Adaptation of MSH Pharmaceutical Management Training Tools for Nigeria in Support of Artemisinin-Based Combination Therapy Policy Implementation: Report of the Stakeholder Workshop, May 2005

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Strategic Objective 05

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RPM Plus works in more than 20 developing 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—medicines, 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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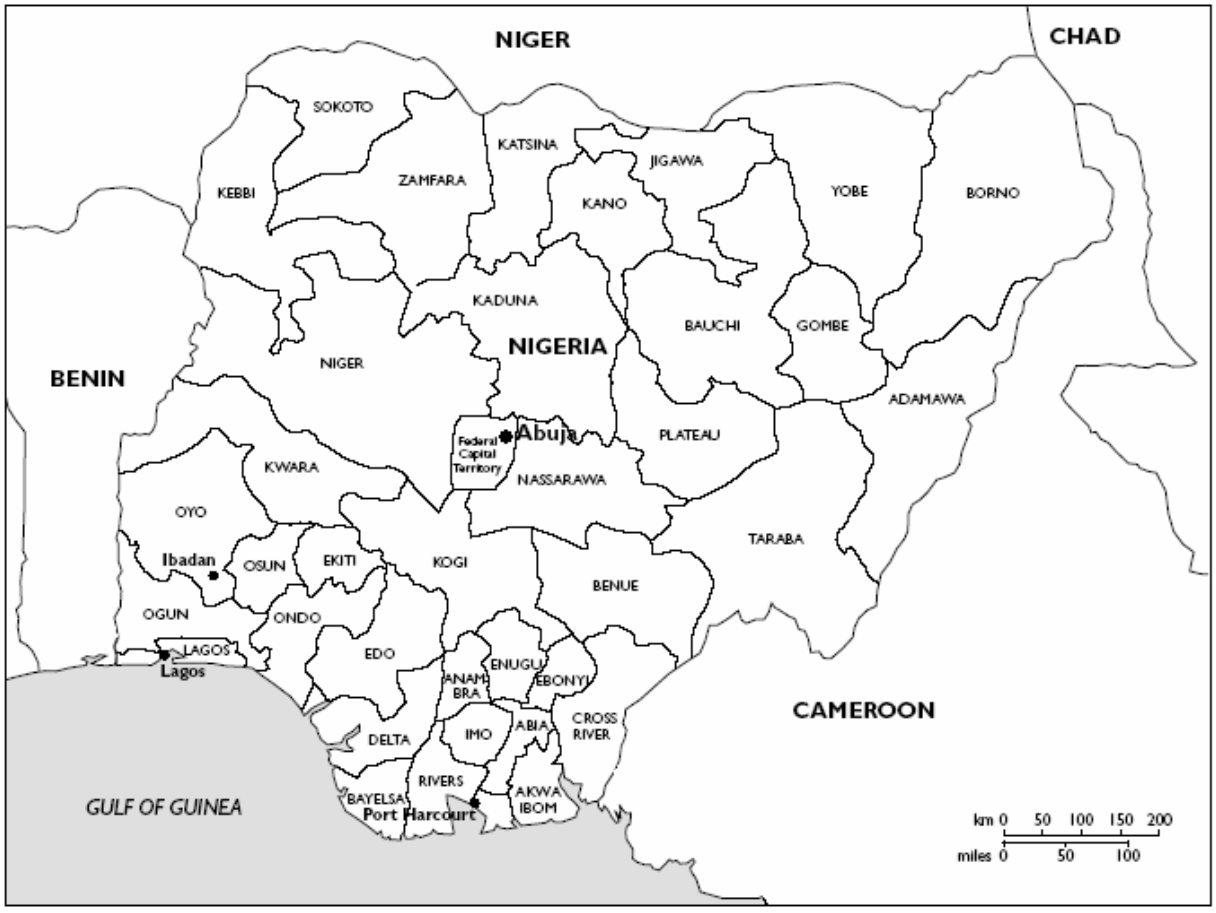
CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapy
ATP	Antimalarial Treatment Policy
CBO	community-based organizations
COMPASS	Community Participation for Action in the Social Sector
CQ	chloroquine
DFDS	Department of Food and Drugs Services
DFID	Department for International Development [UK]
FMOH	Federal Ministry of Health
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
IEC	information, education, communication
IPT	intermittent preventive treatment
ITN	insecticide-treated net
LGA	Local Government Area
MDG	Millennium Development Goals
MSH	Management Sciences for Health
NAFDAC	National Agency for Food and Drug Administration and Control
NGO	nongovernmental organization
NMCP	National Malaria Control Program
NMVCP	National Malaria Vector Control Program
PMV	patent medicine vendors
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SFH	Society for Family Health
SMOH	State Ministry of Health
SP	sulfadoxine/pyrimethamine
TOT	training of trainers
TB	tuberculosis
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

MAP OF NIGERIA SHOWING STATES AND FEDERAL CAPITAL TERRITORY



ACKNOWLEDGMENTS

The stakeholder workshop to adapt Management Sciences for Health (MSH) pharmaceutical management tools to the Nigerian context was carried out by the Rational Pharmaceutical Management Plus (RPM Plus) Program of MSH in collaboration with the Federal Ministry of Health (FMOH), Roll Back Malaria (RBM) partners, and pharmaceutical sector stakeholders in Nigeria. The workshop was carried out using funds provided by the U.S. Agency for International Development (USAID) Mission in Nigeria.

The authors acknowledge and express their appreciation to FMOH, Nigeria, and to other RBM partners and pharmaceutical sector stakeholders who contributed immensely to the planning, activities, and the subsequent outputs of the stakeholder workshop. They include the following—

- National Malaria Control Program (NMCP), FMOH
- Department of Food and Drugs Services (DFDS), FMOH
- National Agency for Food and Drug Administration (NAFDAC), FMOH
- State Ministries of Health (SMOHs), Nigeria
- USAID Nigeria Mission
- World Health Organization (WHO), Nigeria Office
- United Nation Children Fund (UNICEF), Nigeria Office
- Community Participation for Action in the Social Sector (COMPASS), Nigeria
- Society for Family Health (SFH), Nigeria

EXECUTIVE SUMMARY

Nigeria's national Antimalarial Treatment Policy (ATP) was revised in February 2005 on the basis of documented scientific evidence demonstrating parasite resistance to chloroquine (CQ) and sulfadoxine/pyrimethamine (SP). The policy currently recommends artemether-lumefantrine as first-line treatment for uncomplicated malaria. Preparatory activities for implementation of the new policy began in mid-February 2005 and are currently ongoing. The use of artemether-lumefantrine in children under five years and pregnant women will be implemented in 18 states and supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

A major challenge to the implementation of artemisinin-based combination therapies (ACTs) identified by in-country RBM stakeholders is the complexity of pharmaceutical management systems in Nigeria. Following a national consensus on the critical need to identify bottlenecks in the antimalarial pharmaceutical supply system, the RPM Plus Program of MSH in conjunction with the World Health Organization (WHO) undertook, in March 2004, a rapid assessment of various aspects of pharmaceutical management in the public and private sectors.

A key action needed for efficient ACT rollout and recommended by the rapid assessment was capacity building in medical stores and inventory management for states and for Local Government Areas (LGAs) (medical stores and health facilities). Using funds provided through the USAID Nigeria Mission, RPM Plus is working to provide technical assistance to capacity building in pharmaceutical management (stores and inventory management) at the state and LGA levels in preparation for ACT implementation in the selected states.

An initial activity identified was the adaptation of pharmaceutical management generic training tools developed by MSH to the Nigerian context. Therefore, a stakeholder workshop was planned and carried out from May 18 to May 20, 2005, in Lagos, Nigeria, to adapt the training tools for use in-country, with particular emphasis on ACTs and other antimalarials. Workshop participants were drawn from the FMOH (RBM Division, Department of Food and Drugs Services, NAFDAC); Borno, Cross River, and Lagos SMOHs; and RBM partners including USAID, MSH/RPM Plus, WHO, UNICEF, SFH, and COMPASS.

The overall goals of the workshop were to foster RBM stakeholder dialogue on the new ATP and to address the challenges posed by the introduction of ACTs into Nigeria's complex pharmaceutical management systems. Objectives of the workshop were to—

- Review the MSH generic tools and documents for pharmaceutical management training.
- Review other available relevant materials such as forms already in use, manuals, and guides for pharmaceutical management training for store managers.
- Apply various professional competencies to (1) the evaluation and adaptation of the documents into a comprehensive, usable package for training and (2) the implementation of stores and inventory management at all levels. Special emphasis was given to antimalarial drugs, particularly to ACTs.

- Plan for the training of trainers (TOT) at the federal level.
- Discuss and plan for the cascade training to be implemented after the TOT.
- Produce a workplan that is immediately actionable.
- Draft a communiqué for recording and promoting the outputs of the stakeholder workshop.
- Produce a report of the workshop.

The outputs of the stakeholder workshop met the objectives set. Stakeholder interaction, participation, and consensus were visible throughout the duration of the workshop. RBM and pharmaceutical sector partners demonstrated agency support for the need and concept of pharmaceutical management training in preparation for ACT policy deployment. In addition, commitments were made to close financial and technical gaps identified.

Adaptation of the MSH Generic Document

The generic MSH training manual was reviewed by three different working groups. The pharmaceutical and clinical groups examined the contents in detail for needed additions, deletions, and amendments. The training group focused on the general flow and plans for the use of the document. The review of other available relevant material was carried out mainly by the pharmaceutical group, which incorporated some preexisting forms and illustrations into the working document. Extensive editing was done, and insights were provided on complex technical and regulatory issues. The resulting training document is clearly distinguishable as a Nigeria RBM program document, though with a proviso for easy cross-adaptation by other public health programs, especially those addressing HIV/AIDS and TB.

Planning for the Federal-Level Training of Trainers and Subsequent Cascade Training

Stores and inventory management training activities were planned in detail, covering the criteria for the selection and number of participants, timing, venue, responsibilities, and facilitation. Cascade trainings were defined in scope for the levels of implementation after the national TOT. It was agreed that for state- and LGA-level trainings, a large measure of responsibility concerning the methodology and participation is to be delegated to the states to encourage a fitted approach, sustainability, and ownership.

Workplan Drafted on Expected Training Activities

Plans for the federal and cascade training activities have been developed, as well as budgets, responsibilities, and program indicators. A concrete workplan has been put in place, and it will guide the immediate next steps.

Communiqué of the Meeting

A communiqué was developed and will serve as an immediate tool for reporting back on the meeting, as well as providing a focus for advocacy and promoting the objectives of the training of health staff on pharmaceutical management with an emphasis on antimalarial medicines and ACTs (Annex 1).

Recommendations of the Stakeholder Adaptation Meeting

The stakeholder adaptation workshop recommended the following—

1. Training in stores and inventory management at the national, state, LGA, and community level will be held beginning July 4, 2005, and will include pharmacists, pharmacy managers, and storekeepers.

2. The country should establish an appropriate distribution system that would ensure prompt access to antimalarial medicines within 24 hours for children under the age of five and pregnant women.

3. A distribution plan concurrent with a procurement plan for ACTs should be developed to ensure that ACTs are available, accessible, and affordable at all levels of health care.

4. Public/private partnerships in the areas of medicine distribution, storage, advocacy, mass media promotion, and social marketing should be instituted as part of efforts to rapidly achieve the RBM and Millennium Development Goal (MDG) targets.

5. The establishment of a national medicines database through a functional health management information system needs to be achieved.

6. Commitment of the federal government and the partners to the RBM initiative should be sustained, and mobilization of resources to effect ACTs as a public health good should be initiated.

7. Training in pharmaceutical management of malaria medicines needs to be integrated with that of HIV/AIDS and TB medicines at all health care and community levels in the country.

8. RBM progress reports should be delivered to Commissioners for Health and other major stakeholders of RBM. All efforts should be made to give immediate feedback on activity implementation.

9. Appropriate monitoring and supervision tools for drug distribution, stock-outs, and utilization for effective program planning, implementation, and evaluation should be developed.

10. Funding by the FMOH should be provided for operational research on programmatic issues and the appropriate dissemination of findings.

Next Steps

Continuous dialogue and interaction are needed among stakeholders. Next steps include —

- Finalization and circulation of the tentative training programs, budgets, and stakeholder responsibility listings by the FMOH/RBM.

- Finalization of the draft, adapted document for the training on stores and inventory management and circulation of the draft at during the second week in June 2005 for feedback from other RBM stakeholders. The training document will be used in final draft form for the national TOT to ensure incorporation of inputs from the facilitators under training. The national TOT will afford further refinement of the training manual, after which the document will be submitted to the office of the Honorable Minister of Health, Nigeria, for approval and professional editing in preparation for printing.

- TOT at the national level will be conducted in two locations (Kaduna and Ota states) July 4–8, 2005.

- The state trainings and cascade trainings will follow subsequently at the state, LGA, and facility levels.

- The documents and tools for stock management will be made available to stores and facilities to complement the training activities.

- Monitoring and supervision will be rolled out to assess the readiness of the states and LGAs for the ACT management before, and immediately after, the supply and distribution of ACTs.

- A plan for rapid appraisal of ACT pharmaceutical management (in the public and private health systems) will be developed and implemented after approximately six months of operation in the country.

- Organizational follow-up plans to all the decisions made at the stakeholder meeting will be undertaken by all RBM partners.

BACKGROUND

Nigeria lies on the west coast of Africa. It has a surface area of 923,708 square kilometers and a population of about 118,000,000 (projected from the 1991 census). The country is divided into six geopolitical zones: North West, North East, North Central, South West, South East, and South South. It has 36 states plus the Federal Capital Territory. The states are further divided into 774 LGAs. The three tiers of government are federal, state, and local.

Malaria is endemic in Nigeria, accounting for the majority of outpatients seen in all age groups at the health facilities. The disease is a major cause of morbidity and mortality, accounting for 25 percent of infant mortality and 30 percent of childhood mortality (Ejezie, 1990). At least 50 percent of the population suffer from at least one episode of malaria each year. Given Nigeria's total population, this translates to 59 million people suffering from attacks of malaria yearly. It is the most common cause of outpatient attendance in all age groups and the most common cause of mortality in children under the age of five years (NMCP, 1996). Transmission of malaria is stable in all parts of the country, with high intensities in the northern part of the country during the short wet season as compared with low transmission during the long dry season. In the southern part of the country, transmission is intense, stable, and uniform throughout the year. There is also a difference in disease transmission rate between rural areas, where the disease is holo-endemic, and urban areas, where the disease is meso-endemic.

Nigeria, like most malaria-endemic countries, has had a long history in malaria control dating back to its independence era in the 1960s. However, in the last five years, advocacy, political awareness, and commitment to malaria control have continued to improve. In 1987, Nigeria developed its first NMCP. In 1996, the implementation of the malaria policy was accompanied by plans of action for malaria control, revitalization and reestablishment of malaria control units in the states, advocacy for increased funding for malaria control, and resuscitation of national malaria technical committees and training activities.

Recent malaria control efforts are based on the principles of the WHO RBM Partnership, which was launched in September 1998. Nigeria reaffirmed its commitment to the initiative by hosting and cofinancing the African Heads of State Summit on Roll Back Malaria in Abuja in April 2000. Among many other African countries, Nigeria made a commitment at the summit to intensify efforts to ensure that by the year 2005—

- At least 60 percent of those suffering from malaria have prompt access to and are able to use correct, affordable, and appropriate treatment within 24 hours of the onset of symptoms.

- At least 60 percent of those at risk of malaria, particularly pregnant women and children under five years of age, benefit from the most suitable combination of personal protective measures such as insecticide-treated nets (ITNs) and other interventions that are accessible and affordable to prevent infection and suffering.

- At least 60 percent of all pregnant women who are at risk of malaria, especially those in their first pregnancies, have access to chemoprophylaxis or intermittent preventive treatment (IPT).

A major intervention for malaria control proposed by RBM is the provision of effective, affordable, acceptable, and available antimalarial medicines to enhance prompt and effective treatment of malaria episodes within 24 hours of onset of illness. Nigeria's former national ATP, dated 2001 (FMOH/NMVCP, 2001), recommended CQ as the first-line medicine for treatment of malaria and SP as the second-line medicine or as an alternative when circumstances make the use of CQ inappropriate or impossible.

The national ATP was revised in February 2005 on the basis of documented scientific evidence demonstrating parasite resistance to CQ and SP. The policy currently recommends artemether-lumefantrine as first-line treatment for uncomplicated malaria. In addition, the policy recommends parenteral quinine for the treatment of malaria in pregnancy (first trimester), artemether-lumefantrine for treatment of malaria in pregnancy (second and third trimester); and SP for IPT for the prevention of malaria during pregnancy. Preparatory activities for implementation of the new policy began in mid-February 2005 and are currently ongoing incorporating the development, production, and distribution of guidelines; training of health workers and other providers; advocacy and information, education, and communication (IEC) activities; and procurement of artemether-lumefantrine. An implementation phase will follow the preparatory phase and incorporate deployment of artemether-lumefantrine to children under five years and pregnant women in 18 states to be supported by GFATM.

A major pharmaceutical challenge to the introduction of ACTs identified by in-country RBM stakeholders is the complexity of pharmaceutical management systems in Nigeria. Following national consensus on the critical need to identify bottlenecks in the antimalarial supply system, a rapid assessment of various aspects of pharmaceutical management in the public and private sectors was undertaken in March 2004 by the RPM Plus Program of MSH in conjunction with WHO. The assessment found that the pharmaceutical management system in Nigeria is presently functioning at a suboptimal level and needs to be strengthened through systematic and focused training at all levels of health care. Key challenges observed by the rapid assessment included—

- Unconsolidated procurement of medicines
- Inadequate inventory and stock management
- Poor record-keeping in facilities
- Frequent stock-outs of antimalarial drugs

Given these challenges, a key action needed for efficient ACT rollout and recommended by the report was capacity building in stores and inventory management for states and LGAs (medical stores and health facilities).

Using funds provided through the USAID Nigeria Mission, RPM Plus is working to provide technical assistance foor capacity building in pharmaceutical management (stores and inventory management) at the state and LGA levels in preparation for ACT implementation in the selected states. An initial activity identified was the adaptation to the Nigerian context of pharmaceutical

management generic training tools developed by MSH. Therefore, a stakeholder workshop was planned and carried out May 18–20, 2005, in Lagos, Nigeria, to accomplish this, with particular emphasis on ACTs and other antimalarials. The second step in the capacity building activity would be a TOT effort at the federal level followed by cascade trainings in stores and inventory management at state and LGA levels.

RBM STAKEHOLDER ADAPTATION WORKSHOP

FMOH, with the support of USAID through RPM Plus and in collaboration with other RBM partners, organized the three-day national RBM stakeholder workshop to adapt MSH generic pharmaceutical management training tools. The workshop was held May 18–20, 2005.

Workshop participants were drawn from FMOH (RBM Division, Department of Food and Drugs Services, NAFDAC); Borno, Cross River, and Lagos SMOHs; and RBM partners including USAID, MSH/RPM Plus, WHO, UNICEF, SFH, and COMPASS. (Annex 2 provides a list of workshop participants.)

Goals and Objectives of the Workshop

Goals of the Workshop

1. To foster RBM stakeholder dialogue on the new national ATP change to ACT

2. To address the challenges posed by the introduction of ACTs into Nigeria's complex pharmaceutical management systems

Objectives of the Workshop

1. To review the MSH generic tools and documents for pharmaceutical management training

2. To review other available relevant materials such as forms already in use, manuals, and guides for pharmaceutical management training for store managers

3. To apply various professional competencies to (1) the evaluation and adaptation of the documents into a comprehensive, usable package for training and (2) the implementation of stores and inventory management at all levels. This application would give special emphasis to antimalarial medicines, and ACTs in particular.

4. To plan for TOT at the federal level by—

    - Finalizing the training and background documents to be used

    - Finalizing the choice of facilitators

    - Setting the criteria for participation

    - Finalizing the number of participants from the 18 selected GFATM-supported states in Nigeria

- Setting in motion the processes for the TOT meeting—for example, time, venue, and responsibilities.

5. To plan for the cascade training to be implemented after the TOT by—

   - Defining the scope of training activity
   - Defining the methods of training
   - Suggesting the times of commencement of cascade trainings
   - Defining responsibilities of stakeholders in the implementation of the medical stores and inventory management training activities at the federal, state, and LGA levels

6. To produce a workplan that is immediately actionable

7. To draft a communiqué for recording and promoting the outputs of the stakeholder workshop

8. To produce a report of the workshop

Methodology for the Workshop

The methodology for the arrangement and execution of the stakeholder workshop consisted of the following—

- Preworkshop activities
- Workshop activities—plenary and group work

Preworkshop Activities

Activities carried out before the workshop included the following—

- Harmonization of existing MSH generic documents into one package to be delivered to the stakeholder workshop. This activity was carried out by RPM Plus through a local consultant in Nigeria in collaboration with the RPM Plus malaria team.
- Preparations for the adaptation workshop—venue, participants, documents, and templates
- Briefing meetings with FMOH, USAID, and WHO Nigeria Office

Workshop Activities

The workshop was facilitated by the mix of plenary and group sessions (Annex 3, Agenda).

Four plenary presentations were given as captured below—

- Presentation by FMOH (RBM Unit)
- Presentation by WHO
- Two presentations by FMOH (DFDS)

Group discussion guidelines (Annex 4) were used to guide three working groupse—

- Clinical group
- Pharmaceutical group
- Training, stakeholder, and general issues group

Plenary discussions were held every day, following plenary and group work presentations, to discuss issues raised and promote consensus on plans, strategies, and responsibilities.

Summary of Workshop Proceedings

Highlights of Plenary Presentations

Overview of RBM—Focus on the New Antimalarial Treatment Policy
Presenter: Dr. E. Nwokolo (RBM/FMOH)

- Malaria is a national problem in Nigeria responsible for 60 percent of outpatient visits, 30 percent of childhood mortality, 25 percent of infant mortality, 11 percent of maternal deaths. In total, 132 billion nairis (NGN) is lost to malaria annually in form of treatment costs, prevention, and loss of workhours.

- The RBM mobilization plan is effective in Nigeria, and therefore, RBM in Nigeria is effected through a partnership involving the federal governments, the private sector, research organizations, civil society, the media, and development partners.

- The five strategic approaches of RBM in Nigeria include disease management, multiple prevention measures (chemoprophylaxis, use of ITNs, and environmental management), IEC and social mobilization, operational research, and partnership.

- Disease management aims to improve case management at the health facility and community levels through the provision of efficacious drugs, capacity building of health professionals to give appropriate, evidence-based treatment, mobilization of caregivers to recognize symptoms within 24 hours and commence appropriate treatment, and reorientation of community-oriented resource persons to improve their support systems.

- Abuja target reminder—

  - 60 percent prompt access to appropriate treatment in 24 hours
  - 60 percent of (children under 5 years and pregnant women) use ITNs
  - 60 percent pregnant women to use IPT with SP

- Description of emerging multidrug resistance and drug trial and efficacy testing that demonstrates the efficacies of artemether-lumefantrine and artesunate-amodiaquine. The comparative matrix used for the choice of artemether-lumefantrine as first-line treatment is shown in Table 1.

Table 1. Comparative Matrix Used for the Selection of Artemether-Lumefantrine for First-Line ACT in Nigeria

• Result of efficacy studies
• Clinical safety for diverse age groups
• Potential for widespread use (in home-based management for malaria, health facilities, and hospitals)
• Potential for consumer acceptability and compliance ▪ Product formulation and presentation ▪ Dosage schedule ▪ Acceptability ▪ Dosage formulation (adult and pediatric)
• Cost and cost effectiveness
• Potential to delay drug resistance ▪ Compatible half-life ▪ Mode of action ▪ Gametocytocidal activity
• Availability and status ▪ Reliable production source ▪ Adequate production capacity ▪ Local availability ▪ Registered ▪ Available at affordable cost
• Potential for wide geographical application. Consider the following— ▪ Regional efficacy profile ▪ Cost effectiveness ▪ Regulatory status ▪ Production capacity
• Treatment for pregnant women
• Treatment for severe malaria
• Case management in the home

- Description of new policy defining goals, aims, components for special groups, chemoprophylaxis, antimalarial medicines supply management, IEC and behavior change communication, applied research, and monitoring and evaluation.

- Achievements to date with ACT policy implementation—
  - Presentation of policy to the National Council on Health and subsequent approval
  - Inauguration of the Transition Committee with technical working groups to guide implementation
  - Development of prepackaged antimalarial medicines manufactured locally (CQ and SP)
  - Use of existing network to make ACTs available at all levels
  - Regular networking through the Case Management Subcommittee
- The way forward and challenges—
  - ACTs are still not deregulated. The process is ongoing.
  - Staff who handle medicines are not yet trained on ACT handling.
  - Global shortage of ACTs affects implementation.
  - Capacity building of health workers needs to be done in all aspects of the usage and management of ACTs.
- Prospects for ACTs—
  - Deregulation is vital to the widespread availability and use of ACTs.
  - ACTs should be incorporated into the essential medicines list.
  - ACTs must change from prescription-only medicine status to over-the-counter status.
  - Capacity building of health professionals is urgently needed.
  - Massive orientation of caregivers and mothers on ACTs is urgently needed.
  - Pharmacovigilance must be instituted.
  - Monitoring and evaluation of medicines use should be put in place.

Artemisinin-Based Combination Therapy (ACT)—Ensuring Effective Drug Management
Presenter: Dr. B. M. Afolabi (WHO National Program Officer, Malaria)

- Analysis of the malaria burden revealed the following—
  - Global malaria control is being threatened at an unprecedented scale by rapidly growing resistance of *Plasmodium falciparum* to conventional monotherapies, that is, CQ, SP, and amodiaquine, particularly in Africa.
  - Results of drug trial and efficiency testing conducted in the six geopolitical zones of Nigeria in 2002 showed widespread resistance to first- and second-line drugs—CQ and

SP. Stakeholders moved that Nigeria should change to ACT because multidrug resistance has rendered monotherapies for malaria useless.

- Meta-analysis of ACTs versus antimalarial monotherapies showed clear benefit of ACTs—reduction of risk of treatment failure, superior pharmacodynamic action (parasite clearance and fever clearance), and reduction in gametocyte carriage.

- Antimalarial resistance has the following consequences—

  - The cheapest, most affordable antimalarials are ineffective, and the credibility of health providers is at stake.

  - Alternative regimens might be too expensive.

  - When treatments do not cure patiens, more serious morbidity occurs, even in initially uncomplicated cases of malaria.

  - More money is spent, people become poorer, and mortality increases.

- Projected rationale for and aims of ACTs include the following—

  - Patients who no longer respond to standard monotherapies could be helped.

  - Such ACT regimens should be incorporated into strategies aimed at malaria control.

  - Early, effective, and appropriate chemotherapy for malaria has a pivotal role in reducing morbidity and mortality.

  - About 50–70 million individuals yearly with uncomplicated *P. falciparum* malaria will benefit from the identification of an appropriate combination treatment regimen.

- Antimalarial combination therapies recommended by WHO were highlighted.

- Antimalarial combination therapies not recommended by WHO were also highlighted.

- The following antimalarial combination therapies are expected to be used in Nigeria—

  - Artemether-lumefantrine
  - Artesunate-amodiaquine

- The future of ACTs was reviewed—

  - Can an ACT policy be effectively implemented in Africa?

- To refine implementation strategies, FMOH, the Nigeria Institute for Medical Research, and other research institutes should continue to conduct operational research.

- FMOH and nongovernmental organizations (NGOs) should also conduct operational research relevant to program implementation of policies. Comparison of program designs will improve results for individual patients and communities.

- Until better regimens become available, policy makers face enormous demands to choose among existing combinations.

- Further studies are needed for informed judgments to be made.

Drug Supply Systems
Presenters: Mr. D. O. Omoyele (DFDS/FMOH)
Mrs. G. O. Abumere (DFDS/FMOH)

- Path of the pharmaceutical supply systems
- Pharmaceutical supply systems in Nigeria
- Pharmaceutical supply management systems to support medicines and stock management
- Definitions of terms in pharmaceutical supply management
- The pharmaceutical supply management cycle
- Discrepancies between theory and practice in Nigerian pharmaceutical supply and circulation

Distribution and Distribution Networks
Presenter: Mrs. G. O. Abumere (DFDS /FMOH)

- Importance of procurement to run concurrently with distribution plans
- Goals of distribution
- The four elements of a pharmaceutical distribution system—

    - System design
    - Information system
    - Storage system
    - Delivery system

- The pharmaceutical distribution cycle
- Criteria in designing a distributive network
- Characteristics of a pharmaceutical distribution system

Highlights of Group Presentations

Pharmaceutical Group

The essence of the group work was defined as the adaptation of the generic documents for managing medicines, especially ACTs. The adapted manual will be used subsequently to increase the knowledge base of health care professionals (pharmacy managers and storekeepers)

on the use of ACTs, at the same time empowering them to train others in the use and management of ACTs.

The adaptation was guided by the pharmaceutical management cycle—a systematic approach that would be used to ensure that all medicines (in this case, antimalarials) for a complete course of malaria prevention or treatment are available and appropriately used according to Nigeria's effective treatment strategy and timeline.

Relevant topic areas that were defined and discussed by the group included the drug store, storage issues, distribution, and rational medicine use.

Additions, deletions, and amendments to the generic training tool were presented.

Clinical Group

Objectives for the TOT program and cascade training were identified by this group.

The TOT efforts would, in addition to providing facilitation skills and training on stores and inventory management, aim to do the following—

- Empower the trainers and facilitators with the rationale for the change in the ATP
- Disseminate to trainees the details of the policy change and create a forum for feedback
- Build the capacity of facilitators on standard techniques of ACT supply management
- Improve the planning and supervisory skills of the facilitators in ACT management and supplies

The cascade trainings would, in addition to providing requisite training to drug managers and storekeepers, aim to do the following—

- Educate pharmacy managers and storekeepers on the rationale for the change in ATP
- Disseminate the details of the policy change and create a forum for feedback
- Build the capacity of pharmacy managers and storekeepers on standard techniques of ACT supply management
- Update the knowledge of the pharmacy managers and storekeepers on ACT handling and management to ensure delivery of potent and effective ACTs to the end users
- Improve the individual planning skills of the pharmacy managers and storekeepers within states and LGAs
- Define the roles and responsibilities of pharmacy managers and storekeepers

Additions, deletions, and amendments to the generic tool were presented.

Training and General Issues

Objectives

The objectives of the planned trainings (TOT and cascade) on stores and inventory management were identified as follows.

The general objective is to create awareness on ACTs and improve the knowledge and skills of health workers on the supply and rational use of antimalarial medicines for case management, IPT, and chemoprophylaxis, at the same time improving their efficiency in the procurement, supply, and distribution of ACTs.

Specific objectives are to—

- Build capacity on pharmaceutical management at the federal, state, LGA, and facility levels.
- Improve the knowledge and skills of health workers handling antimalarial medicines in general, and the newly introduced ACTs in particular.
- Promote the judicious use of antimalarial medicines to prevent waste.

Core Training

Regional TOT Workshop: Participants to be trained for the Core TOT Workshop (Table 2) were identified as follows—

- FMOH (NMCP officers at federal and state levels; DFDS officials; officers from the Central Medical Store; NAFDAC officials)
- Directors of Pharmaceutical Services in the targeted states
- The State Chief Pharmacists in the State Drug Stores
- Agency staff
- Participants from academic institutions
- Officers from the Ministry of Defense and paramilitary officers

Table 2. Training Plan for Federal-Level TOT

Factor	Decision and Rationale
Duration of training	Three days (four nights)
Venue of training	Planners agreed that the choice of venue should be biased toward places that offer minimum distractions. Kaduna state (northern Nigeria) and Ota state (southern Nigeria) were tentatively chosen.
Time of training	The trainings will commence July 4–8, 2005, starting with the regional TOT.

The group agreed that the trainings should be held concurrently at two locations in the country—one in the north and the other in the south, but with each location having participants assembled from both geographical divisions to ensure a good mix of discussion, cross-fertilization of ideas, and broad outcomes.

Forty-four participants were expected in each of the locations for the regional TOT.

State-Level Training

Participants for the state-level training (first-level cascade) were identified as the following—

- State RBM managers for the selected states
- Pharmacists in charge of drug stores
- Chief pharmacists from tertiary institutions

The duration of training would be two days (three nights).

Facility-Level Training

The selection of participants at the facility level will be based on their responsibilities at the facility. Planning for this training will be mainly delegated to the states, which will clearly define the selection in the letters of invitation. The facility-level training will be conducted in three locations (three zones) in each state. In particular, issues such as monitoring and evaluation, integration of RBM training with other related training activities, and issues of sustainability should be incorporated into the facility- and state-level training activities. The role of FMOH, SMOH, and other stakeholders must be specified to ensure proper ownership of the project.

General Issues

Consultants currently in charge of planning training activities for GFATM will be in charge of the training and other related activities. FMOH staff (RBM and DFDS) who were part of the stakeholder adaptation meeting are to be considered for facilitation of the training activities, along with agency staff and RPM Plus consultants.

The approximate budget for each of the training activities was developed by the training group. Budgets are comprehensive, covering transportation, daily subsistence allowances, hall rentals,

stationery, communication and postage, tea break and lunch break, and so forth. Finalization will be completed and the information communicated to all RBM partners.

The issue of training for states not supported by GFATM was discussed extensively, and the consensus is toward converged support by all RBM partners so that those states will not lag behind, especially because the promotion of the use of ACTs is not limited to the GFATM-supported states.

Issues Arising from Plenary Discussions

1. A plan for capacity building is needed for all 36 states and the Federal Capital Territory simultaneously since the RBM is national and not limited to the GFATM-supported states. Given the fact that funds are already available from GFATM for pharmaceutical management training in support of ACT implementation, with an inclusive and rational budget, RBM partners should be able to buy in to support the gaps, especially within their comparative advantages. These gaps include pharmaceutical management trainings for non–GFATM-supported states, for communities, and for the private sector.

2. The role of the governments at state and LGA levels should be well articulated and communicated to them. The states, especially, need to be sensitized to their expected contribution to the execution and sustenance of these planned pharmaceutical management training efforts.

3. The planned capacity building activities for pharmaceutical management of antimalarial medicines must be integrated with those being undertaken for other health interventions, especially those addressing HIV/AIDS and TB.

4. Advocacy and sensitization are needed for sustained efforts to add value to the capacity building, supervision, and monitoring of pharmaceutical management interventions.

5. The issue of private sector involvement in implementation of the new ACT policy must be given a prominent role because of the private sector's vital role in the distribution and supply of antimalarial medicine, including ACTs.

6. Partners should collectively avoid pooling resources to the federal level of health care. Where possible, resources should be distributed to the lower levels of health care, including the community, where implementation takes place.

7. Access to ACTs at the community level is critical to ensure the success of the RBM program and ACT policy implementation. Community groups and philanthropists should be mobilized into ongoing efforts.

8. All stakeholders and actors potentially involved in the ACT policy implementation must be given orientation to speed up the pace of plans and interventions.

9. The current absence of a central procurement unit in FMOH (Department of Food and Drugs Services) needs to be examined because it will likely have an impact on ACT procurement in Nigeria.

10. The design for private sector distribution of ACTs conceptualized by FMOH's NMCP should be considered in the light of a partnership only and viewed as an add-on to what is essentially a public sector pharmaceutical supply system. There is critical need for the private sector to be guided on how and when distribution plans for ACT rollout are to be put in place. In addition, information systems, as well as a monitoring and medicines tracking system, must be in place. A critical question would be, What plans are being made for the public sector distribution of ACTs? Parallel systems should be avoided.

11. ACTs must be deregulated; parallel importation must be established.

12. The status of ACTs must be changed from prescription-only to over-the-counter. To make this change, more information on the safety profile of artemether-lumefantrine and artesunate-amodiaquine is needed; the Transition Committee established for ACT implementation has to work toward achieving this end.

13. Participants extensively deliberated on how to link a patient suffering from malaria with available health facilities within 24 hours and what the role of the patent medicine vendors (PMVs) is in obtaining ACTs. The need for inclusiveness of PMVs and the definition of criteria for their involvement were highlighted. A strong note of caution was sounded on the potential pitfalls in this proposal, however, especially given the past experiences in Nigeria with PMVs (for example, faking drugs and refusing to comply with the rules of rational medicine dispensing).

14. The need for pharmacovigilance of ACTs was stressed. NAFDAC will take responsibility for these activities.

OUTPUTS OF THE STAKEHOLDER ADAPTATION WORKSHOP

The outputs of the workshop are considered to be in line with the objectives for the meeting. In summary, the outputs of the stakeholder workshop met the objectives set.

Stakeholder interaction, participation, and consensus were visible throughout the duration of the workshop. RBM and pharmaceutical sector partners demonstrated agency support for the need and concept of pharmaceutical management training in preparation for ACT policy deployment. In addition, commitments were made to close financial and technical gaps identified.

Challenges posed by the introduction of the new ATP were discussed, and more plans were made by stakeholders aimed at improving the health care system in a bid to cope with the public health challenge of a devastating health and economic problem—malaria.

Adaptation of the MSH Generic Training Document

The generic MSH training manual was reviewed by three different working groups. The pharmaceutical and clinical groups examined the contents in detail for needed additions, deletions, and amendments. The training group focused on the general flow and plans for the use of the document.

The review of other available relevant material was carried out mainly by the pharmaceutical group, which incorporated some preexisting forms and illustrations into the working document. Extensive editing was done, and insights were provided on complex technical and regulatory issues.

The resulting document is clearly distinguishable as a Nigerian RBM program document, though with a proviso for easy cross-adaptation by other public health programs, especially HIV/AIDS and TB.

Among the changes made to the generic document are the following—

- The title of the document was reworded to read, “Basic Techniques for Managing Medicines—A Manual for Training, Planning, and Supervision.”
- The subtitle was changed to read, “Adapted for Use of Medical Stores and Health Facilities in Nigeria.”
- An initial orientation section on malaria control and the new ATP were added at the beginning of the document.
- FMOH/RBM prepared the foreword and acknowledgment.
- The document was adapted for Nigeria, while acknowledging the author of the original document (Moore, 2000).

- A global replacement of the word "drugs" with "medicines" was made in the document.
- The report forms available in NAFDAC archives on pharmacovigilance were collated for review and possible adaptation.
- The approved listing of antimalarial medicines in Nigeria was inserted.
- Corrections and editions were made to give the generic documents a focus on the management of antimalarial medicines in Nigeria.
- Some definitions were newly inserted or elaborated.
- The stock card was reviewed for adequacy; the reviewers decided that it should be initialed and tagged "Security Card."

Planning for the Federal- (Now Zonal-) Level Training of Trainers

The training activities were planned in detail, covering the criteria for selection and number of participants, timing, venue, responsibilities, and facilitation. The details are under the earlier section "Highlights of Group Presentations—Training and General Issues" and in Annex 5

The choice of other background documents (in addition to the main training manual) was not adequately considered because of the heavy focus on the MSH document. It was established, however, that the fact sheet on ACTs would be included, along with any relevant documents from FMOH. Such materials will be approved and included in the training package.

Deliberations on the Cascade Training Activities

The cascade trainings on stores and inventory management were defined in scope for the levels of implementation after the national TOT. With facilitation from the state officials that will attend the TOT, however, a large measure of responsibility concerning the methodology and participation is to be delegated to the states to encourage a fitted approach, sustainability, and ownership. (Annex 5 shows the planned activities and possible stakeholder participation.)

Workplan Drafted on Expected Training Activities

With the plans for the federal and cascaded training activities compiled, along with budgets, responsibilities, and program indicators, a largely usable workplan has been put in place and will be useful in the immediate next steps.

Communiqué of the Meeting

The developed communiqué (Annex 1) served as an immediate tool for reporting back on the meeting, as well as providing focus for advocacy and promoting the objectives of the training of health staff on pharmaceutical management with focus on antimalarial medicines, and ACTs in particular.

Documentation of Processes and Outcomes

Documentation was completed, aided by the clearly defined objectives of the stakeholder adaptation workshop, which focused on and was matched with detailed group discussion outlines, and templates for the group presentations.

RECOMMENDATIONS FROM THE WORKSHOP

In view of the challenges and complexities at every level that the implementation of an ACT policy brings, the stakeholder adaptation workshop recommends the following—

- Training in stores and inventory management at the national, state, LGA, and community levels to include pharmacists, pharmacy managers, and storekeepers.

- The establishment of an appropriate distribution system that would ensure prompt access to antimalarial medicines within 24 hours by children under the age of five and pregnant women.

- The development of a distribution plan concurrent with a procurement plan for ACTs. Such a plan would achieve an effective distribution system and ensure that ACTs are available, accessible, and affordable at all levels of health care in Nigeria.

- Public/private partnerships in the areas of medicine distribution, storage, advocacy, mass media promotion, and social marketing as part of efforts to rapidly achieve the RBM and MDG targets.

- The establishment of a national medicines database through a functional health management information system.

- Sustained commitment of the federal government and the partners to the RBM initiative and mobilization of resources to effect ACT policy as a public health good.

- The integration of training in pharmaceutical management of malaria medicines with that of HIV/AIDS and TB medicines at all health care and community levels in the country.

- Progress report delivery to Commissioners for Health and other major stakeholders of the RBM. All efforts should be made to give immediate feedback on activity implementation.

- The need to develop appropriate monitoring and supervision tools for drug distribution, stock-outs, and use for effective program planning, implementation, and evaluation.

- Funding by the FMOH for operational research on programmatic issues and the appropriate dissemination of findings.

NEXT STEPS

- The now-tentative training programs, budgets, and stakeholder responsibility listings (see Annex 6 for tentative stakeholder responsibilities) are to be finalized and circulated by the FMOH/RBM.

- The adapted document for the training on stores and inventory management (see Annex 7 for draft list of contents) is to be finalized and circulated in June 2005. After further feedback from RBM stakeholders, the document will be used in final draft form for the national TOT.

- NAFDAC will supply the storage instructions and other relevant properties of the antimalarial medicines that have been inserted into the training manual.

- RBM/FMOH will update the glossary section of the manual.

- The TOT at the national level will be conducted at two locations (Kaduna and Ota states), July 4–8, 2005.

- The national TOT will afford further refinement of the training manual, after which the document will be submitted to the office of the Honorable Minister of Health, Nigeria, for approval and professional editing preparatory to printing.

- The state trainings and cascade trainings will follow subsequently at the state, LGA, and facility levels. Whether a simpler version of the training manual will be needed for the LGA and facility levels will be considered.

- The documents and tools for stock management are to be made available to stores and facilities to complement the training activities.

- Monitoring and supervision will need to be rolled out to assess the readiness of the states and LGAs for ACTs management before and immediately after the supply and distribution of ACTs.

- A plan must be made for a rapid appraisal of ACT pharmaceutical management (in the public and private health systems) after approximately six months of operation.

- Organizational follow-up plans for all the commitments made at the stakeholder meeting are expected from all RBM partners.

CONCLUSION

The stakeholder workshop to adapt the generic MSH training manual on pharmaceutical management for the Nigeria RBM program was highly successful and demonstrated a concerted effort among partners to address the challenges posed to antimalarial pharmaceutical management in Nigeria.

Participants at the workshop expressed their appreciation for the current efforts of FMOH (through the RBM, the Department of Food and Drugs Services, and NAFDAC) and the development partners, especially USAID and the RPM Plus Program, which funded and facilitated the process of the adaptation meeting.

The need for continuous dialogue and interaction among stakeholders was stressed by the NMCP.

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ANNEX 1. COMMUNIQUÉ ON ADAPTATION OF GENERIC TRAINING DOCUMENT FOR ANTIMALARIAL MEDICINES STOCK MANAGEMENT AT AIRPORT HOTEL, IKEJA, LAGOS, 18TH–20TH MAY 2005

The Federal Ministry of Health with the support of USAID through Rational Pharmaceutical Management Plus (RPM Plus) and the World Health Organization organized a three-day National workshop for the adaptation of generic training documents for effective antimalarial medicines stock management to support the implementation of the Artemisinin-based Combination Therapy (ACT) policy of the Roll Back Malaria program in Nigeria.

The objectives of the meeting were to:

a) Foster RBM stakeholder dialogue on the new National Antimalarial Treatment Policy change to Artemisinin-Based Combination Therapies (ACTs)
b) Address the challenges posed by the introduction of ACTs into Nigeria's weak pharmaceutical management systems through the review and finalization of generic training documents.
c) Review other available relevant materials such as: forms already in use, manuals, and guides for pharmaceutical management training for store managers.
d) Mobilize commitment and support for the implementation of the training plan

The participants were drawn from the Federal Ministry of Health (RBM Division, Department of Food and Drugs Services, NAFDAC), Borno, Cross River and Lagos States' Ministries of Health. Also present were Roll Back Malaria Partners including: USAID, WHO, MSH, UNICEF, SFH and COMPASS.

Background information on the malaria medicine supply and management system in Nigeria are:

1. Unconsolidated procurement of medicines
2. Inadequate inventory and stock management
3. Poor record-keeping in facilities
4. Frequent stock outs of antimalarial drugs.

At the end of the meeting, the following observations were made:

1. The pharmaceutical Management system in Nigeria is complex, functioning at a sub-optimal level and needs to be strengthened through systematic and focused training at all levels of health care.
2. Knowledge about the management of the newly introduced artemisinin-based combination medicines is low among health professionals.

Recommendations

1. In view of the pharmacodynamics of the ACTs, a National, State, LGA and community level training that will include Pharmacists and drug store managers should be conducted.

2. An appropriate distribution system, that would ensure prompt access to Antimalarial medicines within 24 hours by children under the age of five and pregnant women should be established promptly.

3. To achieve an effective distribution system, there should be a distribution plan that is concurrent with a procurement plan. This would ensure that ACTs are available, accessible and affordable at all levels of Health care.

4. As part of efforts to rapidly achieve the Roll Back Malaria and MDG targets, Public/Private partnerships in the areas of Medicine Distribution, Storage, Advocacy, Mass media promotion and Social marketing should be promoted.

5. Establish a National medicines data bank through a functional health management information system

6. The present commitment of the Federal Government and the Partners to the RBM initiative should be sustained and resources mobilized to effect ACTs as a public health good.

7. There is need to integrate the training on the management of Malaria medicines with that of HIV/AIDS and TB at all health care and community levels in the Country.

8. There is need to develop appropriate monitoring and supervision tools for drug distribution, stock outs and utilizations for effective program planning, implementation and evaluation.

9. Operational research on programmatic issues should be funded and findings disseminated appropriately.

Conclusions

The participants appreciate the current efforts of the National Malaria Control Program, Department of Food and Drugs Services and NAFDAC of the Federal Ministry of Health and the Development Partners in promoting standard and proven practices and interventions that will reduce the scourge of Malaria in Nigeria.

ANNEX 2. LIST OF PARTICIPANTS

A. RBM/FMOH

1. Dr. T. O. Sofola	National Coordinator, Malaria Control Program
2. Dr. Henry Akpan	Deputy Director, RBM/FMOH
3. Dr. E. Nwokolo	Assistant Director, RBM/FMOH
4. Dr. G. N. Ntadom	Senor Medical Officer, RBM/FMOH
5. Dr. O. Oresanya	Medical Officer, RBM/FMOH
6. Mr. J. Banjo	Senior Medical Laboratory Scientist RBM/FMOH
7. Mrs. Glory Opusunju	Community Health Officer, Public Health Department

B. FDSD/FMOH

1. Mr. D. O. Omoyele	Deputy Director, FDSD/FMOH
2. Mrs. G. O. Abumere	Assistant Director, FDSD/FMOH
3. Mr. E. O. Okibe	Chief Pharmacist, FDSD/FMOH

C. NAFDAC

1. Mrs. M. Ebigbayi	Chief Regulatory Officer, NAFDAC–LAGOS
2. Pharm. U. G. Udoma	Senior Research Officer, NAFDAC–LAGOS

D. SMOHs

1. Mrs. M. O. Beckley	Assistant Director, Lagos State Ministry of Health Lagos State
2. Mr. Eret Ntuwi	Chief Pharmacist, Central Medical Stores, Calabar, Cross River State
3. Mr. Stephen Jasini	D.R.F. Manager (Central Medical Stores) Maiduguri, Borno State

E. RBM Partners

1. Alhaji Abdu Garba	Program Officer, Child Survival, USAID
2. Dr. Gladys Tetteh	Senior Program Associate, MSH/RPM Plus
3. Dr. Catherine Adegoke	Consultant (Nigeria), MSH/RPM Plus
4. Dr. Bayo Fatunmbi	National Professional Officer/Malaria, WHO
5. Prof. Ezedinachi	National Professional Officer/Malaria, WHO
6. Dr. B. M. Afolabi	National Professional Officer/Malaria, WHO
7. Dr. E. Gemade	Program Officer, Health, UNICEF

8. Dr. Uzo Gilpin	Senior Technical Advisor, SFH, Abuja
9. Dr. A. Akinpelumi	Senior Manager, SFH, Abuja
10. Mrs. Magadalene Okolo	Deputy Manager, SFH, Abuja
11. Mr. Michael Alagbile	Manager, SFH, Abuja
12. Mr. Christian Emeche	Distribution Manager, SFH
13. Dr. Joseph Monehin	Child Survival Program Coordinator, COMPASS
14. Dr. Mariam Jinadu	Family Planning/Reproductive Health/HIV Program Coordinator, COMPASS

ANNEX 3. AGENDA OF THE WORKSHOP

Roll Back Malaria Stakeholders Workshop on the Adaptation of Generic Drug Stock Management Documents, Airport Hotel, Ikeja Lagos, 18th– 20th May, 2005

Day One

9.00 – 9.30 A.M.	Registration
9.30-10.00 a.m.	Opening Remarks: *FMOH (RBM & Department of Food and Drugs Services), RPM Plus; other RBM Partners*
10.00 – 10.20 a.m.	The RBM Program in Nigeria, with focus on the ACT policy *(Presentations by FMOH [RBM] and WHO)*
10.20 – 10.40 a.m.	An Analysis of Drug Stock Management Problems in Nigeria (at Tertiary, Secondary and Primary Health Care Levels) *(Presentation by FMOH [DFDS])*
10.40 – 11.00 a.m.	Objectives of the Stakeholders Meeting *(RPM Plus Consultant)*
11.00 – 11.20 a.m.	Tea Break
11.20 – 11.40 a.m.	Profile of the Generic Documents *(RPM Plus Consultant*)
11.40 a.m. – 12.00 p.m.	Break up into Groups (3 working groups) • Pharmaceutical Group—Drugs, Stores and Fund Management • Clinical Group—Treatment Guidelines/Rational Drug Use/Drug Safety and Legislation • Training and General Issues Group
12.00 – 2.00 p.m.	Group Work 1
2.00– 3.00 p.m.	LUNCH
3.00 - 4.00 p.m.	Group Work Presentations—(3 Working Groups)
4.00 4.30 p.m.	General Discussions *(Facilitated by RBM Partner)*
4.30 – 5.00 p.m.	Tea Break/Closing

Day Two:

9.00 – 9.30 a.m.	Recap of Day 1: Issues for Discussion at Group Work 2 *(FMOH [RBM])*
9.30-11.00 a.m.	Group Work 2
11.00 – 11.20 a.m.	Tea Break
11.20 – 12.30 p.m.	Merging of Documents (Phase 1) *(RPM Plus Consultant)*
12.30 – 2.00 p.m.	Joint Editing of Documents • Capacity Building Section • Planning and Supervision Section • Facilitator and Participant's Guides • Background Documents
2.00 P.M. – 3.00 p.m.	LUNCH
3.00 P.M. – 4.00 p.m.	Planning for TOT at Federal Level Planning for Cascade Trainings (*Facilitated by RBM Partner and RPM Plus Consultant)*
4.00- 4.30 p.m.	Responsibilities and Next Steps for ACT Management at All Levels (All Stakeholders) *(Facilitated by RBM Partner)*
4.30 – 5.00 p.m.	Tea Break/Administrative Matters/Closing

Day Three:

9.00 – 9.30 a.m.	Recap of Day 2: Issues in Finalizing the Document (FMOH [DFDS])
9.30-10.30 a.m.	Group Work 3
10.30 – 11.00 a.m.	Tea Break
11.00 – 1.00 p.m.	Presentations of the Working Groups (Edits/Additions) • Pharmaceutical Group—Drugs, Stores, and Fund Management • Clinical Group— Treatment Guidelines/Rational Drug Use/Drug Safety and Legislation • Training and General Issues Group

1.00 – 2.00	Concluding on the Adaptation of Generic Document
2.00– 2.30 p.m.	LUNCH
2.30 – 3.30 p.m.	Outcomes of the Meeting (Plus Resolutions and Communiqué)
3.30 – 4.00	Vote of Thanks by FMOH and RBM Partners
4.00 p.m.	Close of Stakeholders' Meeting
4.00 – 4.30 P.M.	Tea Break

ANNEX 4. GUIDELINES FOR GROUP DISCUSSIONS

Group One: Pharmaceutical Group (Drug and Stores Management; Financial Management)

1. Define the objectives that relate to the pharmaceutical management of ACTs in the new anti-malarial drug policy shift that are to be achieved:

    i. During the stakeholders adaptation meeting
    ii. During the training of trainers meeting
    iii. During the cascade trainings

2. Read through the 4-part documents carefully, noting especially those sections that relate directly to the aspects of drugs management for store officers.

3. Check for clarity, coherence, and comprehensiveness of the generic manual as it relates to the identified objectives.

4. Assemble all available documents that relate to any of the 4 parts of the document:

    i. Capacity building
    ii. Planning and supervision
    iii. Tables
    iv. Forms

5. Compare the documents with the generic manual, taking care to specially note and approve the suitable forms and guidelines that are already in wide use in stores across the different levels in Nigeria.

6. Edit the generic documents as it is. in the 4 different parts, by addition, insertion, rearrangement and deletion as appropriate.

7. Record the above processes for the group work, noting the major changes made in the document for the presentation at plenary.

Group Two: Clinical Group (Treatment Guidelines, Rational Drug Use, Drug Safety and Legislation)

1. Define the objectives that relate to the clinical management of ACTs in the new anti-malarial drug policy shift that are to be achieved by this focus on store officers' training manual:

    i. During the stakeholders adaptation meeting
    ii. During the training of trainers meeting

iii. during the Cascade Trainings

2. Read through the 4-part documents carefully, noting especially those sections that relate directly to the gaps in introduction of ACTs into the facility stores and its subsequent management as it relates to the store officers.

3. Check for clarity, coherence, and comprehensiveness of the generic manual as it relates to the identified objectives.

4. Assemble all available national and international documents on the management of ACTs that relate to any of the 4 parts of the document:

   i. Capacity building
   ii. Planning and supervision
   iii. Tables
   iv. Forms

5. Compare these documents with the generic manual.

6. Insert the approved listing of drugs, as well as the national clinical/treatment guidelines, which will transform the generic document into one with an identified focus on antimalarial treatment, and the management of ACTs in particular, in Nigeria.

7. Edit the generic documents, by addition, insertion, rearrangement, and deletion as appropriate.

8. Record the above processes for the group work, noting the major changes made in the document for the presentation at plenary.

Group Three: Training And General Issues (Training Objectives and Strategies, Stakeholder Coordination, Outcomes of the Meeting and Communiqué)

1. Define what training objectives are to be achieved with the adapted manual as it relates to the management of ACTs in the new anti-malarial drug policy shift:

   - During the stakeholders meeting
   - During the training of trainers meeting
   - During the cascade trainings

2. Read through the 4-part documents carefully, noting especially those sections that relate directly to the training methods and strategies.

3. Check for clarity, coherence, and comprehensiveness of the generic manual as it relates to the identified training objectives.

4. Define the criteria for nomination of participants for:

    i. Federal TOT
    ii. State TOT
    iii. Cascade training to local government and facility levels

5. Suggest the scope of training activities and methods to be emphasized for each of the levels of training.

6. Suggest facilitators for the training activities.

8. Suggest a feasible timeframe and venue for the Federal TOT.

9. Suggest a feasible time frame for the commencement of the cascade trainings.

10. Design a template for stakeholder responsibility and involvement in these activities. This will be transformed into the work plan.

(Please note: The FMOH and all RBM partners will develop a working plan for this component of the RBM intervention—i.e., the Training of Health and Store Officers in the 36 States and the FCT.)

ANNEX 5. TENTATIVE PROGRAM FOR THE TOT AND CASCADE TRAININGS ON DRUG MANAGEMENT

Level	Expected Participants	Course Content	No. to Train	Duration	Commence-ment	Funding	Indicators
Group A—Core Trainers for GFATM-supported states	FMOH, Director of Pharmaceutical Department in the state, Chief Pharmacists in the State Drug Store, participants from academic Institutions, pharmacists from Central Medical Store, NAFDAC, partners	Cover the entire content of the training manual	44	3 days	July 4–7, 2005	GFATM	Number of participants trained
Group B—Core Trainers for GFATM-supported states	FMOH, Director of Pharmaceutical Department in the state, Chief Pharmacists in the State Drug Store, participants from academic institutions, pharmacists from Central Medical Store, NAFDAC, partners	Cover the entire content of the training manual	44	3 days	July 4 – 7, 2005	GFATM	Number of participants trained
State	SMPM, pharmacist in charge of drug store, State Chairman of PMV, State Chairman of Community Pharmacists, and chief pharmacists from tertiary hospitals in the state, zonal officers of the National Primary Health Care Development Agency, pharmacist from LGA. Three training sessions will be conducted at three locations within the state. They will run consecutively in all the participating states.	Cover the entire content of the training manual	30 x 3 x 18	2 days	July 18 – 31, 2005	GFATM	Number of participants trained
LGA	Pharmacy technicians at LGA level, officer in charge of drug store, drug dispensers at primary health care centers, representatives of communities. Training will be conducted in all the LGAs in the participating states. Participants will be drawn from the 10 wards per LGA.	Message same, course content reduced with pictorial demonstrations added. Also advocacy to LGA	50 x 20 x 18	2 days		GFATM	Number of participants trained
Community	PMVs, community-based resource persons, community-based distributors, traditional and faith healers, women's group	Orientation on medicine management		1 day			Proportion of people reached orientation

ANNEX 6. TENTATIVE STAKEHOLDER RESPONSIBILITY

Level	Input Required	Responsible Agency
National	Human resource	FMOH/GFATM, UNICEF, WHO, DFID, USAID, RPM Plus SFH, Médecins sans Frontiers, NGOs
	Training tools	FMOH/GFATM, RPM Plus, UNICEF, WHO, USAID, DFID
	IEC materials	FMOH/GFATM, HSDP, SMOH UNICEF, WHO, USAID, RPM Plus, NGOs
	Advocacy	FMOH/GFATM, UNICEF, WHO, USAID, RPM Plus, SFH, DFID
	Medicines (ACTs, SP, quinine)—procurement and distribution	FMOH/GFATM, WHO, USAID, UNICEF, SFH, DFID, Chinese government
	ITNs and re-treatment kits—procurement and distribution	FMOH/GFATM, UNICEF, WHO, SFH, USAID, DFID, Chinese government
	Resource mobilization	FMOH/GFATM, UNICEF, DFID, WHO, USAID, SFH, stakeholders
	Information system and database	FMOH/GFATM, USAID, UNICEF, WHO,SFH, DFID, stakeholders
	Monitoring and evaluation	FMOH/GFATM, WHO, UNICEF, USAID, DFID
	Pharmacovigilance	NAFDAC, FMOH, WHO
State	Human resource	SMOH, FMOH/GFATM, UNICEF, WHO, USAID, RPM Plus, DFID
	Training tools	SMOH, FMOH/GFATM, HSDP, SMOH UNICEF, WHO, USAID, RPM Plus
	IEC materials	SMOH, FMOH/GFATM, UNICEF, HSDP, WHO, USAID, RPM Plus, SFH, DFID
	Advocacy	SMOH, HSDP, FMOH/GF, WHO, USAID, UNICEF, SFH, DFID
	Medicines (ACTs, SP, quinine)—procurement and distribution	SMOH, HSDP, FMOH/GF, WHO, SFH, USAID, DFID
	ITNs and re-treatment kits—procurement and distribution	FMOH/GFATM, HSDP, UNICEF,DFID, WHO, USAID, SFH,
	Resource mobilization	SMOH, HSDP, FMOH/GFATM, UNICEF, WHO, USAID, SFH, DFID, stakeholders
	Information system and database	SMOH, HSDP, FMOH/GFATM, USAID, WHO, DFID, UNICEF
	Monitoring and evaluation	FMOH/GFATM, WHO, DFID, UNICEF
	Pharmacovigilance	NAFDAC, FMOH, WHO
	Community mobilization	SMOH, NGOs, USAID, SFH, UNICEF, stakeholders

Local	Human resource	SMOH, LGC, UNICEF, USAID, RPM Plus, DFID, NGOs, community-based organizations, community-based resource persons
	Training tools	SMOH, FMOH/GFATM, LGC, HSDP, UNICEF, WHO, USAID, RPM Plus
	IEC materials	SMOH, LGC, FMOH/GFATM, SFH, DFID, UNICEF, HSDP, WHO, USAID, RPM Plus
`	Advocacy	LGC, SMOH, communities, HSDP, FMOH/GFATM, WHO, USAID, UNICEF, SFH, DFID
	Medicines (ACTs, SP, quinine)—procurement and distribution	SMOH, HSDP, FMOH/GFATM, WHO, SFH, USAID, DFID
	ITNs and re-treatment kits—procurement and distribution	SMOH, LGC, FMOH/GFATM, HSDP, UNICEF, DFID, USAID, SFH, NGOs, community-based organizations
	Resource mobilization	SMOH, HSDP, LGC, FMOH/GFATM, UNICEF, WHO, USAID, SFH, DFID, stakeholders
	Monitoring and evaluation	FMOH/GFATM, SMOH, LGC, WHO
	Community mobilization	LGC, communities, NGOs, SMOH, community-based organizations, USAID, SFH, UNICEF, stakeholders in the communities

Note: DFID = Department for International Development [U.K.]
HSDP= Health Systems Development Project
LGC = Local Government Council [Nigeria]

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