

Global Fund Grants for Malaria:

Lessons Learned in the Implementation of ACT Policies in Guinea- Bissau

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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.

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ACRONYMS

ACT	artemisinin-based combination therapies
ADR	adverse drug reaction
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
FPM	Fund Portfolio Manager
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HIV	human immunodeficiency virus
IEC	information, education, and communications
IPT	intermittent preventive treatment
ITN	insecticide-treated nets
LFA	Local Fund Agent
M&E	monitoring and evaluation
MMSS	Malaria Medicines and Supplies Service (hosted by the RBM Partnership Secretariat)
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
NGO	nongovernmental organization
NMCP	National Malaria Control Program
PNDP	National Program for Health Development [Guinea-Bissau]
PR	principal recipient
PSM	procurement and supply management
RBM	Roll Back Malaria [Initiative]
RPM Plus	Rational Pharmaceutical Management Plus
SR	subrecipient
STG	standard treatment guidelines
TB	tuberculosis
TAG	Technical Advisory Group [World Health Organization]
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

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EXECUTIVE SUMMARY

Guinea-Bissau has been awarded a total of 3,613,397 U.S. dollars (USD) in funding from the Global Fund during Round 4 for malaria. Because the country coordinating mechanism (CCM) did not think the Ministry of Health (MoH) or any other national institution was strong enough to manage the grants at the time, the United Nations Development Programme (UNDP) is the principal recipient (PR) for all Global Fund grants. The present consideration is to transfer PR responsibilities from UNDP to the National Health Development Plan (PNDS) and build local capacity for managing the grants during Phase 2.

At the time of proposal development and submission, Guinea-Bissau was using chloroquine as the first-line treatment for malaria, and the change in its first-line treatment policy to artemether-lumefantrine did not occur until July 2005 and was not validated until October 2006. Resources from the Global Fund were not originally planned for procurement of ACTs during Phase 1 of the Round 4 malaria grant; however, the Global Fund communicated to the PR that funds could be made available if an implementation plan for the transition was submitted. There appeared to be some miscommunication because the PR understood that no procurement could take place before Phase 2 of the grant.

In addition, adoption of and subsequent implementation of the new policy was delayed for several reasons. Consensus building and in-country processes were needed to occur to endorse the new policy. In addition, competing priorities, poor planning, and limited human resources capacity contributed to some of the challenges. In-country experience with procurement, quantification, and general pharmaceutical and supply management is limited. Several delays occurred in developing and finalizing an implementation plan for the transition to ACTs, which was a Global Fund requirement before funds could be mobilized for ACT procurement. Resources for hiring of staff are urgently needed. In addition, capacity building in particular aspects of pharmaceutical management, such as quantification, is needed.

The CCM in Guinea-Bissau has not adequately fulfilled its responsibilities. The membership and functions of the CCM need to be evaluated and revised so that membership includes constituencies to ensure that absences of certain individuals do not adversely affect the functioning of this group.

In addition, challenges have occurred in coordination among the various stakeholders involved in the malaria grant implementation. Poor coordination between the PR and the subrecipients (SRs) has led to various problems, including delays in reporting on activities and budgets. Inadequate coordination and communication between the PR and the Central de Compra de Medicamentos (Central Office for Purchasing of Medicines [CECOME]) appear to be creating problems related to the storage and distribution of commodities procured through Global Fund grants. The PR needs to openly and adequately communicate with CECOME on plans, orders, and supplies to ensure that CECOME is able to adequately plan for incoming supplies.

An urgent need exists to develop a detailed distribution plan that includes the quantities of ACTs to be distributed to the various districts and facilities, as well as a training plan for providers on

the new standard treatment guidelines (STGs). Training should be completed just before the medicines arrive to ensure that distribution to the facilities can be immediately carried out. Training too early may result in providers forgetting the information, and training too late will potentially result in irrational use because the medicines will begin to be used without adequate training. In addition, the process of revising the STGs needs to begin immediately.

The respective roles and responsibilities of the PR and implementers with respect to monitoring and evaluation need to be clarified and defined, and mechanisms should be developed for management information systems capacity at the facility level.

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 journal *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 assessment, 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 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 (MSH), 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 Guinea-Bissau.

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.

Objectives of the Study

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

The specific objectives of the study were to—

- Trace the progress and document the key events of implementing the Global Fund grant related to ACTs—from developing the proposal and the Procurement, 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 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 literature review was then conducted for each country, which included documents on malaria, treatment guidelines, MoH and malaria program background documents, and Global Fund–related documentation.

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

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

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

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

The following is a brief description of the Global Fund process after the grant is approved for readers that are unfamiliar with the process, which is taken from the Global Fund's 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 grant agreement for the first two years of the grant (Phase 1), which identifies specific, measurable results to be tracked using a set of key indicators.
3. The grant agreement between the Global Fund and the PR is signed. Based on a request from the Secretariat, the World Bank makes initial disbursement to the PR. The PR makes disbursements to SRs for implementation, as called for in the proposal.
4. Program and services begin. As the coordinating body at the country level, the CCM oversees and monitors progress during implementation.
5. The PR submits periodic disbursement requests with updates on programmatic and financial progress. The LFA verifies information submitted and recommends disbursements based on demonstrated progress. Lack of progress triggers a request by Secretariat for corrective action.
6. The PR submits fiscal year a progress report and annual audit of program financial statements to the Secretariat through the LFA.
7. Regular disbursement requests and program updates continue, with future disbursements tied to ongoing progress.
8. The CCM requests funding beyond the initially approved two-year period (Phase 1). The Global Fund approves continued funding based on progress and availability of funds (Phase 2).

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

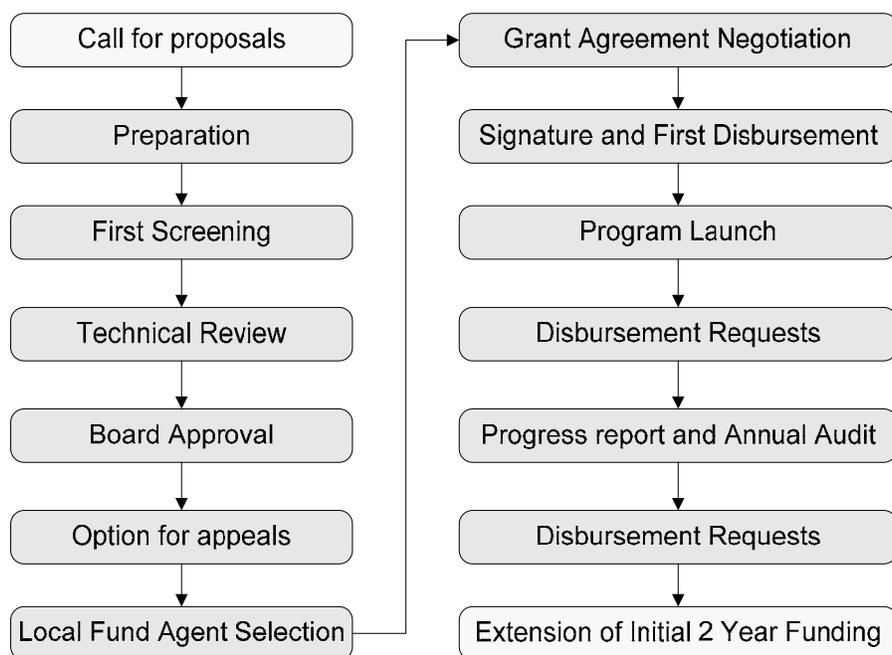


Figure 1. Global Fund proposal approval and implementation process

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

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 as well as coordinating, monitoring, and evaluating malaria activities throughout the health system.

Guinea-Bissau has been awarded a total of USD 3,613,397.00 in funding 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 1. Summary of Grant and Other Data for Guinea-Bissau

Round	Grant Number/ Date Signed	PR/ SR	LFA	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	UNDP/ Multiple	Price waterhouse-Coopers	3,613,397	1,885,791	1,688,828 (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	Not specified	Not named	12,816,656	Not signed	Not signed	Not applicable	Not applicable

Proposal Development

The institutions and organizations involved in the proposal development for Round 4 were the NMCP, WHO, United Nations Children’s Fund (UNICEF), the World Bank, the National Institute for Studies and Research, and health committees (community members), as well as various nongovernmental organizations (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 CECOME, 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 and 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 nongovernmental entities. 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 proposal execution

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. The PSM plan for the malaria grant was general, however, and not specific to malaria. Activities were loosely outlined without specific details or timelines.

The original PSM plan did not include any provisions for ACTs because, as previously discussed, ACTs were not in the grant proposal. After the treatment policy was changed from chloroquine to artemether-lumefantrine, the NMCP requested assistance from WHO to develop a new PSM plan. A time lag of about seven months 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-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 postconflict situation and because of difficulties in obtaining malaria data from all the regions. The morbidity method was used for estimating antimalarial needs. Four regions were selected for implementation⁴ 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 for all Global Fund grants, 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. CECOME had procured antimalarials for the country in the past. No immediate plans are under way to strengthen CECOME's procurement

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

capacities, and some in-country discussion has raised the issue of replacing UNDP with UNICEF as the agency responsible for 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; the 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 has 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.

LESSONS LEARNED AND RECOMMENDATIONS

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

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

Human Resources

Mobilizing resources to hire staff in key areas may assist in the implementation of the grant.

Human resources available to carry out the implementation of the Global Fund grant for malaria in Guinea-Bissau are severely limited. Mobilizing resources to hire staff particularly in the malaria control program may assist in implementation.

Coordination among Stakeholders

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

In Guinea-Bissau, the CCM had not fulfilled its responsibilities of oversight and monitoring, and periodic absences of members adversely affected its functioning. One of the reasons stated for the CCM's inefficiency was the poor understanding of its responsibilities. Although the WHO country office has begun developing a manual to outline all operational procedures and responsibilities, the CCM may benefit from a review of the Global Fund's *Guidelines on the Purpose, Structure and Composition of Country Coordinating Mechanisms*.

MOUs or other contractual mechanisms among PRs, SRs, and other implementers may help establish/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 utilized effectively at the country level. Memorandums of understanding (MOUs) among the partners may create accountability by specifying the individual and interconnecting roles and responsibilities, and what each partner has recourse to, should responsibilities not be met.

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

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) 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 access to malaria medicines in the private sector.

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

The PR, UNDP in Guinea-Bissau, was not involved in the proposal development and has not retained a strong association with the CCM after the grant was signed. This appears to have affected the efficiency of implementation.

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 Guinea-Bissau, poor communication and coordination among the PR, SRs and CECOME has led to various problems, including storage, distribution of other medicines due to CECOME not being informed about in-coming shipments to allow it to plan for capacity accordingly. In addition, delays in reporting on activities and budgets have been reported stemming largely from a lack of timely information being provided to the PR.

Policy Change Processes

Delays in policy change and subsequent implementation may be minimized by mapping the processes for changing policies.

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

Experience of the Principal Recipient

Assuring that PRs have experience and capacity in procurement and supplies management may promote credibility and lead to smoother implementation.

In Guinea-Bissau, UNDP was chosen as the initial PR because capacity in the country 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, but at the end of Phase 1 of the grant, this process had not yet begun mainly due to skepticism on the ability of PNDS to fulfill this role. Furthermore, it is unclear whether UNDP has the human resources to build the PNDS capacity. The PR's experience and knowledge of country policies and contexts 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

An implementation plan outlining the key steps in the process with timelines needs to be developed with the input of key stakeholders in the implementation.

The Global Fund asked the PR to submit an implementation plan for transitioning to ACTs as a prerequisite for making resources available during Phase 1 of the Round 4 malaria grant. Several delays occurred in developing and finalizing an implementation plan for the transition to ACTs (1) the PR had limited experience in developing such a plan and had to ask for support from the WHO country office which caused some delays; and (2) there was some misunderstanding and confusion about the procedure requested by the Global Fund regarding resources for ACT procurement and whether procurement for ACTs could occur before Phase 2 of the grant. The submission of the plan may have enabled the Global Fund to mobilize additional resources to procure ACTs.

The PR may benefit from requests of clarification for additional sources of funding from the Global Fund.

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. At the time of this assessment—two years after the signing of the grant agreement—the ACT procurement process had not started. The PR may benefit from proactive enquires about additional resources for procurement.

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

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 delineated for each activity.
- A **distribution plan** should lay out the distribution steps and describe the roles and responsibilities of the various partners involved in distribution. The plan should list the quantities to be distributed to different districts, and it should include a detailed budget and source of resources for getting the commodities to the facility level.
- A **training plan** should include clear timelines for activities. A training strategy to introduce new standard treatment guidelines should be planned to coincide with the product's arrival in the country.
- A **M&E** 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 have been developed in sufficient detail in Guinea-Bissau.

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 and plan early for technical assistance in areas where capacity is weak. Including capacity building in key areas, such as PSM and M&E, to complement the implementation activities within the proposals ensures that adequate budgets are available for these actions.

PSM Plan Development

Grant implementation may benefit from developing PSM plans soon after the grant agreement is signed.

A delay in lining up the consultant in Guinea-Bissau resulted in a time lag of about seven months between adopting the new treatment policy and completing the PSM plan, which subsequently contributed to the delays in procuring ACTs. Mobilizing a consultant early in the process may have avoided this delay.

Procurement

Strengthening procurement and supply management capacity may assist the PR to improve implementation.

Inadequate capacity for quantification was one reason for the delay in developing a PSM plan for ACT procurement. PRs and partners in-country may benefit from assessing their own capacities in PSM early so that needed external assistance can be engaged to avoid delays in grant implementation. Any possibilities for country level capacity building should be sought early.

Supply Chain Management

Involving existing institutions involved in the country's pharmaceutical management may facilitate adequate buy-in and utilization of existing systems for effective implementation.

CECOME was often unaware of quantities ordered and delivery schedules of Global Fund medicines. The grant may benefit from better PR collaboration with CECOME to ensure adequate planning for storage and distribution is made.

Training and Communication

Developing plans for training may help minimize time lag for distribution while ensuring adherence to the new treatment.

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. At the time of this assessment, no plans for training had been made in Guinea-Bissau.

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

Training in storage, inventory management to be carried out at all levels of the health care system and all cadres of staff may improve the supply chain management of the ACTs when they arrive. As the time of this assessment, no plans for this training had been made.

Program Monitoring, Evaluation, and Reporting

Strengthened capacity in management information systems at all levels, including the facility level benefits performance

UNDP has had difficulties collecting the information needed to report on indicators for Phase 1. Funds for building this capacity need to be identified early. The PR and SR may benefit from recruiting staff particularly for collecting and analyzing data for routine reporting.

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

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

Assigning roles and responsibilities for reporting assists in overall monitoring.

UNDP has had difficulties collecting the information needed to report on indicators for Phase 1. Monitoring to track, document, and address trends in program implementation must be carried out routinely, and a comprehensive framework that delineates the roles and responsibilities of those involved in monitoring and supervising implementation may assist in this function.

Developing a database for reporting and monitoring improves 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. e state and LGA levels.

Strengthening M&E systems positively impacts 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 offers valuable insights into the challenges that affected the implementation of Global Fund malaria grants in Guinea-Bissau and about Global Fund procedures and policies. While each country has unique issues, many of their challenges may be 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. 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 Guinea-Bissau. 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 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 GUINEA-BISSAU
DURING THE STUDY**

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 WHO Guinea-Bissau
Dr. Lori Lee	Program Operations Advisor 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

