

**Rational Pharmaceutical Management Plus
Amazon Malaria Initiative Regional Workshop on Policy Change,
Guayaquil, Ecuador: Trip Report**

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Abstract

The Amazon Malaria Initiative is funded by USAID and provides technical assistance from different agencies and organizations with cooperative agreements with USAID to countries in the Amazon Basin Sub Region. Many of the participant countries have completed *in vivo* efficacy studies of their current recommended antimalarials and are moving into developing new policies for cases where resistance to current drugs has been increasing, mainly for malaria caused by *P. Falciparum*. CDC organized a regional technical workshop to help program managers to assess their preparedness for the process of policy change. RPM Plus staff participated as lecturer for the area of pharmaceutical management in preparation to the policy changes that may follow and collaborated as facilitator for the activities during the workshop.

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Key Words

Malaria, Amazon, Policy change

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ACRONYMS

AMI	Amazon Malaria Initiative
CDC	Centers for Disease Control and Prevention
LAC	Latin American and Caribbean Region
MSH	Management Sciences for Health
PAHO	Pan American Health Organization
RPM Plus	Rational Pharmaceutical Management Plus Program
USP/DQI	United States Pharmacopeia/Drug Quality and Information Program
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

RPM Plus' long-term strategy is to strengthen the ability of policy makers, health care providers and institutions in the region to improve pharmaceutical supply management, including medicine use. For this, RPM Plus works with its partners, international health care organizations, and national and local health officials to develop policies and strategies to improve the use of medicines in the treatment of infectious diseases and slow the emergence of resistance. RPM Plus has been working in the Latin American and Caribbean region (LAC) based on a conceptual framework to improve the use of antimicrobial and antimalarial drugs and therefore decrease the potential for resistance.

In October 2002, RPM Plus started collaborating with the Amazon Malaria Initiative, formed under the support of USAID by partners such as the Pan American Health Organization (PAHO) Malaria Division, the Centers for Disease Control and Prevention (CDC), the United States Pharmacopeia Drug Quality and Information Program (USP/DQI), and USAID Peru and USAID Bolivia. Initiative partners contribute to the process by providing technical assistance according to their particular strengths. Countries participating in the initiative are Brazil, Guyana, Suriname, Venezuela, Colombia, Ecuador, Peru, and Bolivia. These countries are currently finalizing *in vivo* efficacy studies of their current recommended antimalarials and are moving into developing new policies for cases where resistance to current drugs has been increasing, mainly for malaria caused by *P. Falciparum*.

CDC is leading the activity of helping program managers of the participant countries to assess how prepared they are for the process of policy change. For this purpose, a regional workshop will be conducted in Guayaquil. RPM Plus has been invited to participate as lecturer for the area of pharmaceutical management in preparation to the policy changes that may follow.

Purpose of Trip

Patricia Paredes from RPM Plus, traveled to Guayaquil from June 13-19 to participate in the Regional Workshop on Malaria Policy Change, organized by the CDC. Specifically, to conduct a session on the most important issues regarding pharmaceutical management, that need to be taken into consideration before a decision on policy change is done in a country. She also acted as facilitator for other practical sessions beside the one on pharmaceutical management.

Scope of Work

- Lecture and facilitate the practical session on drug management during the CDC-organized workshop on Malaria Policy Change for countries in the Amazon Malaria Initiative.
- Collaborate with CDC and PAHO lecturers and act as facilitators for the practical sessions of the course.
- Meet with the local PAHO epidemiologist to explore feasibility to conduct an assessment of the procurement and distribution system for antimalarials in Ecuador
- Debrief USAID mission officers, as requested

ACTIVITIES

1. Lecture and facilitate the practical session on drug management during the CDC-organized workshop on Malaria Policy Change for countries in the Amazon Malaria Initiative.

In conjunction with AMI partners, this workshop was planned to:

- Provide an overview of the malaria drug policy cycle, with an emphasis on the contextual factors that influence the development and implementation of malaria drug policy (such as political, economic, environmental or socio-cultural)
- Sensitize participants to the wide array of factors that should be considered during the process of policy development
- Discuss indicators of success for malaria drug policy implementation
- Identify potential challenges to the development and implementation of policy, as well as delineate successful strategies used in the various countries to address these challenges

The workshop was designed to be participatory and to encourage attendees to share country-level experience with colleagues from other countries within the Amazon Region. Regional and global field examples were provided from a variety of countries that have undergone recent malaria treatment policy changes. A tool designed to assist national malaria control programs in planning for policy change was described by CDC and another one developed by PAHO was also used in the practical session.

Participants engaged in participatory exercises that were designed to help them critically examine where their respective countries are in relation to the drug policy cycle, and identify challenges and strategies to address those challenges within the context of their own country.

This workshop focused only on malaria policy as it relates to antimalarial drugs and not on other policy aspects of malaria control, such as vector control. The learning objectives of the workshop can be seen in Appendix 1.

Twenty-six participants from six countries attended the three-day workshop. The proposed number of requested participants was three per country, although most countries did not send that number. It was not clear why certain countries sent no one or why other countries did not send the full complement of three participants. Reasons for having less than full participation from individual countries were not clear. Neither Colombia nor Guyana sent participants. As host country, Ecuador had the largest contingent of participants, with a total of seventeen. Representatives from the AMI partner organizations, CDC, Management Sciences for Health (MSH) RPM Plus Program, and Pan American Health Organization (PAHO), functioned as faculty and facilitators, with CDC assuming leadership for this regional activity. Participants received copies of all presentations (PowerPoint notes) as well as numerous articles relating to malaria drug policy issues. Examples of each country's initial strategic plans were circulated to

all participants, as well as a handout showing descriptions of the respective current drug policies in all countries represented.

Patricia Paredes participated as facilitator for the groupwork sessions that other partners organized. The presentation from RPM Plus can be seen in Appendix 2 and the case study used for the groupwork is in Appendix 3. Appendix 4 includes the Facilitator's Guide used.

The participatory exercises gave participants the opportunity to:

1. Identify the components of the policy cycle by:
 - Determining where the participants' home countries are located within the policy cycle, and
 - Identifying gaps in the policy cycle that are specific to the participants' home countries;
2. Describe the types of data that are needed to inform rational malaria treatment policy;
3. List potential stakeholders in the policy process and delineate their possible roles in policy development or implementation by:
 - Identifying stakeholders specific to the participants' respective countries and discussing the roles of those stakeholders in the policy process;
4. Describe contextual factors that influence policy implementation and development, as they relate to the Amazon Region and to the participants' specific countries;
5. Begin the process of performing a situational analysis to inform policy change;
6. Consider a range of potential policy options based on their discussions while performing the situational analysis;
7. Draft a plan of action for antimalarial drug policy change in their respective countries (including time frames and budgets); and
8. Draft a plan of action for implementation of antimalarial drug policy that is tailored to the participants' home countries (including a plan for periodic review and revision of the policy).

Collaborators and Partners

1. Dr. Holly Ann Williams: Course coordinator
Centers for Disease Control and Prevention (CDC), USA
HBW2@CDC.GOV
2. Dr. Arlene Vincent-Mark
Centers for Disease Control and Prevention, USA
ADV6@CDC.GOV

3. Dr. Patricia Paredes – Program Manager for LAC activities
Rational Pharmaceutical Management Plus Program (RPM Plus)
Management Sciences for Health (MSH), USA
pparedes@msh.org
4. Dr. Roberto Montoya – Regional Coordinator for RAVREDA/AMI
Pan American Health Organization (PAHO), Colombia
rmontoya@col.ops-oms.org
5. Dr. Gustavo Bretas – RollBack Malaria Partnership WHO
Pan American Health Organization (PAHO), Suriname
6. Dr. Angel Valencia
Pan American Health Organization (PAHO), Ecuador

Adjustments to Planned Activities and/or Additional Activities

As a request from participants, a short session was conducted during lunchtime to familiarize participants with the International Drug Price Indicator Guide and help them to make a comparison of the purchase price of antimalarials in the different countries.

NEXT STEPS

Immediate Follow-up Activities

As mentioned below in recommendations, the majority of participants agreed that it is important to develop skills and obtain more information on the different aspects of pharmaceutical management before deciding on a policy change. For this reason, RPM Plus will propose to develop and translate training course materials that cover these needs for AMI.

Recommendations

According to the evaluation forms, the majority of the participants found the topics discussed very useful and important to help them in planning policy changes. Areas that were not covered and respondents mentioned as important for their work were: a) more information about different countries' policies, b) how to deal with corruption of public civil servants in the management of health programs, c) more practical lectures and exercises on dealing with politicians, d) guidelines on how to verify good drug manufacturing practices and developing a drug use manual and e) specific aspects for the planning and implementation of strategies and policies.

Regarding the length of the course, participants were equally divided between those who considered that the course was too short versus those who thought the course had an appropriate duration. Participants requested additional discussion time for the following topics: a) treatment for malaria within specific populations, e.g. malaria in pregnant women and in young children, b) development of a plan for drug quality and drug management, c) program sustainability issues, and d) lack of a uniform regional approach to malaria drug policy.

The workshop could have benefited from an additional day being added to the schedule, even though all the proposed topics as indicated in the course outline were covered. This would have allowed for more in-depth discussion of the various topics of interest by the participants who wanted to delve into more detail on specific issues. Regarding the room arrangement for the lectures, there were some participants who experienced difficulties viewing the powerpoint presentations as a result of the location of the equipment and the configuration of the room. A different arrangement of the equipment would solve the problem.

Agreement or Understandings with Counterparts

N/A

ANNEX 1. AMI DRUG POLICY WORKSHOP DESCRIPTION

Date: 17-19 June 2003
Venue: Guayaquil, Ecuador

Description and Purposes of Workshop

In conjunction with AMI partners, this workshop is planned to:

- Provide an overview of the malaria drug policy cycle, with an emphasis on the contextual factors (such as political, economic, environmental or socio-cultural) that influence the development and implementation of malaria drug policy
- Sensitize participants to the wide array of factors that should be considered during the process of policy development
- Discuss indicators of success for malaria drug policy implementation
- Identify potential challenges to the development and implementation of policy, as well as delineate successful strategies used in the various countries to address these challenges

The workshop is designed to be participatory in nature, encouraging attendees to share country-level experience with colleagues from other countries within the Amazon Region. Regional and global field examples will be provided from a variety of countries that have undergone recent malaria treatment policy changes. A tool designed to assist national malaria control programs in planning for policy change will be described, with practice sessions included on how to use the tool. The iterative nature of the policy cycle will be stressed, with an emphasis on the need for monitoring and evaluation.

Participants need to be aware of the status of the current malaria drug policy for their home country. Participants will engage in participatory exercises that are designed to help them critically examine where their respective countries are in relation to the drug policy cycle, and identify challenges and strategies to address those challenges within the context of their own country.

NOTE: This workshop focuses only on malaria policy as it relates to antimalarial drugs and not on other policy aspects of malaria control, such as vector control. It is not planned to highlight any one particular country but, rather, to examine issues related to malaria drug policy from a regional and global perspective.

Intended Participants

Participants must be directly involved with some aspect of antimalarial drug policy development, including, but not limited to conducting research to inform policy development (including drug efficacy testing), policy implementation, evaluation and monitoring (including developing sentinel surveillance systems for antimalarial efficacy), health and community education, and drugs management. Participants need to have a minimum of two years work experience relating to malaria control and a working knowledge of English. Preference will be given to national malaria control programme managers and upper level Ministry of Health officials who are directly involved with the formulation and implementation of malaria drug policy. There should be no more than 3 participants per country.

Required Materials from Participants

Participants are required to send to organizers a one-two paragraph description of their role(s) in relation to malaria drug policy. As well, a one-page description of the status of the current antimalarial drug policy is required from all countries. This description needs to include: a) current treatment guidelines (specifically listing 1st, 2nd and 3rd line drugs), b) policy as it relates to malaria and pregnancy (both treatment and prevention, if available), c) date of last policy change, and d) status of country in relation to a policy change (such as, formed a Task Force to decide on whether a change should occur, change decided upon but replacement drugs not yet decided, no discussion of change). The country level description should also identify the major concerns of the country in relation to antimalarial drug policy. These materials must be received **TWO WEEKS PRIOR** to the start of the workshop. Send by email to Dr. Holly Williams (HBW2@cdc.gov) and Dr. Arlene Vincent-Mark (adv6@cdc.gov) or fax to Dr. Holly Williams, 001-770-488-7794 or 488-4206. These materials will assist the faculty in identifying regional needs in relation to drug policy changes, as well as provide information to include as local field examples.

Learning Objectives

At the successful completion of this course, the participants should be better able to:

1. Identify the components of the policy cycle:
 - Determine where the participant's home country is located within the policy cycle
 - Identify gaps in the policy cycle that are specific to the participant's home country
2. Describe the types of data that are needed to inform rational malaria treatment policy
3. List potential stakeholders in the policy process and delineate their possible roles in policy development or implementation:
 - Identify stakeholders specific to the participant's individual country and discuss the roles of those stakeholders in the policy process

4. Describe contextual factors that influence policy implementation and development, as they relate to the Amazon Region and to the participants' specific countries
5. Perform a situational analysis to inform policy change
6. Identify a range of potential policy options based on information gathered in policy situational analyses
7. Develop a plan of action for antimalarial drug policy change in their respective country (including time frames)
8. Develop a plan of action for implementation of antimalarial drug policy that is tailored to the participant's home country (including a plan for periodic review and revision of the policy)

Proposed Activities

The workshop will combine a variety of process skills (such as critical thinking, team working, problem-solving) to facilitate meeting the learning objectives. Activities currently proposed include: didactic sessions, small group discussions, case situations, stakeholder analysis techniques, and free listing exercises.

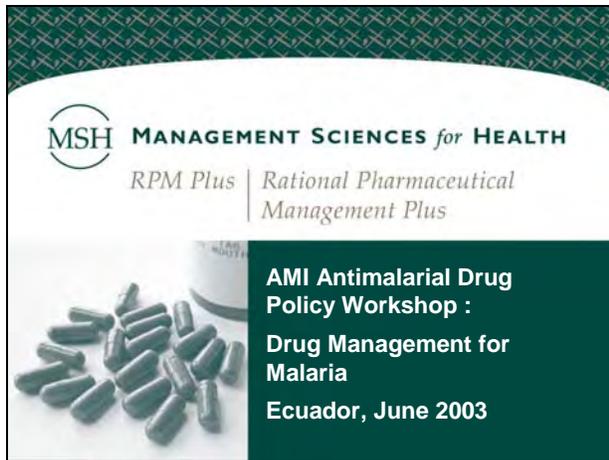
Course Materials Provided to Participants

Note pages from Powerpoint presentations and reprints of pertinent literature will be provided. NOTE: much of the available literature is in English.

Core Faculty

1. Dr. Holly Ann Williams: Course coordinator
Centers for Disease Control and Prevention (CDC), USA
HBW2@CDC.GOV
2. Dr. Arlene Vincent-Mark
Centers for Disease Control and Prevention, USA
ADV6@CDC.GOV
3. Dr. Patricia Paredes
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4. Dr. Roberto Montoya
Pan American Health Organization (PAHO), Columbia
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ANNEX 2. AMI ANTIMALARIAL DRUG POLICY WORKSHOP PRESENTATION



Objectives

- Introduce a framework for understanding, analyzing, and making decisions about pharmaceutical management particularly with respect to malaria
- Describe the pharmaceutical management cycle
- Outline the current challenges to antimalarial chemotherapy

Outline of Presentation

- Rationale of session
- Pharmaceutical management cycle
- Current challenges to antimalarial chemotherapy
- Relevance of pharmaceutical management to effectiveness of malaria treatment
- Participatory exercise

Rationale of session

- Public health is concerned with using available resources to achieve maximum health improvements for the population, therefore, the efficient and effective management of pharmaceuticals can improve important public health outcomes and reduce expenditures

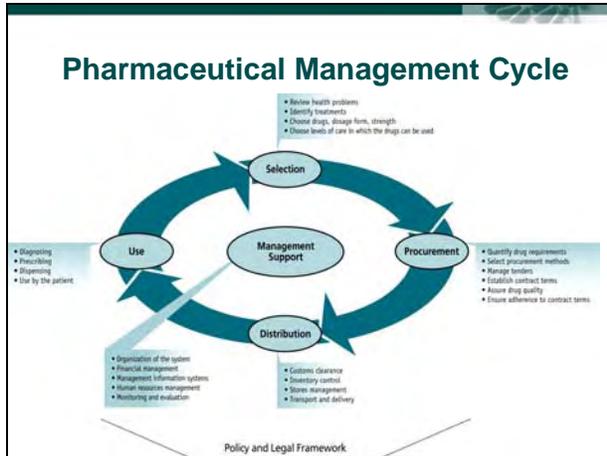
Source: Management Sciences for Health and World Health Organization. 1997. *Managing Drug Supply*. 2nd edition.

Definition of Pharmaceutical Management

- Pharmaceutical management is the set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines and related products and services in any health-care setting

The Pharmaceutical Management Cycle

- Pharmaceutical management involves many activities that must be carefully coordinated to ensure that the right drug, in the right quantities, of good quality, gets to the right patient when the patient needs it.
- Activities can be divided into five main components: drug selection, procurement, distribution, use and management support.



Components of Cycle

- These components operate within a political, social, cultural, and economic context that influences the nature of the activities
- When the system is not functioning well, important drugs will not be used as they should be
- When the system is functioning well, the proper use of drugs will reinforce the proper selection, procurement, and distribution of drugs.

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Pharmaceutical Management Cycle and Malaria

- The Global Strategy for Malaria Control seeks to prevent mortality and reduce morbidity and social and economic losses from malaria.
- One of the four basic elements of the strategy is early diagnosis and prompt effective treatment
- To implement this strategy effectively, a well functioning pharmaceutical management cycle is imperative

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Challenges to Existent Antimalarial Drug Policy in Countries

- Widespread resistance to common antimalarials e.g. chloroquine
- Mounting resistance to replacement therapies e.g. sulphadoxine-pyrimethamine (SP)
- Expensive and more complicated treatment regimens for new therapies e.g. combination therapies: therefore more challenging implementation
- Little guidance on process and choice of replacement therapy for countries needing revision of antimalarial policy

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Challenges to Existent Antimalarial Drug Policy in Countries

- Poor capacity for regulation; monitoring, supervision, quality and enforcement of policy
- Poor monitoring of effectiveness of implementation of policies
- Poor quality or substandard drugs
- Local manufacturers of antimalarials not always aware of policies

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Challenges to Existent Antimalarial Drug Policy in Countries

- Majority of malaria treatment occurs in the community, hence need for development of home based management strategies
- Private sector practitioners are rarely aware of 1st line treatment and recommendations, even though, many individuals seek malaria treatment in the private sector
- Private sector more difficult to control

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Challenges to Existent Antimalarial Drug Policy in Countries



<p>Access</p> <p>Equitable access to reduce mortality and morbidity</p> <p>Emphasis on community management</p>	<p>Rational Use</p> <p>Reduces development of resistance</p> <p>Emphasis on regulation and controlled use</p>
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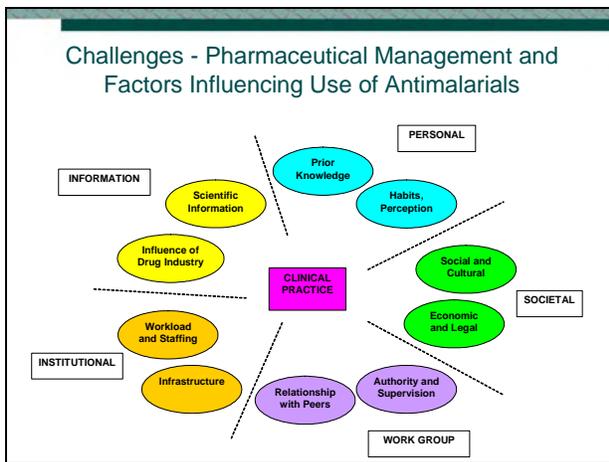
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Challenges to Existent Antimalarial Drug Policy in Countries

- Timely review, update, and implementation of antimalarial drug policy is an all-encompassing process

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Efficacy vs. effectiveness

Program effectiveness:

- Drug efficacy
- Drug use determinants
 - ~ Availability
 - ~ Affordability
 - ~ Acceptability
 - ~ Adherence
 - Frequency and total number of doses
 - Adverse effects and acceptability
 - Ability of users and mothers to follow directions

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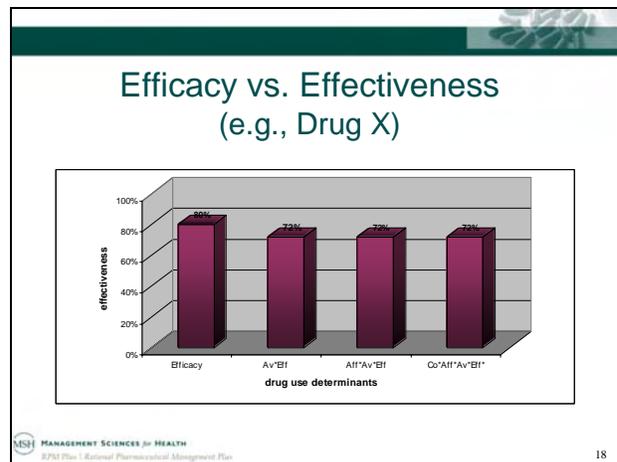
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Efficacy vs. Effectiveness (e.g., Drug X)

- Parasite clearance=80%
- Availability (Av)=90%
- Affordability (Aff) =100%
- Compliance/Adherence (Co) =100% (single dose/DOT)

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Efficacy vs. Effectiveness (e.g., Drug Y [ACT])

- Parasite clearance=99%
- Availability=50%
- Affordability=50%
- Compliance=50%

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Efficacy vs. Effectiveness (e.g., Drug Y [ACT])

Drug Use Determinant	Effectiveness (%)
Efficacy	99%
Av'Eff	50%
All'Av'Eff	24.75%
Co'All'Av'Eff	12.38%

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Drug Management for Malaria

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Pharmaceutical Management Cycle

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Drug Management for Malaria: Selection

- Identification of options for therapies: first line, second line, severe malaria
 - ~ Consideration of currently recommended options
 - Combination therapy is recommended by WHO, however, countries need to decide on combination
 - ~ Analysis of scientific evidence with respect to resistance as well as other evidence such as cost effectiveness, anecdotal evidence, and health seeking behaviour studies
 - ~ Review of lessons learned from similar countries
 - ~ Analysis of barriers to implementation of existent antimalarial drug policy

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Drug Management for Malaria: Selection

- Provision of options for pregnant women (prevention and treatment)
 - ~ Issues of Malaria in pregnancy
 - Need to consider acceptability and compliance with antimalarials for prevention
 - Need to ensure availability of antimalarial for ANC use
 - Review data for safety, in pregnant women, particularly for newer drug regimens e.g. ACT
 - Consider resistance to currently used IPT drug, SP
- Provision of options for other specialized groups e.g infants

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Drug Management for Malaria: Selection

- Choice of individual drug/s and dosage forms
 - ~ Efficacy and safety
 - ~ Useful therapeutic life
 - ~ Ability to curb resistance development (e.g., ACT)
 - ~ Ability to reduce transmission (gametocytocidal) (e.g., ACT)
 - ~ Adverse effects
 - ~ Cost/affordability
 - ~ Compliance/Adherence (ease of use, attitudes and practices, acceptability, formulation)
 - ~ Use in young children and pregnant women

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Drug Management for Malaria: Selection

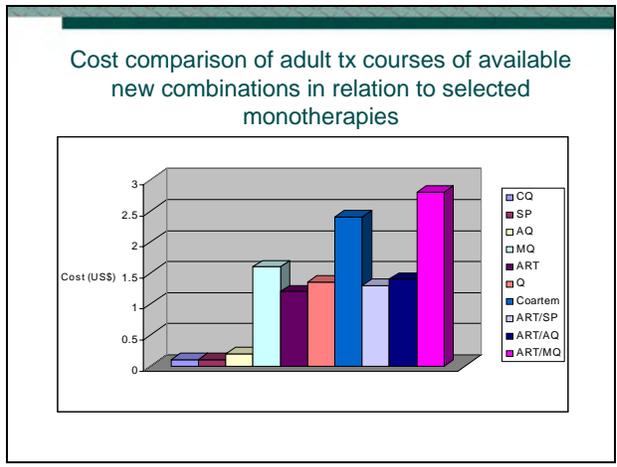
- Decisions on which drugs will be available at each level of health care e.g., hospital dispensary, private sector shops
- Revision of Standard Treatment Guidelines and Essential Drug Lists
 - ~ Change in malaria treatment guidelines must be
 - Harmonized with national drug formulary framework
 - Included into EDL and formulary
 - Harmonized with other relevant guidelines e.g IMCI, RH

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Drug Management for Malaria: Selection

- Consideration of capacity of health system to implement policy
- Adoption of strategies for home-based management
- Commitment of the private sector (franchising, subsidies, social marketing, incentives)
- Financial burden for change
 - ~ Direct cost: more expensive drugs
 - ~ Indirect cost: retraining of HW, new STGs etc.

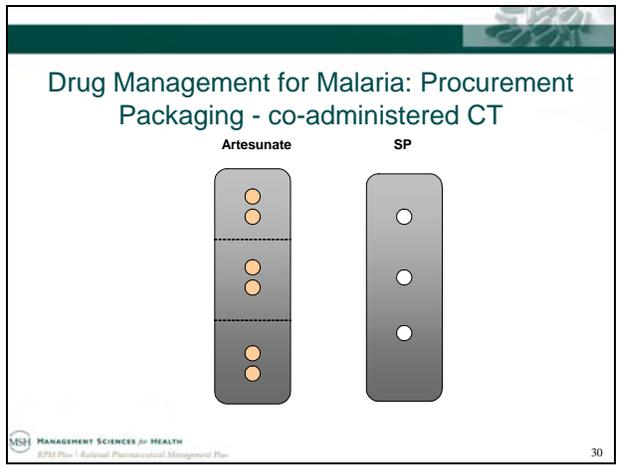
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Drug Management for Malaria: Procurement

- Estimation of drug needs is important (Quantification)
 - ~ Morbidity models
 - ~ Consumption models
- Selection of procurement methods needs to explore all options
 - ~ Competitive/noncompetitive
 - ~ Local/international
 - ~ Consideration of packaging options for antimalarial drug of choice particularly combination therapies
 - ~ Consideration of different dosages of pre-packaged drugs for children

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Drug Management for Malaria: Procurement Packaging: co-formulated vs pre-packaged

Artemeter-Lumefantrine

0 hours 8 hours
24 hours 36 hours
48 hours 72 hours

Amodiaquine/ Artesunate

Day 1
Day 2
Day 3

SP/ Artesunate

Day 1
Day 2
Day 3

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Drug Management for Malaria: Procurement

- Management of tenders
 - ~ Consideration for strength, dosage forms, packaging, labeling requirements such as stability, storage conditions, expiration etc
- Establishment of appropriate contract terms
- Enforcement of adherence to contract terms
- Assurance of drug quality
 - ~ Good Manufacturing Practice (GMP)
 - ~ Regulatory capacity
 - ~ Postmarketing surveillance
- Determination of lead time for delivery
- Consideration for existing stocks/early planning for change

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Drug Management for Malaria: Distribution

- Customs clearance
 - ~ Could limit number of entry points for malaria drugs
- Inventory control
 - ~ CT involves 2 drugs (important issue for quantification)
- Replacement of all monotherapies with CT including those in the private sector
- Need to ensure that if co-formulated/pre-packaged drugs are not available, users co-administer drugs according to the CT treatment guidelines (if have decreased shelf life)

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Drug Management for Malaria: Distribution

- High quality stores management
 - ~ Ideal storage areas (storage – dry/wet conditions)
 - ~ Good record keeping
 - ~ Good system of monitoring, e.g., artemisinin derivatives have shorter shelf life
 - ~ Good systems of recall for expired drugs
 - ~ Good stock control
 - ~ Explicit levels of drug quality violations
- Increased frequency of transportation and delivery to drug depots and health facilities for CT (if have)

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Drug Management for Malaria: Use

- Accurate diagnosis
 - ~ Consider biological versus clinical diagnosis
- Acceptable prescription
 - ~ Prescription of drug and dosage form must be consistent with STGs
- Dispensing
 - ~ Public versus private sector
- Proper consumption by the patient
 - ~ Appropriate packaging (adult/chd)
 - ~ Compliance/Adherence

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Management Support Systems

- Organization of the system
 - ~ Promotion of liaison of MOH pharmaceutical department with NMCP
 - ~ Development of STGs in collaboration with national formulary
 - ~ Reduction of availability of undesired product (e.g. drug being changed)
- Financial management

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Management Support Systems

- Management information systems
 - ~ MIS must support implementation of malaria drug management
 - ~ Should incorporate pharmacovigilance
- Human resources management
 - ~ Training of HW and community outreach worker??
 - ~ Supervision
- Monitoring and evaluation
 - ~ Early collaboration with other data collection activities e.g. DHSS to ensure collection of malaria specific indicators

Policy and Legal Framework

- Support of legal framework for policy
- Registration issues (co-administration vrs co-formulated drugs)
- Regulatory role
 - ~ Regulation of undesirable antimalarials
 - ~ Decrease availability of undesirable antimalarials
- Quality enforcement (Inspections)

Participatory Exercise

- Read the case
- Determine problems
- Identify the factors that contribute to the problems
- List potential solutions

ANNEX 3. CASE STUDY: ENSURING RATIONAL DRUG USE FOR MALARIA

Rising resistance to chloroquine and other monotherapy drugs for managing malaria, particularly *P. falciparum* malaria, led the government to change the treatment policy to the use of combination therapy for case management of malaria. Recommended treatment guidelines were prepared to reflect this new policy. According to the guidelines, the recommended first-line treatment for uncomplicated *P. falciparum* malaria is a combination of artesunate and mefloquine. Second-line treatment for uncomplicated *P. falciparum* malaria is a combination of quinine and tetracycline. First-line treatment for malaria due to other malarial parasites continues to be chloroquine.

A few years after implementing this policy, government officials found that there was only a slight change in malaria morbidity and mortality patterns. This change was less significant than had been expected when the new treatment policy was instituted. A study was recommended to try to get a better understanding of what was actually happening. This study found that more than 80 percent of malaria patients in the country first seek care in the private sector, and more than 90 percent of antimalarials were purchased from private pharmacies and drug shops. The private sector was, therefore, the main source of treatment for malaria. There is currently little interaction between practitioners in the public and private health sectors, and little government oversight of the activities of private health facilities and providers.

The study also found that the diagnostic criteria for malaria used in private sector health facilities often differed from the national standard treatment guidelines (STGs), and also varied among facilities. Further, private sector facilities had limited laboratory diagnostic facilities. Most practitioners at these facilities were making the diagnosis of malaria on the basis of clinical symptoms alone. The ability to correctly diagnose malaria, therefore, varied significantly among the different cadres of providers in the private sector. The licensed prescribers, who had medical backgrounds, were more likely to make a correct diagnosis of malaria. Dispensers working in pharmacies and drug shops were more likely to have incorrectly diagnosed malaria when asked for a diagnosis by their customers. Most of these dispensers were not licensed to diagnose or to prescribe medicines. Laboratory diagnostic facilities were found to be equally limited in the public sector health facilities, although the providers in the public sector relied on the clinical diagnostic criteria outlined in the STGs to make their malaria diagnoses.

A review of the treatment received by patients found that, contrary to the guidelines, more than 80 percent of patients diagnosed with malaria were taking only artesunate monotherapy for their first-line treatment and more than 60 percent were taking only quinine monotherapy for their second-line treatment; only 10 percent of the patients had correctly completed the recommended combination therapy for malaria. This was true irrespective of whether they had sought treatment in public or private health facilities. In most cases, patients indicated that the medicines they were taking were what had been prescribed to them by the provider at the health facility at which they first sought treatment. However, in some cases, patients admitted that they had not filled the full prescription—because they could not afford to do so, the drugs prescribed were not available at the pharmacy, or they did not think it was necessary to take all the drugs. Duration of

treatment varied even among those who were receiving the same drugs. Patients who had first sought treatment at their local drug shop were less likely to have received any of the drugs recommended in the STGs, and in most cases were still using chloroquine.

Interviews with health-care providers working in private health facilities revealed that only about a quarter of them recommended the correct first-line treatment when presented with a hypothetical situation that required the use of first-line antimalarials. An equal proportion gave the correct second-line treatment when presented with a hypothetical situation that required the use of the second-line antimalarials. Providers working in public sector facilities were only slightly better at making the correct recommendations than were private sector providers. Slightly more than half of all providers had received any training on the use of antimalarials. Of those who had been trained, most were working in the public sector and had received training after the new STGs were issued. The private sector providers had received no training on the new STGs.

Based on this information, the government decided that its first intervention to improve the case management of malaria would be to provide the new treatment guidelines to private sector health providers. Other interventions would need to be designed to meet all the challenges identified in the study.

Case Study Questions

1. What are the some of the drug use problems that may be occurring in the country?
2. Could you identify some of the factors that could be contributing to these problems? What component of the drug management cycle is related to each of these problems? What consequences do you foresee arising as a result of these factors?
3. Of the factors you identified, which are factors that, if adequately addressed, would have the greatest impact in addressing the problems with drug use?
4. Based on your analysis, do you agree with the decision of the government? Why or why not? What other steps should be taken to improve the use of the antimalarial drugs?

ANNEX 4. FACILITATOR'S GUIDE CASE STUDY ANALYSIS: ENSURING APPROPRIATE USE OF NEW THERAPEUTIC REGIMEN FOR MALARIA

1. *What are the some of the drug use problems that may be occurring in the country?*

- Provider noncompliance with STGs
- Nonadherence to prescribed treatment by patients
- Self-treatment by patients without consultation of health-care providers

2. *Using the framework provided, identify some of the factors that could be contributing to these problems. What consequences do you foresee arising as a result of these factors?*

Factors contributing to **provider noncompliance with STGs** include—

- Poor public health infrastructure—limited laboratory facilities
- Unlicensed prescribers and dispensers making treatment decisions
- Lack of awareness of the STGs
- Poor understanding of the STGs
- Limited or no access to training in the STGs, particularly among private sector providers
- Providers' preconceptions and habits—private sector providers, in particular, may not believe in the STGs or may not feel bound by the recommendations
- Limited regulatory oversight, particularly of the private sector

Factors contributing to **patient nonadherence to treatment** include—

- Patients' preconceptions about treatment—they may not believe or understand that it is necessary to take all the drugs prescribed
- Cost of treatment
- Availability of drugs prescribed at pharmacies

Factors contributing to the problem of **self-treatment by patients** include—

- Reliance on nonlicensed and nonqualified individuals for treatment advice

- Cost of treatment

Consequences that may arise from these factors include—

- Increased resistance of malarial parasites to the treatment drugs
- Increased morbidity and mortality due to malaria

3. *Of the factors you identified, which factors, if adequately addressed, would have the greatest impact in addressing the problems with drug use?*

- Factors associated with provider noncompliance with STGs—particularly the lack of regulatory oversight of the private sector activities
- Factors associated with patient nonadherence to treatment

4. *Based on your analysis, do you agree with the decision of the government? Why or why not? What other steps should be taken to improve the use of the antimalarial drugs?*

The government's decision is an appropriate first step. However, simply providing the guidelines to the private sector is not sufficient, as it does not ensure that private sector providers will read, understand, and use the guidelines.

Other interventions could include managerial, educational, and regulatory changes.

Managerial interventions could include—

- Reinforcement/strengthening of the public health infrastructure—improve drug and commodity supply; improve lab facilities and access to these facilities
- Strengthening of supervisory systems—develop systems for enhancing private sector activities

Educational interventions could include—

- Development and implementation of regular training programs for all providers on antimalarials and STGs for malaria
- Development of materials to be used for educational and informational activities—target patients; public and private providers at health facilities and local drug stores

Regulatory interventions could include—

- Development and enforcement of guidelines to ensure availability and quality of antimalarial

- Review of licensing requirements and enforcement of regulations stipulating who can prescribe or dispense antimalarials
- Development of regulatory systems to monitor and support private sector activities

ANNEX 5. LIST OF PARTICIPANTS FOR AMI WORKSHOP

Guyaquil, Ecuador, June 17th–19th, 2003

Bolivia

1. Eddy Martinez Avendano, Coordinador Nacional Iniciativa Amazonica, Ministerio de Salud y Deportes, Bolivia
2. Lcdo. Rene Mollinedo, Coordinador Tecnico Programa Nacional Malaria, Ministerio de Salud y Deportes, Bolivia

Brazil

1. Mauro Shugiro Tada, Director, Centro de Pesquisa en Med. Tropical de Rondonia, Brazil
2. Carlos Mangabeira da Silva, Consultor, Ministerio da Saude/Funasa/Cenepi, Brazil

Ecuador

1. Victor Reyes, Epidemiologist, SNEM, Ecuador; Lenin Velez Nieto, Subdirector Tecnico, SNEM, Ecuador
2. Cesar Diaz Cortez, Jefe Zona Malaria Esmeraldas, Servicio Nacional de Erradicacion de la Malaria, Ecuador
3. Hugo Jurado Salazar, Epidemiologist, SNEM, Ecuador
4. Galo Ledesma Hidalgo, Director, SNEM, Ecuador
5. Johnny Real Cotto, Jefe Epidemiologia, SNMT, Ecuador; Franklin Bajana Loor, SNEM, Ecuador
6. Jose Davila Vasquez, Jefe Departamento Epidemiologia, SNEM, Ecuador
7. Eduardo Vargas Tobar, Jefe Departamento de Farmacologia, Instituto Nacional de
8. Higiene, Ecuador
9. Luiggi Martini Robles, Director Tecnico, SNMT, Ecuador
10. Raul Veloz Perez, Epidemiologo, SNEM, Ecuador
11. Luis Enrique Castro Saavedra, Jefe Zona IX Sucumbios Orellana, SNEM, Ecuador

12. Efrain Beltran Ayala, Jefe Zona VIII, SNEM, Ecuador
13. Francisco Hernandez Manrique, Director, Instituto Nacional de Higiene, Ecuador
14. Eladio Vera Fernandez, Jefe de Contingencia, SNMT, Ecuador
15. Jose Enrique Dueñas Zambrano, Jefe Zona V, Servicio Nacional de Malaria, Ecuador
16. Lenin Velez Nieto, Subdirector Tecnico, SNEM, Ecuador
17. Franklin Bajana Loor, SNEM-Santo Domingo, Ecuador

Peru

1. Luis Loyola Garcia, Salud de las Personas, Ministerio de Salud de Peru, Peru
2. Luis Miguel Leon, Coordinador Estrategia Sanitaria Nacional, Ministerio de Salud de Peru, Peru

Suriname

1. Lesley Resida, Director, Bureau of Public Health, Suriname
2. Stephen Vreden, Coordinator of Clinical Trials Program, RAVREDA, Suriname

Venezuela

1. Letty Gonzalez Rebolledo, Jefe de Endemias Rurales, Servicio Endemias Rurales, Venezuela
2. Leopoldo Villegas, Director, Campo “Dr. Francesco Vitanza,” Venezuela

APPENDIX 6. AMI DRUG POLICY WORKSHOP COURSE PROGRAM

Day 1: 17 June 2003:

Morning Session:

- 0800 Opening of workshop and welcome to participants
Subsecretario de Salud de la Provincia del Guayas
- 0815 Introduction of faculty and facilitators and guests
Dr. Angel Valencia, Consultor OPS
- 0820 Introductions of participants
Arlene Vincent-Mark
Name, country, job title, experience with malaria policy
- 0845 Opening exercise: Dr. Williams
What is drug policy?
“Individual assessment” on elements of drug policy
- 0900 Introduction to workshop content: Dr. Williams

Discussion of small group presentations
Time focus: condensed presentation
- 0915 Small group exercises: Dr. Williams and facilitators
Brainstorming policy situations (split into 3 groups)
- 1000 Tea/coffee break
- 1030 Introduction to policy cycle: Drs. Williams

Why is policy a cycle?
What are the objectives of a malaria drug policy?
What are the components of policy?
What are policy documents?
What are the steps of policy?
What is successful policy?
- 1115 Small group free listing exercises: Drs. Williams and Vincent-Mark and facilitators

Who are potential stakeholders?
Types of data needed to inform policy?
Contextual factors that influence policy

1200 Summary of small groups and reporting back to large group (15 mins per group)

1245 Lunch and break

Afternoon Session:

1400 Status of Malaria Drug Policies within Amazon Basin Countries: Dr. Williams and participants

Split into groups by individual countries:

- a) using the policy framework, determine where your respective country is within the policy cycle
- b) summarize what activities are currently happening in your country regarding drug policy changes
- c) identify strengths that will ease policy formulation and implementation
- d) describe challenges that face your country in terms of malaria policy development

1430 Individual versus Regional Perspectives

Return to original morning groups (3 groups of 8):

- a) briefly review, by country, the status of each country represented
- b) identify common regional strengths to assist in policy formulation and implementation
- c) identify common regional challenges
- d) list resources that are available to countries to assist them in making malaria policy changes

1515 Report of small group to larger groups (15 minutes each)

1600 Break

1630 Policy as a Political Process: Dr. Williams or TBA

1700 Drug Efficacy, Drug Resistance: Dr. Williams

1745 Summary of Day 1, preparations for Day 2: Drs. Williams and Vincent-Mark

1800 Close of Day 1 session

Day 2: 18 June 2003:

Morning Session:

0800 Welcome and question/answer period from Day 1: Drs. Vincent-Mark and Williams

0815 Introduction to Drug Management Cycle: Dr. Paredes

0900 Small group participatory exercises: Dr. Paredes and facilitators

Break into 3 groups (8 participants each *)

15 minutes explanation, 15 minutes work time

** Group composition will differ from Day 1*

1000 Tea/coffee break

1030 Report of small group to larger groups (15 minutes each)

1115 Introduction to Planning Tool for Use by Malaria Control Programs: Dr. Montoya

1200 Practice sessions with tool: Dr. Montoya and facilitators

1230 Lunch and break

Afternoon session:

1330 Introduction to Situational Analysis: Dr. Vincent-Mark

What information is needed to inform policy change?

What information exists and what is the source of that information?

What is a stakeholder analysis and how do you do conduct one?

What are options for change?

1400 Assessment of Country Level Situation Analyses: Drs. Vincent-Mark and Williams

Break into country groups

Begin development of situational analysis for your particular country

1500 Break

1530 Report back to larger group

Identify gaps in knowledge and summarize information that is needed for your country (each country team allowed 5 minutes for presentation)

1615 Consensus building: Dr. Vincent-Mark

1645 Implementation: Dr. Williams and TBA

Steps needed prior to actual implementation

Contextual factors that may influence implementation: political, economical, environmental

Regulatory and legal issues

1730 Case scenarios for implementation

Break into the Day #2 small group sessions

Review case scenarios and answer questions

1800 Summary of Day 2 and preparations for Day 3: Drs. Williams and Vincent-Mark

1815 Closure of Day 2

Day #3: 19 June 2003:

Morning Session:

0800 Welcome and question/answer period from Day 2: Drs. Vincent-Mark and Williams

0815 Report back to larger group on implementation case scenarios (each group given 10 minutes)

0845 Implementation Continued: Monitoring and Evaluation: Dr. Williams

How do you know that a policy change is successful?

What types of data need collected over time?

How do you disseminate those data to inform the next policy?

0930 Case example of Policy Change – Peru: TBA, colleagues from Peru

Summary of recent change in malaria policy in Peru

1000 Tea/coffee break

1030 Open discussion and questions/answers to Peruvian colleagues: Group at large

1100 Review of Challenges and Successful Strategies from a Global Perspective: Dr. Williams

1130 Conceptual Model for Malaria Drug Policy Development: Dr. Williams

Framework for a rational malaria drug treatment policy

1200 Development of Country-level Strategic Plans for Policy Change

Break into country level groups

Identify major need of home country: policy formulation, implementation, or monitoring/evaluation (this should be based on information known [i.e., information presented to faculty prior to the start of the conference], as well as information gathered in situation analysis exercise)

1300 Lunch and break

Afternoon Session:

1400 Continuation of development of strategic plans

1600 Break

1630 Country-level presentation of plans: Country level teams

10 minute presentation highlighting plan

1745: Wrap up

1800 Close of workshop: Subsecretario de Salud

