Professional Officer Roll Back Malaria WHO/Nigeria
Dr. Jerome Mafeni	Chairman of CCM and Chief of Party ENHANSE Project
Dr. G. Mokuolu	Consultant for the Malaria Global Fund Round 5 Proposal and Chairman of the Medical Advisory Committee and Director of Clinical Services and Training University of Ilorin Teaching Hospital, Ilorin
Dr. A. Nasidi	Ex-Chairman (old CCM) Director Special Projects Federal Ministry of Health
Dr. Ernest Nwokolo	Director Society for Family Health (Malaria) Formerly with NMCP, former Case Management Officer, NMCP
Mr. John Odey Okache	Procurement Officer Yakubu Gowon Centre
Mr. R.K. Omotayo	Director Food and Drugs Service Federal Ministry of Health
Mr. O.O. Omoyele	Deputy Director Food and Drugs Service Federal Ministry of Health and in charge of the CMS
Dr. Baba Sheshi	Program Manager for Malaria Yakubu Gowon Centre

Name	Organization/Position
Dr. T. O. Sofola	Coordinator NMCP Federal Ministry of Health
Mr. Andrew Taylor	Program Manager Crown Agents Nigeria Limited
Dr. Ogori Taylor	Essential Drugs and Medicine Policy Adviser WHO/Nigeria
Mr. Michael Thaw	Logistics Consultant Crown Agents Health Crown Agents Nigeria Limited
Dr. Ibrahim Umar	Former Program Manager YGC Independent consultant (current position)
Mr. Kashim Yusuff	Head Technical Services NAFDAC

Ghana

Name	Organization/Position
Mr. Louis Agbe	CCM chairman
Ms. Rosina Ampadu	Accountant MoH
Ms. Edith Andrews	WHO Department of Essential Drugs and Medicines
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 Adviser, USAID Member of CCM
Mrs. Martha Gyansa-Lutterodt	Assistant Program Manager Ghana National Drugs Program, MoH
Mr. Peter Gyimah	Head CMS, 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
BethAnne Moskov	Team Leader, Health USAID
Mr. Alex Nartey	Director of Finance MoH

Name	Organization/Position
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 Adviser UK Department for International Development
Ms. Dorothy Rozga	UNICEF Country Representative
Mr. A. Manu Sarpong	PR Administrator MoH
Mr. Sylvester Segbeya	Program Officer National Malaria Control Program
Elena Trajkovska	Supply Officer UNICEF
Dr. Mark Young	Project Officer Health and Nutrition UNICEF

Guinea-Bissau

Name	Organization/Position
Fernanda Alves	National Professional Officer Malaria Guinea-Bissau
Dr. Fernando Agostinho	Manager for Global Fund Malaria Program UNDP Guinea-Bissau
Michel Balima (contacted but not interviewed)	Resident Representative UNDP Guinea-Bissau
Dr. Placido Cardoso	Director General of Health Ministry of Health Guinea-Bissau
Raul Espinosa	Manager for Global Fund Procurements UNDP Guinea-Bissau
Dr. Estevao (contacted but not interviewed)	CECOME
Dr. Alicia Gomez	UNDP/IAPSO Copenhagen
Mr. Kjetil Hansen	Deputy Resident Representative UNDP
Dr. Daniel Kertesz	WHO representative Guinea-Bissau

Name	Organization/Position
Dr Lori Lee	Program Operations Adviser UNDP New York
Dr Evangelino Quade	Coordinator of the National Program to Fight Malaria Ministry of Health Guinea-Bissau
Mrs. Antonia Mendes Teixeira (contacted but not interviewed)	Honorable Minister of Health CCM
Dr. Adrien Ware	Manager for Global Fund Grants, UNDP UNDP Guinea-Bissau

REFERENCES

- The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). n.d. *The Global Fund's Proposals Process in Brief*. Geneva: Global Fund
<<http://www.theglobalfund.org/en/apply/proposals/>>.
- Global Fund. n.d. *Guide to Writing the Procurement and Supply Management Plan*. Geneva: Global Fund. <<http://www.theglobalfund.org/en/about/procurement/guides/>> (Accessed August 21, 2007).
- Global Fund. 2005. *Revised Guidelines on the Purpose, Structure and Composition of Country Coordinating Mechanisms and Requirements for Grant Eligibility*.
(<http://www.theglobalfund.org/en/apply/mechanisms/guidelines/>) (Accessed December 28, 2006).
- Global Fund. n.d. *Country Coordinating Mechanisms*. Geneva: Global Fund.
<www.theglobalfund.org/en/apply/mechanisms> (accessed August 20, 2007).
- WHO. 2006. *Guidelines for the treatment of malaria*. Geneva: WHO.
<<http://www.who.int/malaria/docs/TreatmentGuidelines2006.pdf>>(accessed August 21, 2007).

Nigeria

- Abebe, E., M. E. Mosanya, C. Amajoh, et al. 2004. *Nigeria Roll Back Malaria Consultative Mission: Essential Actions to Support the Attainment of the Abuja Targets*. Nigeria RBM Consultative Mission Final Report.
- Charles Kendall & Partners, KPMG Professional Services, Nigeria & KPMG LLP. August 23, 2004. *Procurement and Supply Management (PSM) Assessment: Yakubu Gowon Center, Scaling up HIV/AIDS, Tuberculosis and Malaria Prevention Care and Support in Nigeria. Round 2-Malaria*.
- Crown Agents. Delivery Notes. April 2006.
- Federal Ministry of Finance. December 19, 2005. Letter to Comptroller General, Nigeria Customs House: Description of import duty exemption certificate.
- Federal Ministry of Health (FMOH), Nigeria. 2005. National Malaria Control Programme 2005 Annual Report. Abuja: FMOH.
<http://www.who.int/countries/nga/areas/malaria/nmcp_annual_report_2005.pdf> (Accessed August 21, 2007).
- Federal Ministry of Health (FMOH). Microplanning Forms: Summary of Transport Needs for State Medical Stores.

FMoH. Microplanning Forms: Summary of Transport Needs for LGA Stores.

FMoH. National Malaria Control Program. Malaria Medicines and Supplies Microplanning Form.

FMoH. National Malaria Control Program. Malaria Prescription Form.

Federal Republic of Nigeria. Form M: Application to Import.

Form M. First shipment.

Form M. Second shipment. 4.10.06.

GFATM. February 2, 2006. Grant Performance Report: NGA-404-G05-M.

GFATM. March 30, 2006. Grant Performance Report: NGA-203-G04-M-00.

Grant Performance Report. Round 2 and Round 4: Quarter 6 (March–May 2006).

.

Letter to the Fund Portfolio Manager, GFATM, from General Yakubu Gowon, Yakubu Gowon Centre for National Unity and International Cooperation, March 1, 2006.

Letter to Ambassador Ekpang, Yakubu Gowon Centre for National Unity and International Cooperation, from Crown Agents, March 23, 2005 (Supply of Coartem by the WHO).

Letter to Ambassador Ekpang, Yakubu Gowon Centre for National Unity and International Cooperation, from Crown Agents, March 4, 2005 (Procurement of Health and Non-Health Product for Roll Back Malaria Project-Procurement of Coartem).

Letter from General Dr. Yakubu Gowon to Chief Olusegun Obasanjo, President and Commander-in-Chief, Federal Republic of Nigeria: Request for Tax and Import Duty Exemption for Global Fund Supported Program, August 5, 2005.

Letter from General Dr. Yakubu Gowon to Minister of Finance, Federal Ministry of Finance, Federal Republic of Nigeria: Request for Tax and Import Duty Exemption for Global Fund Supported Program, August 5, 2005.

Letter from Dr. Sofola, Malaria and Vector Control Program, to YGC: Allocation of artemether-lumefantrine for the treatment of uncomplicated malaria in children under five years, August 15, 2006.

National Malaria Control Program. Malaria Medicines Supply Form.

Nigeria Country Coordinating Mechanism. July 2002. *Scaling Up Roll Back Malaria in 12 States in Nigeria*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria during Round 2.

Nigeria Country Coordinating Mechanism. April 2004. *Improving Malaria Case Management through Promotion and Distribution of Pre-Packaged Artemisinin-Based Combination Therapy (ACT) and Training of Health Service Providers*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria. Round 4.

Documents submitted by the PR to the Global Fund:

Disbursement Request and Progress Update. Round 4: Quarter 2.

Disbursement Request and Progress Update. Round 4: Quarter 1.

Disbursement Request and Progress Update. Round 4: Quarter 3.

Roll Back Malaria (RBM), Federal Ministry of Health. LGA Monthly Reporting Form for Pre-packaged Drugs (PPDs) and Intermittent Preventive Treatment (IPT).

RBM, Federal Ministry of Health. Weekly Health Facility Reporting Form for Pre-packaged Drugs (PPDs) and Intermittent Preventive Treatment (IPT).

RBM, Federal Ministry of Health. State Monthly Reporting Form for Pre-packaged Drugs (PPDs) and Intermittent Preventive Treatment (IPT).

RBM, Federal Ministry of Health. Progress Report on Implemented Activities. Data Collection Format.

RBM, Federal Ministry of Health. Inventory and Order Form for Intermittent Preventive Treatment (IPT), Pre-packaged Drugs (PPDs) and Insecticide Treated Nets (ITNs).

WHO/RBM. Pro forma Invoice for supply of Coartem. April 15, 2005.

Yakubu Gowon Centre (YGC). December 28, 2004. Letter to Dr. Sofola, National Malaria Control Program from Project Manager, Malaria: Taxes and import duties exemption.

YGC. October 19, 2006. List of releases of funds to subrecipient (Round 2 Malaria Program).

YGC. October 19, 2006. List of releases of funds to subrecipient (Round 4 Malaria Program).

YGC delivery notes. October 2006.

Ghana

Banda, J., K. Kamanga, J. Sillah, et al. 2004. *Ghana Roll Back Malaria Consultative Mission (REAPING): Essential Actions to Support the Attainment of the Abuja Targets*.

<http://www.rbm.who.int/partnership/country/docs/WAfrica/reaping_ghana.pdf> (Accessed August 21, 2007).

Ghana Country Coordinating Mechanism. 2002. *Accelerating Access to Prevention, Care, Support, and Treatment of Malaria for Targeted Persons in 20 Districts*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria during Round 2.

Ghana Country Coordinating Mechanism. April 2004. *Accelerating Access to Prevention, Treatment, and Care and Support for Malaria and Achieving the Millennium Goals*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria during Round 4.

Ghana MoH audit report of 2005

GFATM. MoH, Ghana Assessment.

Minutes of CCM meetings.

Documents submitted by the PR to the Global Fund:

GPR: GHN-405-G04-M. February 24, 2006.

GPR: GHN-202-G03-M. March 2, 2006.

Disbursement Request and Progress Update. Round 2: Quarter 1.

<http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr2.pdf>

Disbursement Request and Progress Update. Round 2: Quarter 2.

<http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr3.pdf>

Disbursement Request and Progress Update. Round 2: Quarter 3.

<http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr4.pdf>

Disbursement Request and Progress Update. Round 2: Quarter 4.

<http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr5.pdf>

Disbursement Request and Progress Update. Round 4: Quarter 1.

http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr6.pdf

Disbursement Request and Progress Update. Round 4: Quarter 2.

http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr7.pdf

Disbursement Request and Progress Update. Round 4: Quarter 3.

http://www.theglobalfund.org/search/docs/4GHNM_788_347_dr8.pdf

Program Grant Agreement between GFATM and the Ministry of Health of the Republic of Ghana (PR), Round 4, January 2005.

Program Grant Agreement between GFATM and the Ministry of Health of the Republic of Ghana (PR), Round 2, Phase I, August 2003.

Program Grant Agreement between GFATM and the Ministry of Health of the Republic of Ghana (PR), Round 2, Phase II, August 2005.

Guinea-Bissau

Adriamahefazafy, B. 2006. *Rapport de Mission d'Appui Technique au PNLN de Guinée-Bissau pour l'élaboration d'un plan d'introduction des CTAs : MTT/MAL/AFRO*.

Guinea-Bissau Country Coordinating Mechanism. 2004. *Expanding the Fight against Malaria*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria during Round 4.

Guinea-Bissau Country Coordinating Mechanism. 2006. *Expanding the Fight against Malaria*. Proposal submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria during Round 6.

Republique de Guinée-Bissau, Ministère de la santé publique. 2006. *Plan de gestion des achats et des stocks (GAS) des antipaludiques et commodités : année 2006*. Préparé par T. Adjadi, Février 2006.

Republica de Guinée-Bissau, Ministério da Saúde. Atelier de elaboração do plano de implementação da nova política de tratamento. Bissau, 11 de Abril de 2006.

United Nations Development Program (UNDP). *Procurement & Supply Management Plan: Malaria*. Submitted to GFATM.

WHO. 2006. *Rapport de la Mission d'appui technique au PNLN de la republique de Guinée-Bissau pour l'élaboration de plan d'approvisionnement et de gestion des stocks des antipaludiques et autres produits de lutte contre le paludisme, du 5 au 20 février 2006*. Par T. Adjadi, DRAFT.

