

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

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CONTENTS

ACRONYMS AND ABBREVIATIONS	v
ACKNOWLEDGMENTS	vii
EXECUTIVE SUMMARY	ix
INTRODUCTION	1
Background.....	1
Study Objectives.....	2
Methodology.....	2
Summary of the Standard Global Fund Process from Grant Application to Implementation	3
CASE STUDY	5
Background.....	5
Proposal Development.....	6
Selection of the PR.....	6
LFA Assessment of PR Capabilities Related to Procurement, Supply, and Management.....	7
Role of the CCM.....	8
PSM Plan Development.....	8
Policy Issues.....	8
Quantification of Antimalarial Medicine Needs.....	9
Grant Signing, Receipt of the Funds, and Disbursements	10
Procurement	10
Training.....	13
Distribution and Storage	14
M&E: Program Indicators and Milestones, Action Plans, and Budget	15
Management and Coordination.....	16
KEY LESSONS LEARNED	17
General.....	17
Effective Coordination among Stakeholders	17
Experience of the Principal Recipient.....	19
Procurement and Distribution Planning.....	20
PSM Plan Development.....	21
Training and Communication	23
Program Monitoring, Evaluation, and Reporting	24
CONCLUSION.....	25
ANNEX 1. PEOPLE CONSULTED OR INTERVIEWED IN NIGERIA DURING THE STUDY	27

ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapies
AIDS	acquired immunodeficiency syndrome
BCC	behavior change communication
CCM	country coordinating mechanism
CMS	Central Medical Stores
EDM	[Department of] Essential Drugs and Medicines [World Health Organization]
FDS	Food and Drugs Service
FMoH	Federal Ministry of Health
FPM	Fund Portfolio Manager
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
IEC	information, education, and communications
IPT	intermittent preventive treatment
ITN	insecticide-treated nets
LFA	Local Fund Agent
LGA	local government area
M&E	monitoring and evaluation
MMSS	Malaria Medicines and Supplies Service (hosted by the RBM Partnership Secretariat)
MOU	Memorandum of Understanding
NGO	nongovernmental organization
NMCP	National Malaria Control Program
PR	principal recipient
PSM	procurement and supply management
RBM	Roll Back Malaria [Initiative]
RPM Plus	Rational Pharmaceutical Management Plus
SR	subrecipient
TB	tuberculosis
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization
YGC	Yakubu Gowon Center for National Unity and International Cooperation

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EXECUTIVE SUMMARY

Nigeria was awarded two Global Fund malaria grants—in Rounds 2 and 4. Through both grants, Nigeria plans to treat an estimated six million episodes of malaria in children less than five years of age with artemisinin-based combination therapies (ACTs) in half of the 36 states and in the Federal Capital Territory. The Federal Government was expected to provide treatments to the remaining 18 states and for the population over five years of age in the Global Fund states. The principal recipient (PR) and subrecipient (SR) for both grants are the Yakubu Gowon Center for National Unity and International Cooperation (YGC) and the National Malaria Control Program, respectively.

The grant agreement with Nigeria for the Round 2 proposal was signed in October 2004, just two months before the Round 4 grant agreement was signed. This delay was caused by some clarifications to 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 in February 2005 as the first-line therapy for treating uncomplicated malaria, and procurement of ACTs using Global Fund resources began in May 2005. However, the Coartem did not begin to arrive in the country until March 2006, nearly 15 months after the grant agreements had been signed due to several reasons. The PR, YGC, had little capacity for procurement or supply management. Although Crown Agents was contracted to manage the procurement issues, Crown Agents, too, had limited understanding of the World Health Organization's (WHO) procurement process and failed to meet WHO requirements, including terms of payment and insurance. At the same time, there was a global shortage of Coartem because Novartis, the sole supplier of the medicine, was unable to meet the demand. This added a further nine months to the procurement process. The PR's limited understanding of the documentation needed for importation, poor planning and inadequate follow-up, and slow in-country processes stalled the shipment of the ACTs by an additional five months.

Despite the recommendation from the Local Fund Agent (LFA) to contract with a distribution agency, this was not done early and Crown Agents was hurriedly contracted to perform this function. They in turn subcontracted to a local firm. No distribution plan for the medicines was developed by the PR and SR until the shipment was about to arrive. Although distribution was completed within four days of customs clearance, quantities distributed did not agree with the delivery notes in many states, and some stock that was purchased using Global Fund resources was 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 were developed on how subsequent supplies would reach the facilities. When the initial Coartem stock was consumed, no mechanisms were set up for the facilities to reorder.

Furthermore, because of the late arrival of the medicines, the PR and the SR, the National Malaria Control Program (NMCP), distributed the ACTs to non-Global Fund states to avoid expiration of the Coartem without having a plan for how to or who will replenish the stocks of ACT after this initial supply. Although the federal government was to provide treatment for the non-Global Fund states and the population over five years of age, it did not meet this commitment. In the Global Fund states, this failure caused providers, under pressure from

patients, to prescribe and dispense multiple pediatric packs for the treatment of older children and adults, thereby using up the product faster than expected and confusing actual consumption measurement by specific age groups.

The actual consequences of performance-based disbursements were not understood until the grant implementation was under way. Furthermore, the proposal development and subsequent implementation did not include stakeholders that are key to good pharmaceutical management, such as the Nigeria Food and Drugs Service (FDS). Technical assistance to address shortfalls in capacity was not sought early enough, which led to a crisis management approach to implementation with the result that short-term solutions to problems were sought rather than creating sustainable systems.

Although all the training targets were exceeded, the training was carried out too early in relation to the arrival of the medicines and not enough attention was given to supply management.

Subsequent consignments were distributed by the PR and the SR with little delay however, using a parallel distribution system. At the time of fieldwork for this case study, 2.5 million doses were still available at the YGC warehouse.

Many of the challenges faced can be attributed to a lack of understanding of the mechanisms needed to ensure appropriate procurement, storage, distribution, and management of ACTs. Although certain delays were outside the PR's direct responsibility, many could have been avoided by appropriate planning and the PR's early recognition of its lack of experience in the area of procurement and the need to obtain external assistance in this area. The PR might consider building its own capacity in the areas of procurement and supply management, and subcontract with experts in areas that it can not address while retaining its supervisory role for these activities.

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 However, of the 43 malaria proposals submitted and approved by the Global Fund during Rounds 1, 2, and 3 (April 2002 to September 2003), 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 reprogramming resources from the Global Fund.

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

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

Study Objectives

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

The specific objectives of the study were to—

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

Methodology

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

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

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

Country coordinating mechanisms (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 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.

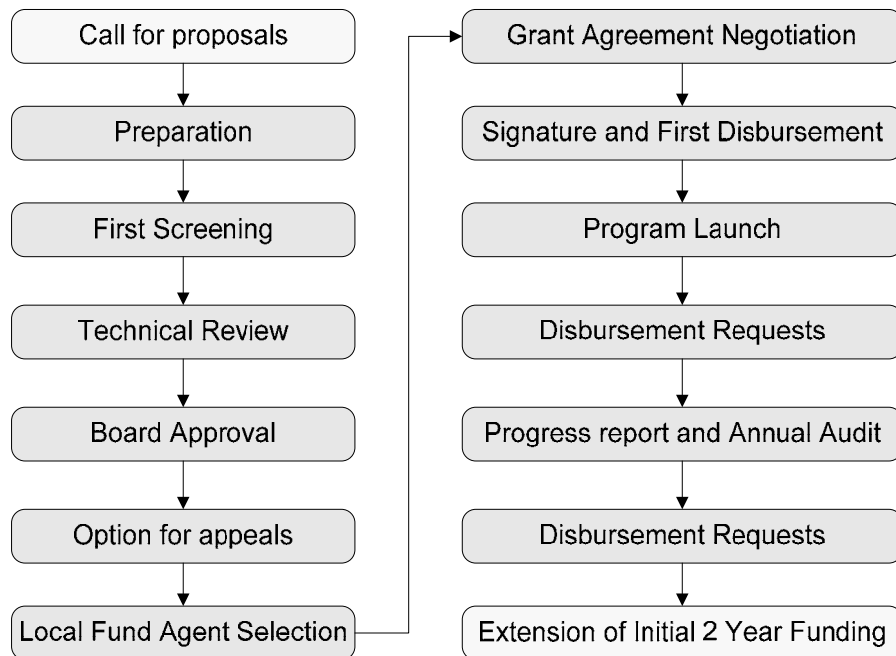
For readers who are unfamiliar with it, the following is a brief description of the Global Fund process after the grant is approved, which is taken from the Global Fund's website³—

1. The Secretariat contracts with one LFA per country. The LFA certifies the financial management and administrative capacity of the nominated PR(s). Based on LFA assessment, the PR may require technical assistance to strengthen capacities. Development partners may provide or participate in such capacity-building activities. The strengthening of identified capacity gaps may be included as conditions precedent to disbursement of funds in the grant agreement between the Global Fund and the PR. In addition, the LFA makes an assessment of the procurement capacity and M&E capacity.
2. The Secretariat and PR negotiate a grant agreement for the first two years of the grant (Phase 1), which identifies specific, measurable results to be tracked using a set of key indicators.
3. The grant agreement between the Global Fund and the PR is signed. Based on a request from the Secretariat, the World Bank makes initial disbursement to the PR. The PR makes disbursements to SRs for implementation, as called for in the proposal.
4. Program and services begin. As the coordinating body at the country level, the CCM oversees and monitors progress during implementation.
5. The PR submits periodic disbursement requests with updates on programmatic and financial progress. The LFA verifies information submitted and recommends disbursements based on demonstrated progress. Lack of progress triggers a request by Secretariat for corrective action.
6. Each fiscal year, the PR submits a progress report and annual audit of program financial statements to the Secretariat through the LFA.
7. Regular disbursement requests and program updates continue, with future disbursements tied to ongoing progress.

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

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).

Figure 1. Global Fund proposal approval and implementation process



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

CASE STUDY

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 NMCP, which hosts the RBM Secretariat. Nigeria has a broad-based RBM partnership made up of 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 was awarded two Global Fund malaria grants in Rounds 2 and 4. The Round 2 proposal covers a population of 4.4 million children under five years of age and 870,000 pregnant women in 12 states. Activities focus on scaling up the coverage of existing strategies, including providing insecticide-treated nets for pregnant women and children under the age of five, prepackaged treatments for children under five, and intermittent preventive treatment (IPT) for pregnant women. Among the key strategies was health personnel training. The Round 4 proposal focused on home-based management, prompt and effective treatment, and monitoring drug resistance.

Although the Round 2 proposal included chloroquine as the first-line treatment, before the grant agreement was signed, the Global Fund announced that countries needed to change their first-line treatments to more effective ACTs in accordance with WHO recommendations and reprogram their budgets for procurement to accommodate the new first-line treatments. In response to this announcement, the PR in collaboration with the NMCP adjusted their budgets and reprogrammed their funds to procure ACTs using funds earmarked from Phase 2 that the Global Fund made 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 36 states. The official endorsement of the new treatment, artemether-lumefantrine (Coartem), occurred in May 2005.

The CCM nominated the YGC to serve as the PR for both grants. The NMCP of the FMoH was nominated as the SR for the malaria grants. The LFA is KPMG Professional Services.

Table 1. Summary of Grant and Other Data for Nigeria

Round	Grant Number and Date Signed	PR/ SR	LFA	Total Amount Awarded (USD)	Approved Funding: Phase 1 (USD)	Amount Disbursed to Date ^a (USD)	Procurement Budget in Agreement (USD)	Current Procurement Expenditure (USD)
2	NGA-202-G04-M-00 October 22, 2004	YGC/ NMCP	KPMG Professional Services	44,314,691.00	20,994,149.00	14,597,437.75	2,880,000.00	3,081,186.00
4	NGA-404-G05-M December 3, 2004	YGC/ NMCP	KPMG Professional Services	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

^a At the time of the assessment

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 which included representatives of national disease programs, members of academia, and others as appropriate. Consensus meetings among a broader range of stakeholders were then held. For Round 4, consultants from outside the CCM were engaged to prepare the proposal, which involved similar consensus building.

In both the rounds, PSM was inadequately covered at the proposal stage, partly because the information requested in the early 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, National Agency for Food and Drug Administration and Control (NAFDAC), Central Medical Stores (CMS), or WHO's Department of Essential Drugs and Medicines, were not involved in the development of the proposal in Rounds 2 or 4. An overarching problem was that no procurement experts were part of the CCM or the technical committee appointed to review the proposals.

Before the proposals were finally approved, the Global Fund TRP requested some clarifications, but none related to 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; the 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

- Proof of ability to provide efficient financial 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 was chosen as PR because of its credibility, having been created by the former Nigerian head of state, General Yakubu Gowon, and because of its previous experience in implementing a vertical Guinea worm program in Nigeria that was based on the management of donated goods. YGC is 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 Global Fund grant's magnitude 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 existing PSM capabilities, including the Central Medical Stores, 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. 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 precedent 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 all of which were satisfied. Other requirements for fund disbursement were developing a procurement plan and contracting with a distribution agent. Concerns about PR capacity for PSM were identified quite early in the grant implementation, however, capacity building was not a condition to disbursement of funds and the PR failed to take adequate and immediate action to bridge those gaps.

Role of the CCM

The PR did not adequately understand or recognize the oversight role of the CCM, and the CCM did not have any power over the PR or the implementation process of Global Fund grants. The CCM also did not have any mechanism to enforce the accountability of the PR or to make recommendations to the PR on how challenges might be addressed.

Furthermore, the CCM did not have an operating budget for meetings. The Global Fund expects the 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. Neither the CCM nor the PR clearly understood those mechanisms; 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. The Global Fund is now planning to support the CCM up to a maximum of USD 30,000, after which the CCM must find another source of funding.

On the recommendation of the Global Fund, in June 2006, the CCM underwent major changes in both leadership and membership. These changes were inspired in part by the potential threat of losing the malaria grants because of poor performance in grant implementation. The phasing out of the old CCM and phasing in of the new CCM has been challenging, with some documentation lost during the process. The new CCM is based on constituency membership, as opposed to individual membership, and an electoral process. Plans are under way to develop a Memorandum of Understanding (MOU) between the CCM and the PR to establish roles, responsibilities, and a process for better accountability of the PR to the CCM. In addition, discussions have 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 state levels of the healthcare system to establish a process and lines of accountability in implementation. This 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. 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 the implementation of the Global Fund malaria grants in Nigeria.

According to Global Fund requirements, Coartem could not be procured until the national treatment policy had been changed. By December 2004, therapeutic trials had been conducted, 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 May 2005—six months later—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 also named as an alternative to enable the private sector to obtain affordable treatment with ACT.

Other policy issues that contributed to the implementation challenges included—

- The need for 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, which included a change in policy from preshipment inspection to destination inspection in January 2006; before the Coartem could be shipped, Nigerian authorities required a number of forms that were not obtained in advance, resulting in delays.
- Nigerian authorities required an insurance certificate issued by a Nigerian insurance company for the goods being imported. The Coartem procured through WHO also had to be insured by WHO, and communication to resolve these issues contributed to some delays.
- All medicinal products entering Nigeria are subjected to quality testing by NAFDAC. A waiver allows the products to be cleared while NAFDAC processes the results of product quality testing.

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 less than five years of age.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 were requested to estimate the amount of ACTs for the Global Fund grant. Because no data on medicine consumption or malaria cases are 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. Furthermore, the estimates were not based on accurate country-level data, and no direction was

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.

given 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. Other reasons for the delay included the change from the originally nominated PR German Technical Cooperation Agency to YGC caused by the former's possible conflicts of interests and a poor understanding of the grant approval processes.

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 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 contracted in November 2004 as the procurement agent for the purchase of all medical products, including antimalarials. This date coincided with the approval of the change in first-line treatment to Coartem by the FMOH. Many of the interviewees believed that a reason for the delay in procurement was that the Global Fund had stipulated that no procurement for ACTs could occur until the first-line treatment policy had been changed; however, these claims were not substantiated in this study because the grant agreements were not signed until October and December 2004.

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 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 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—in this case, an additional nine months for procuring the first shipment.

In-Country Factors

- Neither Crown Agents nor YGC was aware that the application for the subsidized price of Coartem must be approved by WHO's technical advisory committee on Coartem, which was next scheduled to meet in March 2005.
- WHO's procurement process was not understood and its requirements were not met. YGC made only a partial payment for the initial order. Neither Crown Agents nor YGC realized that full payment was 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. The final documentation was not obtained until February 2006.
- YGC did not obtain the official documentation needed for customs clearance on time. The required documentation ("Form M") and approval was obtained in February 2006. WHO shipped the first order of Coartem to Abuja in March 2006.

The delays in the duty and customs requirements effectively stalled the shipment of the ACTs by an additional five months. The reasons for these delays were slow in-country processing of the required importation documentation for the Coartem shipments, poor planning on the part of the PR, poor understanding of the regulatory requirements for importation and the necessary documentation required for the process, and not understanding 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 for direct payment to the supplier for the ACTs, 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.

In the meantime, Novartis approached Crown Agents to discuss direct procurement of Coartem, which eliminated advance payment and the 3 percent fee that MMSS (on behalf of WHO procurement division) charged for handling. In addition, direct procurement is expected to eliminate WHO's administrative delays and give Crown Agents direct access to cost, delivery, and shipping information directly from Novartis. In addition, direct procurement through Novartis eliminated the insurance cost, the WHO handling fee, the WHO requirement of advance payment, and administrative delays.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.

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

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.

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	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, which informs Crown Agents of a November 2005 delivery.
November 4, 2005	MMSS sends communication that the order will 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 was 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 staff movement. 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 training series in stores management, during which standard forms and templates were developed to aid distributing and managing ACTs, pharmaceutical management was not sufficiently addressed in the training. The NMCP expected that the ACTs would arrive soon after the orders were placed and proceeded to plan for and implement the training of health workers in the public health system on the new treatment guidelines, with the result that 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, burglar-proofing, or air-conditioning—all 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 was assessed by the LFA. The LFA recommended that a distribution agent be contracted to deliver the ACTs to the state level, which would then 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. YGC carried out distribution using two vehicles with assistance from NMCP staff. The ACTs arrived in the YGC store in Abuja and were then dispatched to the various tertiary and federal facilities and the states. At the state level, the RBM managers of the NMCP distributed the Coartem to the LGAs. Although this procedure was a short-term answer to the problem at hand, parallel systems were created with little consideration for finding a sustainable long-term solution. These issues still needed to be resolved at the time of the assessment 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. Inventory management forms and templates developed earlier in collaboration with FDS for the movement and control of medicines at the state, LGA, and facility levels 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 stock-outs at many facilities. Furthermore, supervisors have no way to track, except by accessing patient medical records, which age groups are consuming the medicines or to determine at what level of the distribution chain stocks are leaking. Although the FDS was involved at the time of training, 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. Some misunderstanding between Crown Agents and the PR also existed about their respective roles and how payment for carrying out distribution would occur.

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 at 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 understanding of the mechanisms needed to ensure appropriate storage, distribution, and management of pharmaceuticals, particularly ACTs. Inadequate planning caused a crisis management approach to implementation; short-term solutions were sought for bottlenecks without planning for sustainable systems. Many of the

interviewees believed, in retrospect, that the logistical costs for distribution and inventory management were 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.

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. No procurement experts were consulted for either grant. 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.

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 another organization, HealthFocus International, this plan was developed soon after receiving the first disbursement for the Round 2 grant. 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.

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 three additional M&E staff were recruited. The primary source of information for PR reporting is the SR. For ongoing data recording, the NMCP has set up a database that staff can manually log in information on monthly commodity distribution, IPT, and case management which can be accessed by the YGC data manager. However, this database is not linked to any other health information system and is not automatically updated with actual consumption figures. 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 of the two plans 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, in Nigeria 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 parties in the country routinely involved with pharmaceuticals, such as the FDS, CMS, and NAFDAC, resulting in inefficient implementation. 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.

KEY LESSONS LEARNED

The case study identified the various bottlenecks that Nigeria faced when implementing its Global Fund malaria grants. 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 distributing and reordering supplies.

Some of the challenges experienced 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 important, a lack of planning and coordination of the implementation process. In addition, there were inadequate systems for monitoring and evaluation, insufficient human resources capacity, and poor investment in overall health systems.

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

General

CCMs and PRs may benefit from familiarizing themselves with written guidelines and procedures.

Some of the problems faced in Nigeria during proposal development and implementation could be attributed to a lack of understanding of the Global Fund procedures and regulations, including the consequences of performance-based disbursement linked to the possibility of grant termination.

Countries may benefit from PRs and CCMs openly discussing with the partners in-country and the Global Fund Portfolio Managers any potential implementation challenges.

Recipients often may not consult with donors regarding potential problems or lack of understanding for two reasons: (1) the need to demonstrate ability and efficiency, and (2) the fear of losing funding. PRs and implementers may consider putting aside their misgivings and be more transparent so that any challenges faced can be dealt with early to avert bigger challenges later.

Effective Coordination among Stakeholders

Clearly articulated stakeholder roles and responsibilities may lead to smoother implementation.

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. Nigeria had clear difficulties in determining and defining roles and responsibilities of the CCM, PR, SR, and other partners.

The Global Fund guidelines on CCMs recommend that the CCM's 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.

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

Applicants for Global Fund grants must ensure compliance with the Global Fund requirements, which stress the need to develop clear mechanisms for accountability between the PR, CCM, and implementing partners. However, these guidelines had not been used effectively at the country level. In addition, because of decentralization, there are no clear lines of accountability established between the federal and state levels, making implementation, including distribution and reporting, difficult. MOUs among the partners can create accountability by specifying the individual and interconnecting roles and responsibilities, as well as recourses, if responsibilities are not met.

Incorporating potential stakeholders in the grant implementation early in the process may promote ownership and subsequent acceptance of and adherence to the policy.

In Nigeria, key institutions within the public sector that could have been instrumental to the success of the project, 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 proposal development process as well as earlier stages of Global Fund grant process. Although an implementation committee existed in Nigeria, it did not regularly meet nor was it involved in planning or making decisions. 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.

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

YGC was not actively involved in the proposal development, and subsequently did not retain 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."

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

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. In Nigeria, the CCM faced challenges caused by limited operating funds, in part because the CCM as well as 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, although 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.

Decentralizing resources for implementation can enable a more rapid implementation process.

In Nigeria, states were provided initial resources for distribution of the ACTs to the facility level. However, no such arrangement was made for subsequent deliveries. Decentralizing resources for specific functions may facilitate their implementation.

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

The PR may benefit from a review of its own capacities in the various implementation processes. The PR has a specific role to play and was recruited for its particular strengths. It is not expected to carry the entire burden of implementation. Experts in particular areas should be subcontracted for specific activities to free the PR (and SR) to focus on larger, more important activities. In Nigeria procurement was contracted out to Crown Agents. Although some obstacles impeded the procurement process, mostly caused by other issues, contracting out was able to overcome the PR's lack of procurement capacity as well as liberate them for other functions. Nigeria also used the MMSS to broker the procurement of Coartem. At the time, all procurements of Coartem had to go through MMSS. While this mechanism may have worked well in some countries, in Nigeria it appeared to add costs as well as an additional layer of communication. In all cases, the PR needs to ensure that it can provide appropriate oversight and supervise the contractors because the PR ultimately will be held accountable for their actions.

Experience of the Principal Recipient

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

The CMM may consider reviewing its criteria for choosing a PR to include demonstrable capacity for project, financial, and procurement management, as well as experience in managing large public health projects. 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, affecting the subsequent implementation of the grant.

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

Before proposing a PR for a Global Fund grant, the CCM should consider an extensive assessment 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. The feasibility of having multiple PRs and SRs can be explored to broaden the expertise in program implementation.

Procurement and Distribution Planning

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

One of the biggest problems in implementing the Global Fund grant in Nigeria was insufficient planning that led to delays and inefficiencies during the early stages of implementation and a crisis-management approach to implementation. Nigeria created an implementation committee, but it is nonfunctioning.

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

- An **implementation plan** should describe 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** should outline each stage of the procurement process, the roles and responsibilities of all the stakeholders in the procurement process, and an inventory of any documentation that may be needed, with specific timelines attached to each activity.
- A **distribution plan** should lay out the distribution steps and describe the roles and responsibilities of the various partners involved in distribution. The plan should list the quantities to be distributed to different districts, and it should include a detailed budget and list of resources for getting the commodities to the facility level.
- A **training plan** should include clear timelines for activities. A training strategy to introduce new standard treatment guidelines should be planned to coincide with the product's arrival in the country.
- A **monitoring and evaluation plan** should outline targets and milestones and list activities, roles and responsibilities, data needs and sources, frequency of data collection, and supervisory schedules. A logical relationship should exist between the indicators and targets proposed in the M&E plan and the rollout of the PSM plan.

None of these had been developed in sufficient detail in Nigeria.

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

Entities involved in developing proposals ought to consider the country's capacity and make provisions for accessing external assistance as needed. They should 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.

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.

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. 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.

PSM Plan Development

The PSM plan lacked details, including specific timelines with clear-cut roles and responsibilities. In addition, the milestones and targets were neither aligned with fund disbursement nor realistic, which made reporting difficult. Key PSM stakeholders, such as the FDS and the CMS were not involved in developing the PSM plan, which was needed to reflect the country context.

Procurement

Understanding the procedures of suppliers, procurement agents, and others involved in the procurement process, including the payment terms, may reduce lead times.

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 related to terms of payment and insurance. This 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.

The procurement process needs to anticipate common and specific problems that countries could face. The PR should determine in advance required documentation and fees and the procedure to

obtain waivers. An essential component is planning well in advance for space, equipment, and personnel needed to import shipments of medicines.

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

Deposit of YGC funds in Crown Agents' bank in the United Kingdom facilitated payment for the Coartem and reduced losses due to currency fluctuations. Thereafter, the Global Fund arranged for direct payment to the ACT supplier, which reduced payment delays.

Direct procurement from the supplier may alleviate communication issues and additional costs.

Procuring directly from Novartis alleviated some delays that were caused by communication problems. It also eliminated having to pay twice for insurance, as the Nigerian authorities required that the goods be insured by a Nigerian company despite insurance being already paid by MMSS.

Planning and placing orders early may reduce lead times.

When Nigeria placed an order for Coartem, Novartis announced that it was unable to meet the demands for production of this product. Countries need to consider the implication of choosing a single-source first-line treatment; placing orders early may avoid delays due to supply and demand issues.

Strengthening procurement capacity may assist the PR to improve implementation.

The PR needs to increase and improve its capacity in procurement. Even though a procurement agent has been subcontracted, experts with the skills in the documentation needed and the ability to inspect arriving goods and keep efficient records need to be recruited to improve future procurement processes.

Supply Chain Management

Involving the country's pharmaceutical management institutions and using the country's distribution agency as a central information system may facilitate buy-in and use of existing systems.

Distribution is a key area in which countries may be able to take advantage of existing stakeholder technical expertise. However, none of the expertise available in pharmaceutical management in Nigeria (e.g., FDS, CMS) was involved in the distribution process. Although the Nigerian CMS did not have the capacity to distribute ACTs, the PR may consider inviting the country's existing distribution agency to act as a central information system by documenting all receipts and keeping appropriate distribution, consumption, and stock records.

Clear standard operating procedures with forms and documents needed for recording will facilitate inventory management, monitoring and reordering of supplies.

Available standard documentation for tracking and monitoring of supplies was not given to the facilities, resulting in confusion over procedures for inventory management and reordering of supplies.

Clear security measures and strengthened inventory management may prevent the leakage of medicines to the private sector.

Coartem purchased with Global Fund money was found in the private sector in certain areas. Improved security measures and strengthened supervision and monitoring may help ensure that inventory is managed appropriately.

Establishing systems to ensure that medicines are distributed to facilities beyond the state and LGA levels should improve availability at the lower levels of the health system.

Establishing partnerships with distribution agents and the public sector to ensure that sustainable distribution systems will help to maintain stock availability at the peripheral levels.

Training and Communication

Coordinating training to begin before medicines arrive in country and end before distribution begins minimizes distribution time lag while ensuring health providers' effective recall of issues.

Training schedules need to be coordinated 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. 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.

Nigeria exceeded all its training targets; however, training was carried out too early, leading to challenges with provider adherence to and rational use of the new therapy. A regular review of training activities should ensure that they are inclusive and continuing to meet program needs.

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

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

Program Monitoring, Evaluation, and Reporting

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

Overall, a clear and logical fit among the grant's targets and milestones, the disbursement of funds, and the planned activities may help to ensure that funds are available for activities and facilitate meeting the targets.

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

Monitoring and evaluation, although crucial, are also extremely time consuming. The PR and SR would benefit from recruiting staff, particularly for collecting and analyzing data for routine reporting.

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

Monitoring to track, document, and address trends in program implementation must be carried out routinely, and a comprehensive framework that delineates the roles and responsibilities of those involved in monitoring and supervising implementation is crucial. 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. Good malaria expertise is required in order to develop and include the right indicators and subsequently track them.

Developing a database for reporting and monitoring may improve implementation.

Strengthening the system for collecting, analyzing, and reporting the results of monitoring activities at the state level will be a major factor in generating accurate country data. Nigeria has developed a central database for M&E that the PR and SR can regularly access. This system has positively affected reporting, but the system would benefit from being linked to the state and LGA levels.

Strengthening M&E systems may improve overall health systems.

The Global Fund's required linkage between reports on key indicators and disbursement has forced countries to improve their information systems, which has had a positive impact on overall health systems. However, countries would benefit from continuing to build capacity for supervision and monitoring.

CONCLUSION

The lessons learned from this case study offer valuable insights into the challenges that affected the implementation of Global Fund malaria grants in Nigeria.

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

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

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

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

Name	Position/Organization
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
Mr. Ali Bukar	Monitoring and Evaluation Officer, Yakubu Gowon Center
Mr. Kenneth Chukwuemeka	Country Director, Crown Agents Nigeria, Limited
Dr. Polly Dunford	Director, Office of Health, HIV/AIDS & 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 GF Round 5 Proposal and Chairman of the Medical Advisory Committee & 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 SFH (Malaria), Former Case Management Officer, NMCP
Mr. John Odey Okache	Procurement Officer, Yakubu Gowon Center
Mr. R.K. Omotayo	Director, Food and Drugs Service, Federal Ministry of Health
Mr. O.O. Omoyele	Deputy Director (FDS) and in charge of the National Central Medical Store
Dr. Baba Sheshi	Program Manager for Malaria, Yakubu Gowon Center
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Mr. Andrew Taylor	Program Manager, Crown Agents Nigeria Limited
Dr. Ogori Taylor	Essential Drugs and Medicine Policy Advisor, 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

