Global Fund Grants for Malaria:

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

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

USAID
FROM THE AMERICAN PEOPLE

Rima Shretta

June 2007

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

Rima Shretta

Printed June 2007

About RPM Plus

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

Recommended Citation

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

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

Key Words

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

CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapies
ADR	adverse drug reaction
CCM	country coordinating mechanism
CECOME	Central de Compra de Medicamentos (Central Office for Purchasing Medicines) [Guinea-Bissau]
CMS	Central Medical Stores
CP	condition precedent
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
IEC	information, education, and communication
LFA	Local Fund Agent
M&E	monitoring and evaluation
MOU	memorandum of understanding
PR	principal recipient
PSM	procurement and supply management
RPM Plus	Rational Pharmaceutical Management Plus
SR	subrecipient
TRP	Technical Review Panel
UNDP	United Nations Development Program
USD	U.S. dollar
WHO	World Health Organization
YGC	Yakubu Gowon Centre for National Unity and International Cooperation [Nigeria]

ACKNOWLEDGMENTS

BACKGROUND

The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has approved malaria grants amounting to 2,584,874,749 U.S. dollars (USD) over five years, which includes funding for more than 264 million treatments of artemisinin-based combination therapies (ACTs). Despite the availability of these resources, however, grant recipients are finding it difficult to effectively conduct procurement and appropriate supply chain management to get the products to the service delivery points. At a March 2006 Global Fund workshop on bottlenecks to implementing malaria grants in West Africa, countries presented on their progress. At this time, the Global Fund recognized that countries in the region were facing similar challenges in implementing their malaria grants and that they would benefit from the experiences and lessons learned from other countries. Ghana, Guinea-Bissau, and Nigeria were selected as case studies to document the process of implementing malaria grants, to identify bottlenecks that the countries experienced, and to show steps taken to address these bottlenecks. The Global Fund selected these countries for review based on their West African location and the stage of their malaria grant implementation as presented at the March 2006 workshop: Ghana appeared to have few challenges in procuring ACTs, Nigeria had significant challenges and delays at the procurement stage, and Guinea-Bissau had not yet begun the process to procure ACTs. The Rational Pharmaceutical Management (RPM) Plus Program was asked to conduct the case study assessments in collaboration with the Global Fund and the Roll Back Malaria Partnership Secretariat.

Objectives of the Study

The study objectives were to describe the implementation of the Global Fund malaria grants in Ghana, Guinea-Bissau, and Nigeria; to identify the bottlenecks that the countries faced at each step of the implementation process; and to draw key lessons learned. The case studies are descriptive and focused on the procurement, supply, and distribution aspects of implementing ACTs as the new first-line treatment for malaria in the countries. While rational medicine use is key to the success of the malaria grants, assessment of this concern is beyond the scope of these studies. The three study countries' principal recipients (PRs) can use the lessons learned to take remedial action to ensure that future procurement and distribution of ACTs will go more smoothly. In addition, PRs from other countries in the region can use these experiences to identify barriers to effective implementation, adapt the recommendations and strategies to tackle similar challenges, and facilitate the implementation of their own grants.

The specific objectives were to—

- Trace the progress and document the key events of implementing the Global Fund grant related to ACTs—from developing the proposal and the Procurement, Supply, and Management (PSM) plans to distributing ACTs to health facilities

- Identify bottlenecks in the processes that contributed to delays

- Describe the steps taken to address these bottlenecks

- Draw lessons learned about how the three countries implemented their grants

The assessment team reviewed documents and conducted in-depth interviews in the field with key stakeholders in each of the three countries in October and November 2006. In addition, discussions were held with Global Fund portfolio managers and other partners involved with pharmaceutical procurement processes. The assessments for each country (available in a separate report) contain detailed study findings that will help those countries' PRs as well as other PRs address similar challenges. This report summarizes the findings of the authors' assessments, presents the similarities and differences among the countries, and discusses the key lessons learned and their implications for future programming.

SUMMARY OF GLOBAL FUND GRANTS IN
GHANA, GUINEA-BISSAU, AND NIGERIA

Ghana

- **Round 2**: Grant agreement signed July 2003/start date September 2003
- **Round 4**: Grant agreement signed February 2005/start date March 2005
- **Total commitment**: USD 47,737,273 (5 years)
- **Principal Recipient**: Ghana Health Service of the Ministry of Health
- **Subrecipient**: National Malaria Control Program
- **Local Fund Agent**: PricewaterhouseCoopers

Guinea-Bissau

- **Round 4**: Grant agreement signed November 2004/start date January 2005
- **Round 6**: Grant agreement not signed
- **Total commitment**: USD 16,430,053 (5 years)
- **Principal Recipient**: United Nations Development Program (UNDP) (with eventual transfer to the National Health Development Plan)
- **Subrecipients**: Multiple
- **Local Fund Agent**: PricewaterhouseCoopers

Nigeria

- **Round 2**: Approved January 2003/Grant agreement signed October 2004/start date December 2004
- **Round 4**: Approved June 2004/Grant agreement signed December 2004/start date January 2005
- **Total commitment**: USD 95,536,436 (5 years)
- **Principal Recipient**: Yakubu Gowon Centre for National Unity and International Cooperation
- **Subrecipient**: National Malaria Control Program
- **Local Fund Agent**: KPMG Professional Services

The diagram in Annex 1 taken from the Global Fund website illustrates the actual process of proposal submission, acceptance, and renewal.

SUMMARY OF KEY FINDINGS FROM THE THREE CASE STUDIES

Ghana

In Ghana, both malaria grants were signed five to six months after approval. This report describes the process for the round 4 proposal only as the round 2 proposal did not include the procurement of ACTs. In general, the procurement process in Ghana was fairly smooth, facilitated in part by a direct disbursement sent by the Global Fund to the supplier for the procurement of the ACTs and by good coordination among the PR, subrecipient (SR), and other implementing partners. The first consignment of ACTs arrived in Ghana two months after the grant agreement was signed and four weeks after the order was placed. Distribution of the product, however, did not occur until six months after they arrived in country as training of the providers on the new standard treatment guidelines had not yet begun. Meanwhile, the Ghana National Drug Program (GNDP), the regulatory body in Ghana had registered a locally-manufactured dosage form of artesunate and amodiaquine with a higher content of amodiaquine than recommended in the WHO treatment guidelines. Some public health facilities procured this artesunate-amodiaquine combination directly from the local manufacturers before the official launch using government funds. Adverse drug reactions (ADRs) to the higher dosage of the amodiaquine component of the locally manufactured combination have resulted in low acceptance of the new policy by providers and users.

ACT implementation timeline in Ghana

First-line treatment: artesunate-amodiaquine

January 2005:   Treatment policy change to ACTs
March 2005:   ACT order placed
April 2005:   ACTs arrive in Accra, Ghana
October 2005:   Distribution begins

Key Findings

Positive Factors

- The pharmaceutical procurement process in Ghana was fairly smooth. ACTs arrived in the country within one month after the order was placed

- The procurement process was further simplified by the Global Fund's arranging direct disbursement to the supplier (through the Malaria Medicines Supply Service [MMSS]) for ACTs procurement

- Ghana's procurement and implementation process was free of conflict with clear lines of accountability, enabled in part by an existing relationships and good coordination and collaboration among the PR, the SR, the country coordinating mechanism (CCM), and other implementers

- Partners and implementers had ownership of the process with clear lines of accountability facilitated by early involvement in the planning. The PR organized several planning meetings very early involving the key stakeholders in the implementation process.

- ACTs were distributed to the health facilities only after the providers in the facilities had been trained in the new treatment guidelines, thus avoiding mistakes or time lapses between training and practicing the guidelines

- The PR burden of monitoring, supervision, evaluation, and reporting procedures was reduced and made more timely through the hiring of additional staff and an improved reporting database

Limiting Factors

- The product was not distributed until six months after it arrived in country due to a late start in training providers in the new standard treatment guidelines and an underestimation of the time needed to complete the training.

- There were ADRs as a result of the higher dosage of the amodiaquine component in the locally manufactured combination procured directly from the local manufacturers by some health facilities before distribution of the Global Fund-purchased official product. The Ghana National Drug Program had registered this locally-manufactured compressed dosage form of artesunate 200 milligrams (mg) and amodiaquine 600 mg that was being marketed and sold in the private sector. This experience points out to the need to ensure the quality of the commercially available products in the country to avoid repercussions in the adherence of health care providers and users to the official combination.

- Public and provider acceptance of and compliance with the new policy has been poor due to the negative experience with ADRs.

- Health facilities experienced stock-outs during the early stages of implementation due to the NMCP and the GNDP's limited experience in quantification and use of inaccurate data to estimate demand forecasts.

- The Government of Ghana failed to procure ACTs for the non-Global Fund states; this resulted in Global Fund procurement funds being used for those states not initially intending to be covered by these resources.

- Some reporting delays from the SR to the PR and subsequently to the LFA led to some holdup in disbursing subsequent funds.

- Monitoring and evaluation was initially cumbersome, taking up a large portion of the PRs' and SRs' time.

- In general, there is poor congruence between the indicators and targets and the rollout of the PSM plan and weak performance recording due to poor harmonization of implementation and monitoring and evaluation (M&E) at the planning level.

Guinea-Bissau

The grant agreement in Guinea Bissau was signed four months after approval. At the time Guinea-Bissau developed and submitted its Global Fund proposal, the country was using chloroquine as the first-line treatment for malaria. The first-line policy was not changed until almost one year later, a delay mostly caused by lengthy in-country processes and consensus building. Although Global Fund resources were not originally planned for procurement of ACTs during Phase 1 of the Round 4 malaria grant, funds could have been made available upon the submission to the Global Fund and approval of an implementation plan for the transition to ACTs. However, some breakdown in understanding appeared to occur regarding accessing Global Fund resources to procure ACTs. 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.

ACT implementation timeline

First-line treatment: artemether/lumefantrine

June 2005:   Treatment policy change to ACTs announced
October 2006:   Treatment policy change endorsed

Positive Factors

- UNDP was appointed as the PR to circumvent the capacity gaps in country to manage the program with the expectation of transferring PR's responsibilities to the National Health Development Plan (PNDS) during Phase 2 while building their capacity.

Limiting Factors

- Many stakeholders interviewed in Guinea Bissau opined that the CCM had not adequately fulfilled its responsibilities; regular attendance at CCM meetings was poor.

- Although the plan was to transfer PR responsibilities from UNDP to PNDS, UNDP had not started building the PNDS's capacity to take this role. It is unclear whether UNDP can carry out such capacity building.

- There have been delays in implementation and reporting on activities and budgets due to poor coordination and cooperation between the PR, SR, and implementing partners.

- 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. The PR did not submit a final plan for two reasons: (1) it 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.

- ACT procurement had not yet begun at the time of this assessment; however, there were problems related to the storage and distribution of other commodities procured through other Global Fund grants created mainly by poor coordination and communication between the PR and the Central de Compra de Medicamentos (Central Office for Purchasing of Medicines–CECOME)

- Although Guinea-Bissau already had changed its first-line treatment policy to Coartem at the time of the assessment, it had not carried out any preparatory activities to implement ACTs, such as training or guideline revisions.

Nigeria

Grant agreements in Nigeria for rounds 2 and 4 were signed within two months of each other; 21 months and 6 months after the respective proposals were approved. Selection of the PR contributed to delays in signing the grant agreement for round 2. Crown Agents was contracted as the procurement agent because the PR had insufficient capacity and experience with procurement and supply management. Nevertheless, the procurement process in Nigeria took over one year and was marked by challenges at various levels. The first consignment of ACTs arrived between 15–17 months after the grant agreement was signed and eight months after placing the order. The delay was mainly caused by inadequate planning; lack of procurement and supply management (PSM) capacity at Yakubu Gowon Centre (YGC); the PR's and procurement agent's poor understanding of WHO's procurement process which delayed communication; the global shortage of Coartem; limited understanding of documentation needed for importation, including the processes of obtaining duty waivers; and inadequate follow-up of relevant applications and documentation. Procurements of ACT for both rounds were eventually combined. At the time of this assessment, two shipments of Coartem had been delivered to Abuja, and over two million treatments were stored in the central storage facility.

ACT implementation timeline

First-line treatment: artemether/lumefantrine

February 2005:	Treatment policy change to ACTs
July 2005:	Full payment for ACT order sent
November 2005:	ACTs ready to ship
February 2006:	Required documentation and approvals for importation received
March 2006:	First shipment of ACTs arrives; implementation begins

---

Positive Factors

- Delays subsequent to the second shipment were minimized in part due to a better understanding of the process and through direct procurement from Novartis, which removed the extra layer of communication

- In all cases training targets were exceeded

- Once the ACTs arrived in the country, customs clearance and distribution to the state level was completed within four days of arrival through the contracting of a distribution agent

- Crown Agents was contracted to develop the PSM plan and to carry out the procurement process to circumvent the PR's PSM capacity gap

Limiting Factors

- Procurement and subsequent implementation were challenging because key stakeholders were not included in the grant process from proposal development to implementation.

- There was a crisis-management approach to implementation due to the lack of detailed written plans for procurement and distribution.

- The procurement process was further stalled because of communication delays process between Crown Agents, MMSS, and the PR.

- Crown Agents was hurriedly contracted to carry out distribution as no provisions for distribution agent were made in advance.

- The PR and the NMCP did not make a distribution plan for the medicines until the shipment was about to arrive.

- The quantities that were distributed by Crown Agents through its subcontract did not agree with the delivery notes in many states.

- In addition, stock purchased using Global Fund resources leaked into the private sector. Many stakeholders attributed this to have occurred during the distribution of the first shipment.

- Many states experienced early stock-outs while others had excess stock.

- The PR gave the states funds to distribute ACTs to the local level for the first consignment; however, no plans existed for distributing subsequent supplies to the facilities, nor were mechanisms set up for the facilities to reorder.

- Stock outs were also experienced due to failure of the federal government to provide treatment for those states not covered by the Global Fund and to the population over five years of age.

- Staff had problems recalling elements of the standard treatment guidelines as training was carried out too early in relation to the arrival of the medicines

- Implementation targets, indicators, and milestones were not realistic or achievable, and did not mesh with key activities and disbursements.

DISCUSSION OF FINDINGS AND LESSONS LEARNED

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

- In Ghana, there were challenges related to quantification, provider acceptance, and adherence to the treatment policy; and planning for complementary activities, such as training and supply chain management.

- In Guinea-Bissau, the challenges centered on the policy change processes, the development of a transition plan to ACTs, and coordination between the PR and other implementers in the country.

- In Nigeria, many of the challenges and delays centered on procurement and planning for procurement, mainly because of the PR's lack of capacity and experience in those areas. In addition, Nigeria experienced problems in the distribution and re-ordering of supplies.

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

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

Effective Coordination among Stakeholders

Key Lessons Learned

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

---

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

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

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

Applicants for Global Fund grants must ensure compliance with the Global Fund requirements, which stress the need to develop clear mechanisms for accountability between the PR, CCM, and

implementing partners. However, these guidelines had not been utilized effectively at the country level, nor had any of the three counties established written contracts among the implementing partners. In Ghana, it appeared that there was a verbal understanding of the roles of the PR, SR and other partners which worked well. In addition, key stakeholders within the MoH and external partners with specific strengths were involved at all stages of proposal development and program implementation, which had a significant positive impact on Ghana's grant implementation. The PR and SR there enjoy open channels of communication and mutual respect, while in Guinea-Bissau, the Central Office for Purchasing Medicines (CECOME), was often unaware of quantities ordered and delivery schedules of Global Fund medicines.

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

Experience of the Principal Recipient

Key Lessons Learned

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

---

The choice of the PR seems to have significantly affected the speed and efficiency with which Global Fund malaria grants were implemented in Ghana, Guinea-Bissau, and Nigeria. In Ghana, the PR was experienced in all areas of implementing malaria treatment policies and had access to procurement and supply chain management networks and external assistance that helped the implementation planning and process. Furthermore, the GHS/MOH had established credibility through its existing relationships, its channels of communication with the SR and other implementing partners, and its chains of accountability within the public health sector. It therefore did not have to invest time and resources in building capacity or in establishing these relationships. In Nigeria, the PR, although highly credible, had no previous experience in implementing malaria programs and had little capacity in procurement and supply chain management. The PR was not familiar with importation documentation or with the processes needed to implement health programs in the public sector. In Guinea-Bissau, UNDP was chosen as the initial PR because the country capacity was so limited. However, the UNDP country office had little experience in managing malaria programs and did not have the credibility that a familiar local entity would have had. Furthermore, part of UNDP's role was to build capacity within the PNDS to become the PR; however, at the end of Phase 1 of the grant, this process had not yet begun mainly due to UNDP's and others' skepticism on the capacity of PNDS to fulfill

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

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

Procurement and Distribution Planning

Key Lessons Learned

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

---

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

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

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

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

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

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

- A M&E plan that outlines targets and milestones and list activities, roles and responsibilities, data needs and sources, frequency of data collection, and supervisory schedules. A logical relationship should exist between the indicators and targets proposed in the M&E plan and the rollout of the PSM plan.

Technical assistance was not adequately built into or budgeted for the three proposals. Entities involved in developing proposals ought to consider the country's capacity and make provisions for accessing external assistance as needed and plan early for technical assistance in areas where capacity is weak. Including capacity building in key areas such as M&E, quality assurance, and systems strengthening to complement the implementation activities within the proposals ensures that adequate budgets are available for these actions. The Global Fund does not expect countries to show that they have the ability to complete all activities on their own, and indeed, it encourages countries to mobilize support for activities for which they have limited local skills or expertise.

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

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

PSM Plan Development

None of the three countries placed adequate emphasis on PSM plan development; the plans lacked details, including specific timelines with clear-cut roles and responsibilities. In addition, the milestones and targets were neither aligned with fund disbursement nor realistic, which made reporting difficult.

In Ghana, the PSM plans were developed by the SR in consultation and collaboration with institutions and external partners in the country. Although the plans lacked essential details, they were at least developed by parties that understood the country's PSM system. On the other hand, external consultants developed the PSM plans in Nigeria and Guinea Bissau. A delay in lining up the consultant in Guinea-Bissau resulted in a lag of about seven months between adoption of the new treatment policy and completion of the PSM plan, which subsequently contributed to the delays in procuring ACTs. In Nigeria, key PSM stakeholders, such as the Food and Drugs Service and the central medical stores (CMS) were not involved nor consulted in developing the PSM plan, which was needed to reflect the country context. While the Global Fund encourages external assistance to address capacity gaps, remaining engaged in the PSM planning may assist the PR and SR in implementing a plan with which they are familiar.

Procurement

Key Lessons Learned

- Understanding the procedures of suppliers, procurement agents, and others involved in the procurement process, including the payment terms may reduce lead times
- Direct disbursement by the Global Fund to the suppliers reduced procurement lead times

---

In Ghana, the procurement process was fairly smooth, facilitated in part by the Global Fund sending a direct disbursement to WHO for ACT procurement. Besides simplifying the logistics, the direct payment also circumvented losses from converting currency caused by foreign exchange fluctuations. The first consignment of ACTs arrived in Ghana four weeks after placing the order. Clearly the selection and ordering of an ACT which was not in short supply also facilitated the short procurement lead time.

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

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

- Crown Agents began procuring Coartem directly from Novartis. This arrangement eliminated the three percent procurement fee that WHO charged and bypassed the advance payment requirement. In addition, direct procurement was expected to eliminate the administrative delays at WHO and give Crown Agents access to cost, delivery, and shipping information directly from the supplier.

- The deposit of YGC funds in Crown Agents' bank in the United Kingdom facilitated payment for the Coartem and reduced losses due to currency fluctuations.

- The Global Fund arranged for direct payment to the ACT supplier at the request of the PR, which reduced payment delays

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

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

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

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

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

Supply Chain Management

Ghana used its existing pharmaceutical supply chain that facilitated the procurement and distribution of ACTs to the facility level. In addition, standard forms and templates were disseminated to the facilities with the medicines to enable providers to track inventory. In contrast, Nigeria created a parallel distribution system, and poor planning meant that Crown Agents was hurriedly contracted as the distribution agent before the ACTs arrived in the country. Crown Agents, in turn, subcontracted with local transport company to deliver ACTs to the state level. There was no distribution plan developed by the PR and SR outlining the quantities and delivery schedules for each state, the transportation to be used, or the roles and responsibilities of each partner. Although distribution was completed within four days of the arrival of the ACTs, problems encountered included the delivery of incorrect quantities as well as leakage of Global Fund-procured ACTs into the private sector.[1]

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

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

---

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

Training and Communication

Key Lessons Learned

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

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

Training schedules need to be correlated with procurement and distribution of the medicines, so that health care providers are familiar with the new treatment guidelines before they receive the medicines in the health centers. In addition, training should occur shortly before the medicines arrive; providers may forget training that occurs too early, and training too late may encourage irrational prescribing, because providers will not have received any information on how the new medicines are used. If procurement is delayed, training should also be delayed. In Nigeria, training was carried out before the medicines arrived; whereas, in Ghana, training began after the ACTs had already arrived in the central storage facility, which delayed distribution of the medicines. Insufficient planning also led to Ghana underestimating the time needed to train all the cadres of health providers throughout the country, which resulted in a delay in meeting the training targets. In contrast, Nigeria exceeded its training targets, but, training was carried out too early relative to the arrival of the ACTs. In both countries, the poor timing led to challenges with provider adherence to and rational use of the new therapy.

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

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

Involving practitioners in collecting data on ADRs lets them assess for themselves whether the data justify concerns over ADRs. In addition, countries should consider investing in a system for monitoring ADRs, particularly when introducing new medicines, and develop plans to respond quickly to potential problems. An additional challenge in Ghana was that stakeholders at the teaching hospitals perceived the new treatment policy as belonging to the Ghana Health Service and not applying to them. Broad communication messages may not be enough to target key stakeholders, and behavior change communication strategies may need to be developed.

Program Monitoring, Evaluation, and Reporting

Key Lessons Learned

- Aligning milestones and targets with activities and fund disbursement facilitates the continuous availability of funds for planned activities
- Developing realistic targets improves the likelihood that targets are effectively met
- Coordinating the system for monitoring for malaria with other diseases may assist in efficient utilization of resources for similar activities and avoids duplication recording
- Recruiting staff to collect and analyze data helps with efficiency and long-term cost effectiveness
- Standardizing reporting systems avoids overburdening the system with multiple streams of data and reporting mechanisms

---

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

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

positive impact on overall health systems; however, countries would benefit from continuing to build capacity for supervision and monitoring.

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

Annex 2 summarizes the key actions needed for ACT implementation from proposal development to implementation and summarizes the key challenges identified in the three cases studies. The figure in Annex 3 illustrates the ideal situation in proposal development, grant approval, and implementation from the country-level perspective.
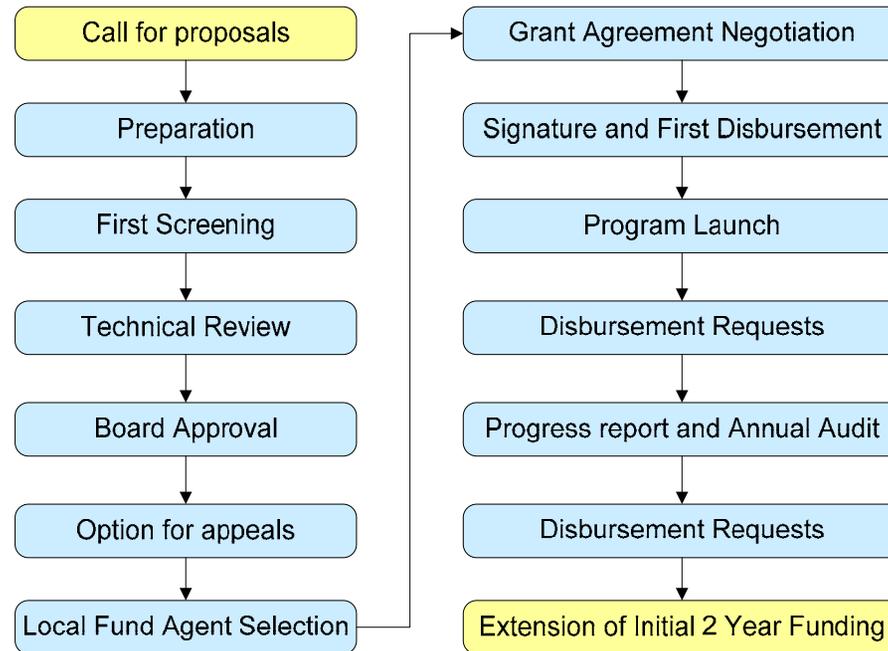
CONCLUSION

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

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

Early planning which may include written documentation outlining activities with timeline estimates, and any needs for external technical assistance may facilitate the implementation process. However, while having detailed written plans is helpful, mechanisms need to be created to ensure that agreed-upon plans are implemented and that commitments are fulfilled. Plans also need to address the coordination of components such as policy changes, procurement, training, and communication to ensure that the preparatory steps are completed before medicines begin to be distributed to the facilities. Systems to ensure quality assurance in supply chain management should be built in early and include mechanisms for monitoring and evaluation. 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 the activities and facilitate the meeting of the targets.

Many of the cases have evolved since the studies were conducted and therefore all recommendations may not currently apply to the specific cases. Nevertheless, the lessons learned from these case studies offer valuable insights into the challenges that affected the implementation of Global Fund malaria grants in Ghana, Guinea-Bissau, and Nigeria and about Global Fund procedures and policies. It must be noted that some of the challenges experienced in the three countries, such as delays in developing treatment protocols and training staff and producer capacity bottlenecks, were peculiar to the introduction, transition, and implementation of ACTs with which many PRs, malaria control programs, and other implementers had little experience. These lessons may not be relevant to Global Fund recipients that are not implementing new limited source therapies. However, many of the identified issues such as the capacity to manage the procurement and distribution processes, bureaucratic importation and customs procedures, inadequate information systems, and inadequate planning are valid for malaria grants for most PRs of other countries but also for other products and commodities.

ANNEX 1. GLOBAL FUND KEY PROPOSAL APPROVAL AND IMPLEMENTATION PROCESS

```
┌─────────────────────────┐          ┌─────────────────────────────┐
│    Call for proposals    │     ┌───▶│  Grant Agreement Negotiation │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│       Preparation        │     │    │ Signature and First Disbursement │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│     First Screening      │     │    │       Program Launch         │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│     Technical Review     │     │    │    Disbursement Requests     │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│      Board Approval      │     │    │ Progress report and Annual Audit │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│     Option for appeals   │     │    │    Disbursement Requests     │
└─────────────────────────┘     │    └─────────────────────────────┘
             │                   │                  │
             ▼                   │                  ▼
┌─────────────────────────┐     │    ┌─────────────────────────────┐
│  Local Fund Agent Selection │──┘    │ Extension of Initial 2 Year Funding │
└─────────────────────────┘          └─────────────────────────────┘
```

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

ANNEX 2. KEY ACTIONS NEEDED AND POTENTIAL BOTTLENECKS FROM PROPOSAL DEVELOPMENT TO IMPLEMENTATION

Grant Stage	Key Actions	Stakeholders	Challenges
CCM appointment	- Appoint broad-based CCM, involving key stakeholders including drug regulatory authority and mix of technical and political institutions - Establish membership by constituency - Ensure partners are committed to CCM and participate regularly in meetings - Appoint CCM chair and co-chairs - Develop regular schedule of meetings - Develop working groups and implementation committee with appropriate terms of reference - Appoint PR and SR with capacity to carry out activities - Ensure CCM understands its roles - Plan for funds for CCM operations	CCM	- Appointment process not transparent - Key stakeholders not involved or informed - Membership based solely on political criteria rather than technical need - Members not committed to process and meetings - CCM does not understand roles - CCM does not raise funds from various sources for its administrative functions
Proposal development	- Map and analyze relevant stakeholders of the process - Involve key stakeholders that will be involved in implementation - Consider activities to be supported by government and other partners and identify gaps to be filled by Global Fund - Consider and budget for external assistance - Identify and budget for complementary activities (e.g., distribution, M&E) - Ensure that potential PRs and SRs understand their roles - If consultant hired, maintain involvement and understanding of all aspects of plan - Give PSM appropriate importance - Identify realistic activities and targets in the proposal	- CCM - Technical bodies in country - Technical partners	- Key stakeholders not involved or informed - Funds for external assistance and complementary activities not identified and budgeted - Potential PRs and SRs do not understand roles - Consultant hired to develop proposal without involvement and understanding of implementers of the plan - PSM issues are not given appropriate importance - Activities and targets in the proposal are not realistic - Implementation of activities in proposal are not given adequate importance - Lack of procurement capacity

Grant Stage	Key Actions	Stakeholders	Challenges
Proposal approval	CCM/PR promptly respond to queries and conditions of Technical Review Panel (TRP)	• Global Fund (TRP and Board) • CCM	• TRP does not query key operational aspects of proposal • Queries not responded to adequately in sufficient time
LFA assessment	• Assesses PR on financial management, program management, and PSM • Gaps identified and recommendations made • Conditions identified	• LFA • PR • CCM	• LFA does not sufficiently identify gaps in PSM, and disbursements are not adequately linked to satisfying conditions • Recommendations are not adequately communicated to PR
PSM plan developed and submitted	• Develop PSM plan through broad consultation with key stakeholders • Coordinate targets and milestones in PSM with key activities and funds • Carry out quantification for national level as well as by district (ensure quantification or parallel procurement efforts are coordinated) • If consultant used to prepare plan, maintain involvement and understanding of all aspects of plan	• PR • CCM • Technical partners • Consultant	• PR does not understand or have capacity for PSM plan development • PR does not have access to consultants for developing the plan • Consultant hired to develop plan without involvement and understanding of plan implementers • Indicators and targets are not realistic or coordinated with activities and fund disbursal • Key stakeholders are not involved
Grant negotiation, signing, and fund disbursement	• Agree on realistic targets and milestones • Identify and agree upon conditions precedent (CPs) based on LFA assessments • Negotiate and sign grant • PR mobilizes immediately to satisfy CPs	• Global Fund • PR	• PR does not fully understand process • PR delays satisfaction of CPs
Policy and regulatory issues	• Alert policy makers to the need for policy change • Fast-track any policy or regulatory processes as needed, including registration of medicines • Consider changing regulatory status of medicine to over the counter • Evaluate whether any regulatory process will affect implementation and develop mechanisms to address this issue • Promulgate appropriate regulations	• CCM • Policy makers • Drug regulatory authority	• Slow in-country processes for policy change • Changing policies may affect planning for implementation • Slow registration process for medicines

Grant Stage	Key Actions	Stakeholders	Challenges

Planning	• Develop plans in collaboration with appropriate stakeholders—
	   o Implementation plan
	   o Procurement plan
	   o Training plan
	   o Distribution and storage plan
	   o Phase-out plan for old medicine (determine pipeline, adjust future procurements, and develop mechanisms for phasing out)
	   o M&E plan
	• Develop list of documentation needed at each stage of plans
	• Identify roles and responsibilities of stakeholders
	• Define timelines for activities
	• Ensure PRs and SRs and other implementers and partners understand roles and responsibilities
	• Establish mechanisms for accountability
	• Develop MOUs
		• PR
		• SR
		• Other implementers
		• Partners
		• CCM
			• Plans not developed or not developed appropriately
			• Lack of understanding and mapping of key steps and documentation needed
			• Stakeholders are not involved
			• PRs and SRs and other implementers and partners do not understand roles and responsibilities
			• Mechanisms for accountability are not established (e.g., MOUs or other contractual agreements not developed)
			• Poor communication exists among CCM, PR, and SRs

Training and communication	• Revise and disseminate new guidelines, including standard treatment guidelines and essential medicines lists • Carry out training workshops just before medicines arrive in-country according to training plan • Train on pharmaceutical management and inventory management • Disseminate treatment guidelines and forms and documentation needed for recording • Train on quantification for pull system • Launch communication strategy • Develop and disseminate behavior change communication strategies and information, education, and communication (IEC) messages (coordinate widespread communication with distribution)	• PR • SR • Other implementers	• Training and communication not coordinated with arrival and distribution of goods • Training plan not implemented appropriately • High attrition rate of staff • Lack of capacity for training in all issues • Poor communication among stakeholders, e.g., CCM, PR, and SRs

Grant Stage	Key Actions	Stakeholders	Challenges
Procurement	• Identify procurement agent if necessary • Identify supplier through procurement agent or tender system • Obtain appropriate procurement, import, and other documents, including any waivers • Initiate and manage procurement processes • Procure medicines and commodities • Make timely payment • Contract clearing agent	• PR • SR • Other implementers (CMS, procurement system)	• Lack of capacity in procurement • Unclear understanding of process and procedures, including documentation, waivers needed • Poor communication between procurement agent and PR • Miscalculation of amounts needed
Quality assurance/quality control	• Establish mechanisms for quality control of incoming medicines • Establish mechanisms for quality assurance of each implementation step (including supervision) • Coordinate surveillance systems	• PR • SR • Other implementers (drug regulatory authority)	• Lack of capacity for quality assurance/quality control • Regulatory body not involved in process
Distribution	• Contract distribution agent if needed before goods arrive in the country • Test quality of procured medicines • Provide distribution list and delivery schedule to distributor • Clear medicines and store in central warehouse until ready for distribution • Distribute medicines to district stores and health facilities according to distribution plan • Distribute documentation for recording inventory and stocks • Establish mechanisms for reordering; develop and distribute appropriate documentation • Establish mechanisms for quality assurance of distribution processes • Develop systems for tracking consumption • Phase out old medicines • Develop/review transportation • Develop/review strategies for preventing leakage to private sector • Develop/review systems to ensure management of shelf life	• PR • SR • Other implementers (CMS, distribution system)	• Poor communication among PR and SRs • No systems for inventory management, tracking consumption, and reordering • Poor distribution capacity • Lack of planning for distribution • Poor transport capacity • Inadequate storage • Stock-outs caused by miscalculation of amounts needed • No mechanisms for quality assurance of distribution processes

Grant Stage	Key Actions	Stakeholders	Challenges
Rational use by patient/caretaker	• Disseminate IEC messages • Develop supervisory system for monitoring provider adherence • Develop system for monitoring patient use	• PR • SR • Providers • Patients	• Inadequate IEC • Inadequate quality assurance, including supervision • No systems for monitoring rational use
Reporting and M&E	• Identify data needs and sources • Build capacity for M&E (human and information technology) • Develop and implement systems and schedules for routine and accurate data collection • Enter data into database ad store in central location easily accessible by PR and SR • Ensure SR reports on key indicators to PR promptly each month • Convene quarterly meetings of PR, SRs, and CCM • Provide quarterly reports from PR to CCM • Provide quarterly reports from PR to LFA • Conduct periodic supervisory visits by PR to validate accuracy of data	• PR • SRs • Other implementers • LFA • CCM • Global Fund	• Poor systems for monitoring • Poor data collection • Inadequate planning for reporting to chain of accountability • No central storage of data • No mechanisms for validating accuracy of data

ANNEX 3. KEY ACTIONS NEEDED AT THE COUNTRY LEVEL FROM PROPOSAL DEVELOPMENT TO IMPLEMENTATION

CCM convened
Broad participation
Dedicated members
Clear understanding of role

Proposal approved

LFA assess-ment

Proposal developed
Participation of key stakeholders
Activities and targets matched
Complementary activities considered
Technical assistance (TA) considered

PSM plan developed
Participation of key stakeholders
Activities and targets matched
Complementary activities considered
TA considered

Grant negotiated and signed
Realistic targets and milestones
PR selected using criteria
CPs agreed upon
Clear understanding of roles and expectations

CPs satisfied
TA obtained to address capacity gaps
Gaps in capacity filled

Implementation

Policy and regulatory changes
Policy and regulatory changes fast-tracked and implemented

Planning
Develop relevant plans with key stakeholders that include timelines, information, and documentation needed at each stage

Training and communication
Health workers trained at right time
IEC strategy launched
IEC materials disseminated
Other forms and templates disseminated

Guideline revision
STGs, EMLs, and other guidelines revised and disseminated

Quality assurance and ADR monitoring
QA/QC interventions developed and implemented
ADR monitoring system implemented

Procurement
Quantification by district completed
Procurement agency contracted
Supplier identified
Procurement management process implemented

Supply chain management
Distribution agent contracted
Distribution completed according to plan
Mechanisms for reordering established
Old medicines phased out

Monitoring and evaluation
Data sources identified
Schedule defined
Monitoring of activities implemented according to plan
Monitoring of consumption
Reports provided to PR, LFA, and CCM on time

Ongoing reviews, disbursements, and grant revisions

Phase II grant renewal
Phase I implementation satisfactory