

The Amazon Network for the Surveillance of Antimalarial Drug Resistance (RAVREDA) and the Amazon Malaria Initiative (AMI) are part of the joint efforts of the Amazon countries and institutions (PAHO/WHO, USAID, CDC, USP, MSH) for Roll Back Malaria in the Americas (Roll Back Malaria Initiative / RBM).



RAVREDA-AMI Newsletter

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The RAVREDA-AMI Newsletter is a quarterly news and information publication of RAVREDA-AMI where the latest activities and progress of the Amazon Network for the Surveillance of the Antimalarial Drug Resistance are reported and shared.

Regional News from RAVREDA

Regional Malaria Meeting

A meeting of malaria program coordinators and national chiefs of epidemiology from the 21 malaria-endemic countries in the Region of the Americas was held in San José, Costa Rica on 7-10 November. The meeting was organized by PAHO's Regional Malaria Programme within the Communicable Disease Unit. The objectives were to update National Directors of Epidemiology and Malaria Programs in the Americas on the current situation of malaria worldwide and in the Region of the Americas; provide an opportunity for National Malaria Programs to present epidemiological data on the status of malaria in their country; and provide a venue for countries to share experiences, networking and exchange information. The meeting also provided the opportunity to highlight the content of the Resolution on malaria adopted by PAHO's 46th Directing Council, Washington D.C, September 2005, www.paho.org/english/gov/cd/CD46.r13-e.pdf, to discuss a strategic plan for malaria control in the Region, share experiences and tools, and define areas for technical and South-South cooperation. Working groups reviewed the proposed strategic plan, offering suggestions to enhance and review it. As for RAVREDA-AMI, this was an opportunity to share its progress with the other endemic countries of the Region. Participants examined the results of the antimalarial drug resistance assessment and the tools currently being promoted to improve access and diagnostic and treatment quality, as well as the proposal to approach vector control in a more streamlined fashion. Additionally, there was a presentation on the DDT/GEF project currently under way in Central America, and a proposal was made to cultivate the sharing of experiences between the two subregions in 2006. The presentation on how the PAHO Strategic Fund for medication operates was of great interest in terms of RAVREDA-AMI objectives and improvements presently promoted in the area of antimalarial drug management. Details of the presentation can be found at the end of this Newsletter. Finally, working groups reviewed the management indicators for malaria programs, resulting in a very useful discussion for guiding the task of defining indicators that PAHO is coordinating.

Meeting on Malaria in Pregnancy

Investigators and experts on malaria in pregnancy from seven countries of the Amazon region met on 25-28 October in the city of Santa Cruz, Bolivia to share experiences and propose an approach to this problem in the Amazon region. The "International Malaria and Pregnancy Colloquium in the Americas: Baselines and Prevention Strategies" was organized by the Research Institute for Development (IRD), the Ministry of Health of Bolivia, with the participation of PAHO, the CDC of Atlanta, and professionals from the region working in this field. The available information in the countries was reviewed, and it was agreed to recommend a rapid assessment of the problem using a standard protocol developed by the CDC that is being adapted by PAHO within the framework of RAVREDA-AMI for the epidemiological conditions and health services in Amazonia.

Guide for Streamlining Control of Malaria Vectors

Progress made over the past three months in the preparation of a Guide and supplements for the implementation of a strategy to streamline control of malaria vectors in the countries of the Amazon region. In January 2005, this area of work within RAVREDA-AMI was designed at a meeting held in Lima with entomologists from the eight countries, while work on the instruments for its implementation has been under way over the past few months. The paradigm guiding this strategy is that of stratification from a control perspective and the need to strengthen local capacity for making and implementing decisions and to generate standardized information on entomology and vector control that is also useful to higher levels so that they can provide the necessary support. In the upcoming months, entomologists from the Region will be analyzing the documentation that is being prepared in order to begin entomological characterization of the areas under study in 2006 and the preparation of intervention baselines.

Managing Antimalarials

In keeping with the timeline for work agreed to at the meeting held in Bogotá in July 2005 on tools for assessing the management of antimalarials, during the last quarter of the year, the coordinating body of MSH/RPM Plus'

cooperation activities within RAVREDA followed up on activities under way in Colombia and Bolivia. The two countries began their assessments in October and November with the training of interviewers and data collection. MSH/RPM Plus worked in coordination with Ecuador on preparing the assessment protocol, in addition to identifying its technical assistance needs in relation to the procurement and distribution of antimalarial drugs. To do so, experts used a tool that was developed to assist countries with the implementation of new policies for combination treatment with Artemisinin. In Guyana, in collaboration with MSH/RPM Plus, priority was given to drug quantification and management of the supply chain, which were addressed in early 2006. Guyana expects to share its experience in needs quantification with the other RAVREDA-AMI countries during a regional workshop on the topic that has been planned by RPM Plus, tentatively scheduled for June.

News from the Countries

◆ Bolivia

Study on the Cost-effectiveness of Using Rapid Tests by Volunteers in Bolivia's Amazon Region

This study is currently in the process of analyzing the data obtained from readings of blood samples, patient records, the records of volunteers and technical collaborators in malaria, as well as work conducted with focus groups regarding treatment acceptability. Presentation and publication of the final report are slated for January 2006.

Study on Pharmaceutical Management of Malaria, Bolivia

This study was launched in November 2005, with training for the staff in charge of data collection. Training was carried out with participation of personnel from the AMI, Ministry of Health and Sports (trained in Colombia in "Tools for Analyzing Pharmaceutical Management"), and Melissa Thumm from of MSH-Headquarters (Washington, DC.). Up until the end of December 2005, data was collected from the 21 health facilities in Cover (Pando), Riberalta and Guayamerín (Beni), in addition to Yacuiba in the department of Tarija, thus completing the database.

Training Workshop on Microscopic Malaria Diagnosis, Treatment, and Microscope Maintenance

The "Training Workshop on Microscopic Diagnosis and Treatment of Malaria" was held from 29 November to 13 December in Riberalta. The department was chosen as the venue for the training since nearly 80% of the population working the chestnut harvest in Pando comes from the City of Riberalta (one of the largest population migrations in the country). This workshop was aimed at nurses, technical personnel working with malaria, and volunteers working at urban and rural centers in this municipality.

Structure and Organization of the Medical Entomology Laboratory of the Institute of Health Laboratories (INLASA)

Through INLASA, which heads the Health Laboratory Network, work is under way on structuring the Network of Medical Entomology Laboratories. To date, four levels of laboratory management have been defined on the basis of response capacity, activities to be carried out, human resource needs, physical infrastructure, and equipment.

"Sensitivity/Resistance of Anopheles to Insecticides"

Bioassays continue to be done on the sensitivity/resistance of *Anopheles* to insecticides, but are currently in their final phase. The insecticides used in the bioassays have included cyano and non-cyano pyrethroids (Deltamethrin and Permethrin), with testing conducted at different concentration levels based on the results of reconnaissance surveys. The *An. pseudopunctipennis* strain was used in Yacuiba-Tarija and Chaco-Chuquisaca (the valleys), while the *An. darlingi* strain was employed in Guayamerín, Riberalta-Beni, and Puerto Rico-Pando. At present, this article is being prepared for publication.

"Inventory of Anopheles" in the Yacuiba Municipality

As part of a strategic partnership with IRD, a study on the Dynamics of Malaria Transmission is under way in Yacuiba-Tarija. To this end, longitudinal studies on *An. Pseudopunctipennis* are also being conducted. The objective is to determine basic entomological parameters such as the degrees of anthropophilism, exophagia and endophagia, exophilia and endophilia, parity, and longevity. Similarly, work is under way on mapping the species in southern Bolivia.

Manual for Malaria Diagnosis and Treatment in Bolivia

Preparation of the Manual for Malaria Diagnosis and Treatment in Bolivia is complete, and it is currently in the editing phase. Its target audience consists of network and health facility personnel, and it aims to standardize knowledge on malaria diagnosis and treatment. Furthermore, it includes the new treatment regimen for children under 12 months and pregnant women.

Manual of Entomology Standards in Malaria

Preparation of the Manual of Entomology Standards in Malaria is complete, and it is currently in the editing phase. This manual provides technical entomologists from the different laboratories with basic information on entomology, methodologies for conducting baseline and other studies, and the recommendations of the AMI-RAVREDA Entomology Workshop held in Lima in February 2005.

Participation in Other Regional Events

In September 2005, Bolivia participated in the International Congress for Tropical Medicine and Malaria, held in Marseilles, France. The purpose of the trip was to disseminate the preliminary findings of the work carried out in coordination with entomologists from the IRD, with

USAID and IRD funding. These results were displayed on two posters: “Ecological and entomological factors in *Plasmodium vivax* transmission in the Bolivian Andes” and “Insecticide susceptibility of *Anopheles darlingi* and *An. pseudopunctipennis*, the main vectors of malaria in Bolivia.”

◆ Brazil

Training on Methodology for Therapeutic Studies in Malaria

On 21–25 November, a training workshop was held near the city of Cuiabá on research methodologies for therapeutic studies in malaria. The activity was organized by the group that supports RAVREDA in the state of Mato Grosso, in coordination with the Ministry of Health and PAHO. Attendees included professionals in charge of coordinating RAVREDA field activities in the states of Belém, Maranhão, Amapá, Amazonas, Rondonia, and Mato Grosso, and also in the state of Acre. Aspects related to study design, survival analysis, and protocol analysis were reviewed, and a discussion was held on the application of the intent-to-treat analysis. A demonstration was given on the WHO instrument for analyzing antimalarial drug efficacy studies. Additional study designs used in RAVREDA for other subjects were also examined

External Performance Evaluation in Malaria Diagnosis

A first experience in external performance evaluation in malaria diagnosis (AEQ-MAL1) came to an end. The activity was coordinated by the General Office for Laboratory Coordination of the Ministry of Health and the Evandro Chagas Institute reference laboratory for malaria. Eleven laboratories from endemic municipalities in the state of Pará participated in this first evaluation, and panels with five slides were prepared. Using the guide prepared at the RAVREDA meeting held in Caracas in July 2004, qualification criteria were defined according to the capacity of the laboratories studied to identify the presence of the parasite, species, and stage. Concurrence was 55% by species and 91% by stage of *P. falciparum*. In keeping with the pre-established criteria, five of the 11 laboratories (46%) were considered adequate, while the remaining six were identified as being in need of training (55%).

Assessment of Efficacy of MQ+ASU Combination in Mato Grosso

Patients with uncomplicated cases of *P. falciparum* malaria continued to be enrolled in studies on the therapeutic efficacy of the MQ+ASU combination that are being conducted in the states of Mato Grosso and Amapá, and in the study to assess the efficacy of Coartem®, which is being conducted in Rondonia.

Meeting of the Technical Group in Belém

Within the framework of the 11th Meeting for the Assessment of the National Malaria Control Program, held

in the city of Belém on 8–10 November, the Technical Group for Malaria Treatment met to discuss the therapeutic alternatives for changing the first line of treatment for uncomplicated *P. falciparum* malaria as follow up to a previous meeting of this same group held in June in Brasilia. At this meeting, the group recommended replacing the Quinine + Doxycycline regime with a therapeutic combination of Artemisinin derivatives. The meeting concluded by recommending the use of Coartem® as a first option for high-risk areas in the Legal Amazon region.

Preparation of Letters of Agreement with Amapá and the Medical School Foundation at the University of São Paulo

Two letters of agreement were prepared and signed in November and December, allowing RAVREDA activities to be carried out in 2006. In the state of Amapá, several activities are planned, including rapid diagnostic tests for malaria in pregnancy, an assessment of the therapeutic efficacy of the ASU+MQ combination, implementation of the second phase of *in vitro* testing and measurements of antimalarial drug levels in blood. With the malaria group from the University of São Paulo, an intervention study on the use of a therapeutic combination of Artemisinin derivatives will be conducted in high-risk municipalities in the states of Pará and Acre.

Malaria in Pregnancy

Following the recommendations from the Santa Cruz meeting, work was done to revise modules 1 and 2 of the approach for the rapid diagnostic tests for malaria in pregnancy. In coordination with the Tropical Disease Reference Center and the Office for Studies and Research in Health of the State of Amapá's Secretariat of Health, planning got under way on the application of these instruments at state health units.

◆ Colombia

Study on Access and Use of Antimalarials

The Ministry of Social Protection, CIDEIM, and PAHO/WHO held three training workshops for data collectors—the first two were held in the cities of Tumaco and Medellín, followed by one in Montería with MSH participation. At the end of the year, analysis began with CIDEIM on information collected at the national level and in the Departments of Antioquia, Córdoba, and Nariño, along with preparation of the study's final report.

Quality of Antimalarials

The two minilabs donated to Colombia by the regional level of Project RAVREDA-AMI through PAHO/WHO, through an agreement with the Ministry of Social Protection and Departmental Health Secretariats, were strategically located in the Departmental Public Health Laboratories of Antioquia (Medellín) and el Valle (Café),

which, in February 2006 will begin scheduling training and evaluations of the quality of antimalarials.

Rapid Malaria Diagnostic Tests

In keeping with regional directives, the INS began applying the protocol for diagnosing malaria with rapid Core malaria Pan/Pv/Fp tests in Port Leguizamo, Department el Putumayo, to move towards the development of national guidelines for the use of rapid tests.

Monitoring Mosquito Resistance to Insecticides

With PAHO support, information on malaria vectors in Colombia was updated, and a national plan for monitoring the resistance of malaria vectors to insecticides was prepared and coordinated with research activities conducted with the support of CONSCIENCES and the MPS, thereby promoting work in selected localities in Tumaco, Villavicencio, and Chocó.

2006 National Planning Workshop

From 30 November to 2 December 2005, the annual evaluation and comprehensive planning 2006 workshop for vector-borne disease control activities was held, with emphasis on malaria, dengue, and leishmaniasis, and joint educational supervision sessions were scheduled between MPS–INS–PAHO/WHO for the priority departments.

◆ Ecuador

Assessment of the Therapeutic Efficacy of Antimalarials

Currently underway is an assessment of the therapeutic efficacy of Coartem®, a second-line therapy in Ecuador for uncomplicated *P. falciparum* malaria. At year-end, approximately 55 patients had participated in a multicenter study with no detection of any therapeutic failure.

Management of Antimalarials

The RAVREDA coordinating body in the SNEM prepared a manual on good practices for the storage of antimalarials to offer guidance at the provincial and local levels for better drug management. Similarly, two workshops on drug management and good storage practices were held during the last quarter of the year. Attendees of these two workshops included individuals in charge of the warehouses in SNEM's area headquarters and at the main office's warehouse. Also, in keeping with the commitments taken on at the Bogotá meeting regarding tools for assessing antimalarial drug management, the RAVREDA coordinating body in Ecuador prepared an initial proposal for a study on access to and use of antimalarials in endemic municipalities. A workshop to train interviewers in how to conduct the study is scheduled for February 2006. A preliminary diagnosis of the procurement and distribution process for antimalarials at the regional and central levels was conducted from 29 November to 1 December with support from MSH and PAHO, in order to plan future interventions in this area.

Quality Management in Malaria Diagnosis

Following the workshops held during the beginning of the second half of the year, implementation of the quality management system began in two pilot provinces. Approximately 80 laboratories participated in Esmeraldas and nearly 130 in El Oro. The methodology includes an external performance evaluation conducted by way of panels with slides that had already been distributed in Esmeraldas and Machala. A computer application was also developed to aid in the analysis of the results of diagnosis quality control.

Assessment of the Quality of Antimalarials

Field activities for the second round of antimalarial drug assessments concluded in November through the use of minilabs, which began during the second week of November. The field test results and respective samples were sent to the reference laboratory in Guayaquil. Preliminary results indicate concurrence between the findings of the minilabs and those of the reference laboratory.

Improvements in the Malaria Information System

The development of software for recording morbidity from malaria is nearly complete. The previous program, which was designed as part of a RAVREDA activity, was upgraded to facilitate its implementation in the health services, and the process is practically concluded. It will allow for the individual registration of malaria cases with basic epidemiological variables, and it also includes databases of cantons and even localities, appropriately coded, which will permit spatial analysis for the stratification and planning of interventions. The software was developed on a computer platform that is compatible with systems used by the country's Ministry of Public Health.

Malaria in Pregnancy

Changes have been made to the prenatal check-up card used by health units providing primary health care, to include a record of the thick blood film reading. Malaria diagnosis is already a routine practice in 74 health subcenters and posts in the Esmeraldas Province, 55 of which are operating appropriately. From October 2004 to November 2005, this approach was successful in detecting approximately 54 cases of pregnant women with malaria, concentrated in approximately 10 health units in the Province. Beginning in March, similar activities will be carried out in the other health units within the malaria-endemic area.

◆ Guyana

Access, Distribution, and Use of Antimalarials

Together with the MSH/RPM Plus group in Guyana, a technical group made up of staff from the Malaria, Health Services and Pharmacy Program, Drug Management Unit, and PAHO Guyana, defined the 2006 areas of work.

Activities were launched with the preparation of a questionnaire to assess the availability of antimalarials and the supply mechanisms in the regions and health units. The questionnaire was administered to regional health chiefs, and it is expected to be administered to the operational units in the endemic regions next quarter.

The working group agreed to carry out the following activities in the future:

- Review the national malaria treatment guide
- Inspect and improve the storeroom where drugs are kept at the central level
- Confirm registry of antimalarial drugs in Guyana
- Improve regions' drug requisition mechanism by using some new instrument or software

Evaluating the Problem of Malaria in Pregnancy

In coordination with the Maternal and Child Health Program of the Guyana Ministry of Health, and PAHO Guyana with technical assistance by Dr. Paola Marchesini, preparation began on the work plan designed to evaluate the scope of malaria in pregnant women. Some of the activities to be carried out in 2006 are as follows:

- An analysis of malaria data disaggregated by gender and age groups
- Adaptation of the CDC modules to be applied in regions 8, 9 and 10 of Guyana.

Integrated Planning of RAVREDA Activities with other Malaria Projects for 2006

For the purpose of leveraging efforts and resources better, a plan of activities was prepared in coordination with the Ministry of Health to harmonize RAVREDA efforts with activities included in the Global Fund project for malaria and the PAHO-European Union project for malaria (ECO)

Training Workshop on the Use of Equipment for Quality Control of Antimalarials

A workshop was held in the city of Georgetown on 6-9 December 2005 to train professionals from the official drug quality control laboratory (FDD), academia (School of Chemistry, School of Pharmacy) and the private sector (New GPC), in the quality control of first-line antimalarial drugs for the *vivax* and *malariae* species. The workshop focused on the calibration and use of equipment for high-performance liquid chromatography and dissolution testing, including a quality assessment of chloroquine and primaquine manufactured locally by the New GPC laboratory and used in the National Health Program. Methodological guidelines were also set for the quality control of second-line antimalarial drugs for *P. falciparum* malaria (mefloquine, artesunate, and quinine.)

Malaria Information System

During the last quarter of the year, preparation was finalized of a computer application that relates the databases of the routine malaria system to a free geographical visualizer (Health Mapper). The routine system was improved and is now poised to begin

decentralizing the data entry process for regional data to improve data analysis and timely decision-making

◆ Peru

Intermittent Irrigation Initiative in Rice Farming for Malaria Control along the Northern Coast of Peru

After launching the Lambayeque initiative (northern coast of Peru) in October, a meeting was held to decide on the work areas and activities plan for the Initiative, with the participation of representatives from all institutions signatory to the Minutes of the Agreements (Lambayeque Regional Government, Regional Director of Agriculture, Chancay Lambayeque Board of Irrigation Users, Roundtable to Build Consensus for Poverty Reduction, Vista Florida Experimental Station-National Institute for Experimental Research and Agrarian Extension, Lambayeque Regional Health Bureau and *Proyecto VIGIA*). The Initiative's main objective is to promote sustainable management of the water resources and soil used in rice farming in order to reduce the incidence of malaria vectors along the northern coast, by launching a general plan to replace the traditional irrigation technique with intermittent irrigation.

It was agreed to begin with a pilot intervention in the district of Pítipa that has extensive areas of rice farming and also reports the greatest number of cases of malaria in Lambayeque. Nineteen farmers and 60 hectares of land have been selected to participate in this pilot intervention. Commencement of the Lambayeque rice farming campaign was delayed until late December due to drought along the northern coast; however November and December marked the beginning of training and technical assistance for farmers in preparing cropland and managing seedlings.

Strengthening Reference Centers for Monitoring Antimalarial Drug Resistance and Treatment of Serious Malaria

In order to render activities for monitoring antimalarial drug resistance and hospital management of patients with severe forms of malaria more effective, reference centers for monitoring antimalarial drug resistance and treating severe malaria are being set up, so that each may operate as a system based on health service networks.

In this context, basic medical equipment for treating severe malaria was acquired and distributed in Loreto and Sullana (three infusion pumps, a medicinal air compressor for mechanical ventilators, two pulse oximeters, and two hemoglobinometers) during the early months of 2005. In December 2005, three additional pieces of equipment (an eight-parameter monitor, five-parameter monitor, and a gas and electrolyte analyzer) were acquired and will be distributed in 2006. Additionally, a trinocular microscope

and a computer were obtained for the National Institute of Health' Malaria Laboratory for training and research on activities related to the surveillance of antimalarial drug resistance.

Coordination Meeting for the Incorporation of PAMAFRO Components into Regional Health Plans.

From 29 November to 01 December, a preliminary meeting was held in Iquitos to incorporate the activities of the project entitled "Malaria Control in Border Areas of the Andean Countries: A community Approach" (PAMAFRO) into the regional plans of the Regional Health Bureaus involved (Loreto, Cajamarca, Amazonas). The emphasis at this meeting, emphasis was on the need to define a profile and policy for health promoters (community agents) in the Amazon region by hiring a consultant through *Proyeto VIGIA*. Coordinated efforts are currently under way with PAMAFRO, so that the activities take into account all the progress achieved thus far by the Ministry of Health, Proyecto VIGIA, and RAVREDA-AMI.

◆ Suriname

Assessment of Therapeutic Efficacy of Artecom and Coartem

At the RAVREDA sentinel site in Paramaribo, a study is in progress on the therapeutic efficacy of Artecom (piperquin-dihydroartemisinin-trimpethoprim) and Coartem (artemether-lumefantrine). By the end of the year, approximately 30 patients were enrolled and some therapeutic deficiencies were already recorded in the two schemes.

Assessment of the Efficacy of Primaquine in the Prevention of Recurrent *P. vivax* Infections: 7- and 14-Day Regimens

December 2005 marked the beginning of an assessment study on the efficacy of primaquine in seven- and 14-day regimens for preventing recurrent *P. vivax* infections. The study is being conducted in Kwamala, near the Brazilian border. A standardized protocol is being used with RAVREDA in Peru, and supervision of all doses of primaquine is guaranteed.

Monitoring of Resistance to Insecticides

In keeping with the methodology established at the workshop held in Paramaribo with Venezuela and Guyana in December, monitoring of anopheline resistance began, using the bottle method. Testing was conducted in the city of Paramaribo, evaluating deltamethrin in samples of *Anopheles aquasalis*.

◆ Venezuela

Malaria in Pregnancy

As part of the country's strategic plan and its efforts to reduce maternal and child morbidity and mortality,

Venezuela's Ministry of Health agreed to use a thick blood film for all pregnant women at every prenatal checkup in malaria-endemic areas. Likewise, the Ministry decided to begin applying the methodology agreed to at the meeting in Santa Cruz, Bolivia for evaluating the extent of the problem of malaria in pregnancy. The activities will first take place around Km. 88 in the Sifontes Municipality, State of Bolivar.

Assessment of Chloroquine Efficacy in Treating *P. vivax* Malaria

The study on Chloroquine Efficacy for *P. vivax* came to an end in the state of Amazonas and is in its final phase in the state of Bolivar. Determining the levels of Chloroquine and Desethylchloroquine in patients presenting therapeutic failure remains pending.

Assessment of Efficacy of Mefloquine plus Artesunate for two days in *P. f* Infections (Indigenous Population, Miners)

The study has concluded in the state of Bolivar, and more than 50% of the patients have already been registered in the state of Amazonas. Preliminary results indicate 100% efficacy.

Management of Antimalarials

The malaria coordination area of the National Office for Environmental Health agreed to begin a study to assess the use and availability of antimalarials in the states of Amazonas and Bolivar in January, followed by the states of Sucre and Delta Amacuro.

Quality of Antimalarials

Along with the drug management-related activities, it was also agreed to take a sampling of the antimalarials—through minilabs—to determine where they are located. Those in charge expect to have obtained samples from the state of Amazonas and from part of the state of Bolivar in February. The samples will be analyzed in early March.

Other News of Interest

Strategic Fund

Within the framework of the Regional Malaria Meeting held in Costa Rica in November 2005, a presentation was given on the operations of the Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund), highlighting the new operating guidelines and the significant contribution they may represent for malaria programs throughout the Region. Details on Fund operations are presented here since this is considered to be a matter of great interest for the management of antimalarial drugs, along with other input related to the RAVREDA-AMI areas of work:

The PAHO Strategic Fund is a mechanism created to promote access to strategic public health supplies in the

Americas. In September 2004, the 45th Directing Council of PAHO adopted a resolution designed to foster access to drugs and public health supplies in the Region. As a key element of the strategy, Member States endorsed a proposal to strengthen regional procurement mechanisms, including the PAHO Strategic Fund. The Fund links the procurement of drugs and essential public health products to the technical processes of demand planning and programming. First- and second-line antimalarial drugs used in the Region are among the inputs that can be acquired through the Fund. In 2005, the Strategic Fund supported antimalarial procurement plans in the Dominican Republic, Global Fund projects in Honduras, Nicaragua, Haiti, and Guatemala, and has recently provided support for the procurement of Coartem® for Brazil. Highlighted is the fact that cooperation also entails support for the managerial processes involved in the systems for supplying, planning, and procuring low-cost products that meet quality standards. Additional information on how the Strategic Fund operates can be obtained at www.paho.org/fondoestrategico.

Methodological Considerations on Assessments of Antimalarial Drug Efficacy

Although monitoring of Antimalarial Drug Resistance is not research *per se*, the studies on efficacy conducted in RAVREDA-AMI are part of research activities, where: i) a protocol is followed, ii) new knowledge is generated, and iii) human beings are involved as participants. As a result, all efficacy studies directly financed through PAHO (RAVREDA-AMI USAID resources) must be authorized by 2 ethics committees, 1 national, and 1 by PAHO. Ethic committee review is a practice that have been promoted in the Network and should continue including the two

clearances. In order to facilitate this, standardized protocols drawn up for efficacy studies in RAVREDA have been provided and are available on the PAHO website at <http://www.paho.org/English/AD/DPC/CD/mal-antimalarials.htm>. Similarly, WHO is preparing a basic protocol, based on the “*Assessment and monitoring of antimalarial drug efficacy for the treatment of uncomplicated falciparum malaria*” which is being revised.

Another methodological aspect related to efficacy assessments refers to the drawback of *in vivo* assessments with two study arms. It is emphatically recommended that comparative studies for monitoring purposes (resistance surveillance) be avoided, since they could be assimilated into Phase III studies, which entail other ethical and methodological aspects (randomization, differences in informed consent and ultimately record-keeping, etc). Non-compliance with such methodological requirements could result in the work being rejected by scientific journals, which are adopting the criteria for the registration of clinical trials that have recently been promoted. www.controlled-trials.com

The considerations on the authorization of study protocols by duly constituted ethics committees must also be a requirement for new activities promoted within the framework of RAVREDA-AMI that involve human beings, such as entomological studies that require capturing mosquitoes with people as bait. The preparation of entomological baselines and assessment studies on insecticide resistance interventions and monitoring, which use such procedures within the RAVREDA framework, must be duly approved by ethics committees.

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