USP DQI: VIII AMI/RAVREDA Meeting, Semi-annual AMI Steering Committee Meeting, and Meetings with Country Partners
Bogotá, Colombia

March 17- 20, 2009

Trip Report

Victor S. Pribluda, Ph.D.
Manager, Latin America Programs

Drug Quality and Information Program
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8160
Fax: (+1) 301-816-8374
Email: uspdqi@usp.org

Cooperative Agreement # HRN-A-00-00-00017-00
Sponsoring USAID Missions: USAID Bureau for Latin America and the Caribbean
Health Program Element: AMI Program
Grantee: United States Pharmacopeia Drug Quality and Information (DQI) Program
Author(s) Name: USP DQI Staff
Language: English and Spanish
Date of Publication: May 11, 2009

This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement number HRN-A-00-00-00017-00. The contents are the responsibility of the Drug Quality and Information Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of the United States Government.

About DQI

The Drug Quality and Information (DQI) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00017-00) and implemented by the United States Pharmacopeia (USP), provides technical leadership to more than 30 developing countries to strengthen their drug quality assurance programs, ensure the quality of medicines and promote public health. DQI helps build local, national and regional capacity to improve the standards of drug manufacturing and distribution, reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic, and advance the appropriate use of medicines. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to DQI and USP.

Abstract

Dr. Victor Pribluda traveled to Bogotá, Colombia, to attend the VIII Amazon Malaria Initiative/ Red Amazónica de Vigilancia de la Resistencia de los Antimaláricos (AMI/RAVREDA) Annual Meeting and the Semi-annual AMI Steering Committee Meeting. The trip had three main objectives: attend and present at the VIII AMI/RAVREDA Annual Meeting; participate in the semi-annual AMI Steering Committee Meeting; and discuss advances in the work plans and issues related to quality assurance and quality control (QA/QC) of antimalarials with AMI National Malaria Control Program (NMCP) representatives and other stakeholders.

Recommended Citation

Pribluda, Victor. VIII AMI/RAVREDA Meeting, Semi-annual AMI Steering Committee Meeting, and Meetings with Country Partners; Bogotá, Colombia, March 17-20, 2009. Submitted to the U.S. Agency for International Development by the U.S. Pharmacopeia Drug Quality and Information Program. Rockville, Maryland: United States Pharmacopeia.

Key Words

AMI, RAVREDA, Quality Assurance, Quality Control, Drug Quality, Minilabs®, Malaria, Resistance, USP DQI

Table of Contents

ACKNOWLEDGEMENTS

USP DQI would like to express sincere appreciation to all national and international AMI partners, and national stakeholders, who participated in and contributed to the success of the meetings during this trip.

The author wishes to express his appreciation to the USP DQI administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

The author would like also to thank the USAID Bureau for Latin America and the Caribbean, in particular Dr. Peg Marshal and Dr. Jamie Chang; and Mr. Anthony Boni and Veerle Coignez at USAID Washington, D.C., for their support and advice.

ACRONYMS

AMI	Amazon Malaria Initiative
CDC	U.S. Centers for Disease Control and Prevention
cGMP	Current Good Manufacturing Practices
CNCC	Centro Nacional de Control de Calidad
DHA	Dihydroartemisinin
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas
GPHF	Global Pharma Health Fund
INVIMA	Instituto Nacional de Vigilancia de Medicamentos y Alimentos
MRA	Medicines Regulatory Agency
MSH/SPS	Management Sciences for Health/ Strengthening Pharmaceutical Systems
NMCP	National Malaria Control Program
OMCL	Official Medicines Control Laboratory
PAHO	Pan American Health Organization
QA	Quality Assurance
QC	Quality Control
RAVREDA	Red Amazónica de Vigilancia de la Resistencia de los Antimaláricos
RTI	Research Triangle Institute
SC	Steering Committee
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information program
WHO	World Health Organization

Background

The Amazon Malaria Initiative (AMI) is a USAID-funded initiative whose primary role is to focus the USAID Latin American and the Caribbean (USAID/LAC) Bureau's financial and technical resources toward improving malaria control and decreasing national morbidity and mortality in seven South American countries (Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname) participating in RAVREDA (Red Amazónica de Vigilancia de la Resistencia de los Antimaláricos). AMI is implemented and coordinated by six international partners: Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS), Links Media, Research Triangle Institute (RTI), and USP DQI. In 2002, USP DQI joined AMI to work on QA/QC of antimalarials.

To improve QA/QA systems in AMI countries, USP DQI provides technical support to Official Medicine Control Laboratories (OMCLs) and National Malaria Control Programs (NMCPs). With USP DQI assistance, each participating country developed a process to monitor the quality of antimalarials at peripheral sites with Global Pharma Health Fund (GPHF) Minilabs®.

USP DQI provides theoretical and hands-on training in analytical tests, sampling methodologies, the use of Minilabs®, and quality data reporting procedures for OMCLs and field personnel. Minilabs® are operational in all countries, most of which have conducted multiple rounds of sampling and analysis. More recently, USP DQI efforts were directed to ensure the sustainability of the changes introduced to improve QA/QC systems for antimalarials.

Each year, representative members of AMI/RAVREDA participate in an annual meeting to share their respective activities and accomplishments from the previous year and to discuss prospective activities. At this forum, the international partners organize the semi-annual Steering Committee (SC) Meeting to discuss future plans, strategic approaches, and other pertinent issues.

Purpose of Trip

Dr. Victor Pribluda traveled to Bogotá, Colombia, with three main objectives:

1. Attend and present at the VIII AMI/RAVREDA Annual Meeting
2. Participate in the semi-annual AMI Steering Committee Meeting
3. Discuss advances in the work plans and issues related to QA/QC of antimalarials with AMI NMCP representatives and other stakeholders

Source of Funding

This trip was supported with funds from the USAID Bureau for Latin America and the Caribbean for the AMI Program.

Overview of Activities

Objective 1: Attend and present at the VIII AMI/RAVREDA Annual Meeting
Dates: March 17-19, 2009
Agenda: See ***Annex 1*** for a detailed agenda of events
Participants: See ***Annex 2*** for the full list of participants

Highlights from this meeting as they relate to USP DQI are the following:

During the Antimalarial Drug Quality Session, USP DQI gave a presentation – included in ***Annex 3 –*** addressing the following topics:

- Strengthening QA/QC Systems
- Institutionalizing a three-level approach for quality control
- Minilab® results and subsequent studies

Strengthening QA/QC Systems

USP DQI activities have concentrated mostly in providing technical assistance and training to OMCL and NMPC field personnel for monitoring the quality of antimalarials. Since last year, efforts have been devoted to ensuring that the changes and improvements in QA/QC systems are properly institutionalized, clearly identifying processes and responsible actors to ensure sustainability. This is particularly important at this stage in which the number of cases of *P. falciparum* and *P. vivax* malaria has decreased significantly in several AMI countries (K. Carter presentation and documentation distributed at the meeting) and strategies have to address countries' needs. With lower transmission rates, it is expected that the variety of malaria medicines and stockpiles of different lots at dispensing sites will be significantly smaller, and USP DQI stressed the need to ensure good quality during acquisition and distribution processes.

E. Barillas (MSH/SPS) remarked that under low transmission conditions, the turnover of medicines at dispensing sites will be lower, and with prolonged storage periods, quality surveillance has to be stringent. He further stressed the need to establish standardized operation procedures (processes and responsible actors). Y. Lopez Arango (Universidad de Antioquía, Colombia) added that the processes need to be adapted to particular regions where conditions may vary.

K. Carter and R. Montoya emphasized the need for vertical programs, such as NMCPs, to integrate common processes horizontally. This will result in better use of resources and management, and support sustainability of these processes.

Institutionalizing a three-level approach for quality control

The draft of a paper prepared by USP DQI (*Institutionalizing a Three-Level Approach for Ensuring the Quality of Medicines in Resource-Limited Countries*) was distributed to the participants. The paper's main concepts and related topics were addressed during USP DQI's presentation. Briefly, this paper describes and discusses the benefits of an approach to increase the extent and effectiveness of QC activities throughout the supply chain, relying on the use of basic analytical tests as a low-cost and time efficient methodology. Minilabs® have been the tool used to perform basic tests at the sentinel sites in AMI countries and other regions of the world.

J. Chang mentioned the need to emphasize the concept of basic tests as a methodological approach and to move away from referring to Minilabs® when discussing this approach because these tests may be carried out in laboratories with or without Minilabs®. He also recommended that USP DQI work with Links Media to promote the use of the basic tests methodology.

N. Girón (PAHO), in relation to the use of Minilabs®, mentioned the need to promote this tool as a complement for OMCL activities and the necessity of involving the OMCL in the process.

Minilab® results and subsequent studies

USP DQI presented a summary table of results for 946 samples as of June 2008; however, it should be noted that as of March 2009, approximately 1500 medicines have been sampled. Since the last AMI/RAVREDA meeting, only Guyana and Colombia reported new results from sentinel sites studies. The date when these reports were received did not allow for a thorough evaluation of the results so they were not incorporated in the summary table presented.

The summarized results for the QC activities performed utilizing the Minilabs® indicate that:

- The percentage of samples that failed critical analytical tests (Disintegration and Thin Layer Chromatography - TLC) is relatively low (7%, 70 of 946)
- The number of expired medicines was 8% (78 of 946). However, 56 from those 78 were found during the initial rounds in Bolivia, and the situation in this country has been corrected; no expired medicines were identified in subsequent rounds in 2008.
- No failure in critical quality attributes were reported for artesunate or any other artemisinin derivatives. However, due to a lack of standards and analytical methods in the Minilabs®, no TLC tests have been performed on samples containing Dihidroartemisinin (DHA) sampled in Suriname. (For further details on possible solutions to this problem, refer to the meeting with Suriname representatives under Objective 3)
- Most of the medicines analyzed were sampled from the public sector, and the proportion of substandard/counterfeit medicines available to the population in the private and informal sectors may be different.

USP DQI recommended adapting the number of rounds performed per year to countries' conditions and involving the Medicines Regulatory Authority (MRA) and OMCL more extensively in the supervision of the results.

USP DQI also stressed the need to increase sampling in the private and informal sectors. Plans for future activities for monitoring the quality of antimalarials available to the public include gathering information in the private and informal sectors through three case studies to be done in Colombia, Guyana, and Suriname.

J.P. Escobar (PAHO) stressed that based on its size, it is very important to include the private sector in the Colombia study. (For further details on this topic, refer to the review of the SC Meeting under Objective 2)

Objective 2: Attend AMI Semi-annual Steering Committee Meeting

Date: March 20, 2009

Participants: See ***Annex 2*** for the full list of participants. In addition to regularly participating SC members, representatives from Brazil, Ecuador, and Colombia joined the meeting.

There was no formal agenda for this meeting. After reviewing the minutes from the last SC meeting, the members presented their conclusions from the AMI/RAVREDA meeting and topics related to future plans.

USP DQI addressed the following issues:

1. Development of Operational Procedures: In the development of operational procedures for ensuring the supply of good quality malaria medicines, developed by the countries following

the workshop in Colombia on May 2008, there is a need to include more detailed procedures for QC processes throughout the supply chain, specifying the participation and responsibilities of the OMCL and MRA. USP DQI suggested the possibility of including in these processes the three-level approach presented at the meeting.

2. Case studies to assess the quality of malaria medicines in the private and informal sectors in Colombia, Guyana, and Suriname: The need to contract additional personnel to perform the study was discussed. It is probable that the available antimalarials in private and informal sectors have not been subjected to routine QC at OMCLs; therefore, it is important to obtain information on all critical quality attributes. Some of the critical quality attributes can not be assessed through basic tests with the Minilabs® at sentinel sites. Originally USP DQI suggested sending the samples to USP to perform compendial analyses. (Note: After the meeting, it was agreed with the representatives of Colombia, Guyana, and Suriname that after sampling is completed, the location of analysis and the methodology to be used will be discussed on a case-by-case basis)

   For the Colombia study:

   - J.P. Escobar reiterated the need to include the private market in the Colombia study
   - E. Barillas suggested including a parallel assessment of the availability of antimalarials in the private sector.
     - It was agreed that USP DQI will work with MSH/SPS to include this aspect in the Terms of Reference for the consultant
   - J.P. Escobar proposed utilizing the services of COHAN as the consulting entity to perform the study.
   - USP DQI and MSH/SPS will evaluate the protocol sent by COHAN

3. Quality Control monitoring at sentinel sites: USP DQI expressed the need to integrate the MRA into the process to ensure that the proper corrective actions are implemented. It is especially important to incorporate the MRA to ensure adequate actions are implemented if non-compliance issues for the same medicines reappear. USP DQI reiterated the need to disseminate any corrective actions implemented.

Additionally, USP DQI addressed specific issues with three countries:

- Peru has not yet initiated monitoring activities at any sentinel site. Logistic problems with some reagents that are considered controlled substances have prevented implementation of monitoring activities; however, these issues are now apparently resolved.
- Ecuador has not reported any activity since 2006. During 2007 and most of 2008, analyses were not performed because the standards sent by USP DQI could not be released from customs. However, this situation has now been resolved.
- There have been communication problems with the NMCP in Brazil, which impaired receiving full information about sentinel site monitoring activities and other planned activities with the OMCL.
  - Due to the different and various responsibilities of QC labs in Brazil, J. Ladislau (NMCP, MoH) requested USP DQI to consult with the NMCP in Brazil before providing training to Brazilian labs (INCQS and LACENs)

- J. Ladislau and A.C. Santelli (PAHO-Brazil) were identified as the points of contact for planning and requesting information related to activities in Brazil
- Post-marketing surveillance activities, the use of the three-level approach methodology, and laboratory training activities will be discussed in Brazil at a subsequent meeting, and the results/decisions will be communicated to USP DQI

Objective 3: Discuss advances in the work plan and issues related to QA/QC of antimalarials with AMI NMCP representatives and other stakeholders
Participants: See ***Annex 4*** for the full list of participants

USP DQI organized ad-hoc meetings with each country's NMCP representatives and stakeholders, to address issues related to current and future USP DQI activities in the respective countries.

The salient points from these discussions were the following:

- QC studies in the private and informal sector: Logistics of the study were discussed with Colombia, Guyana, and Suriname. Suriname has already completed sites mapping and sampling in Paramaribo; identification and sampling at the 'garimpos' (gold mines) will start after a consultant is hired.
- Brazil: The policies and practices for post-marketing surveillance of antimalarials and other medicines will be discussed internally in Brazil (this discussion might include using the three-level approach proposal). The results of this meeting will be communicated to USP DQI for programming future activities. USP DQI volunteered to provide any information on monitoring and/or the three-level approach methodology.
- Ecuador: Medicines sampled in Esmeraldas during 2008 were not submitted for verification/confirmatory testing (unknown reasons). Sampling in El Oro was performed in March 2009. NMCP will send results for both rounds.
- Guyana: The OMCL has moved, and it is still not able to perform verification/confirmatory testing. The possibility of sending samples to USP or a regional reference lab was discussed. It was agreed to address this issue in subsequent discussions in conjunction with the Food and Drug Department (Guyana's MRA)
- Peru: Monitoring activities have not been initiated with any of the three Minilabs® because of licensing problems with some reagents that are classified as controlled substances by the Dirección Nacional de Antidrogas (DINANDRO). In Piura, licenses were granted recently, and in Loreto and Alta Amazonia, the licenses will be re-granted soon. USP DQI financial support for purchasing antimalarials at private and informal sites might be required. A. Añez (PAHO, Bolivia) volunteered to provide a refresher-training for sampling methodologies and Minilab® use in Peru, if that would be necessary before initiating activities. Y. Herrera said that she will assess the need for this training when she returns to Peru.
- Suriname: Samples containing DHA can not be assessed with the Minilabs® because of a lack of standards and methods. USP DQI suggested sending these samples to USP for analysis. There will be a follow-up on this with G. Bretas after the meeting.
- Farmanguinhos: E. Daemon, Project Coordinator at Farmanguinhos, Fiocruz, Brazil, mentioned that they will send USP DQI documentation for the development of a Non-U.S. Monograph (previously known as SALMOUS) for the fixed dose combination of Artesunate and Mefloquine. This medicine was developed in conjunction with the Drugs for Neglected Diseases Initiative (DNDi). Farmanguinhos will also inform USP DQI of their decision

regarding USP DQI's proposal to perform a current Good Manufacturing Practices (cGMP) assessment prior to a World Health Organization (WHO) audit for pre-qualification. USP DQI's cGMP assessment would help Farmanguinhos identify and implement any necessary corrective actions to ensure the WHO cGMP audit would be successful.

Next Steps

- USP DQI will travel to Peru, Ecuador, and Colombia in May 2009, to support the development of QA/QC operational procedures along the supply chain.
- USP DQI will finalize the Terms of Reference for the consultants to be hired for the studies that will be performed in Colombia, Guyana, and Suriname, including a component of availability for the Colombia study.
  Note: Terms of Reference have been sent to the three countries on April 2009. Advances on implementation of the process in Colombia will be assessed during USP DQI visit on May 2009.
- NMCPs and USP DQI will continue coordinating monitoring activities at sentinel sites
  - USP DQI will send updated forms for data collection and reporting of results
  - USP DQI will support purchases of antimalarials at private and informal sectors
  - Bolivia and Ecuador will send a list of standards required for Minilab® testing
- USP DQI will present the three-level approach methodology to MRAs and other interested stakeholders during visits to Colombia, Ecuador, and Peru, on May 2009
- Farmanguinhos will send USP DQI documentary information for monograph development of the Artesunate-Mefloquine Fixed Dose Combination. Additionally, Farmanguinhos will update USP DQI on the status of the proposed cGMP assessment.
  Note: Since the meeting, USP DQI received partial documentation (monographs for the active pharmaceutical ingredients) and Farmanguinhos suggested discussing again the cGMP assessment by the end of 2009.

Amazon Malaria Initiative (AMI)
Amazon Network for the Surveillance of Antimalarial Drug Resistance (RAVREDA)

VIII Annual Evaluation Meeting
XII Steering Committee Meeting

Bogota, Colombia
17 - 20 March 2009

Agenda

Tuesday, 17 March 2009

08:30 - 09:00	Registration
09:00-09:15	**Introduction to the Meeting** (Ministry of Social Protection of Colombia, USAID Mission, PAHO/WHO Representation, Area of Health Surveillance and Disease Prevention Control of PAHO in Washington, AMI Coordination in USAID)
09:15 - 09:30	**Contributions of AMI and RAVREDA to malaria control efforts in the Region** (K. Carter)
09:30 - 09:45	General aspects of the Meeting, introduction of participants (K. Carter)
09:45 - 10:45	– Implications of climate change on malaria control in Latin America (conference) (S. Connor) – Experiences in Colombia (V. Cerón) – Questions
10:45 - 11:00	*Coffee*
11:00 - 12:30	**Surveillance of Antimalarial Drug Resistance** – Progress in 2008 o Situation of the Surveillance Network in 2009 (R. Montoya) (:10) o Studies implemented during 2008 (Peru, Suriname, Guyana) (:30) o Use of molecular markers: Progress in 2008 and strengthening the capacity in countries (CDC) (:20) o Discussion (:30)
12:30 - 14:00	*Lunch*
14:00 - 15:30	**Surveillance of Antimalarial Drug Resistance (continuation)** – Update on the situation of monitoring resistance to ACT and recommendations for monitoring in areas of low transmission (P. Ringwald) (:35) – Questions (:20) – Discussion on studies and activities planned for 2009-2011 (PAHO) (:25)
15:30 - 16:30	**Access and use of antimalarials** – Progress in activities during the period of 2008–2009 (E. Barillas) (:20) – Examples of activities in the countries during the period of 2008-2009 (:40)
16:30 - 16:45	*Coffee*
16:45 - 17:30	**Access and use of antimalarials** (Continuation) - Concrete problems as regards antimalarial supply during the period of 2008-2009 (Sharing of country experiences) (:05 per country) - Discussion (:20)

Wednesday, 18 March 2009

08:00 - 09:00 **Quality of antimalarials**
- Activities in progress and preliminary results during 2008-2009 (V. Pribluda)
- Discussion

09:00 - 10:30 **Vector control**
- Strategy of targeted vector control and entomological surveillance with standardized parameters during 2008-2009 (:20)
- Monitoring resistance to insecticides (CDC) (:30)
- Discussion (:30)

10:30 – 10:45 *Coffee*

10:45 - 12:30 **Vector control**
- Experiences in the implementation and monitoring of LLINs (:20)
- Evaluation of the effect of LLINs on experimental houses (:15)
- Monitoring of residuals in LLINs (CDC)
- Discussion (:30)

12:30 - 14:00 *Lunch*

14:00 - 14:30 **Access and quality of diagnosis**
- Lines of work in AMI (R. Montoya)
- Discussion

14:30 - 15:15 **Management of epidemiological information**
- Activities in progress and preliminary results during 2008-2009 (G. Bretas)
- Discussion

15:15 - 16:00 **The Roll Back Malaria Initiative and the Global Fund projects**
- Inclusion of AMI approaches and tools in the Projects of the Global Fund for Malaria in the Region (G. Bretas) (:15)
- RBM Initiative and Global Malaria Action Plan (PAHO) (:15)
- Discussion (:15)

16:00 - 16:15 *Coffee*

16:15 - 17:15 **Dissemination of information in AMI (Links Media)**
- Progress (:10)
- Need for dissemination and communication by countries (groupwork) (:35)

Thursday, 19 March 2009

08:30 - 12:30 **Panel on the strategic approach of AMI for the coming years**
- Approach of AMI and RAVREDA regarding epidemiological changes in the Region and the transition toward the status of elimination
  - General considerations (J. Chang) (:20)
  - Surveillance of cases, diagnosis and treatment (active case detection, rational use of RDT versus microscopy) (PAHO) (:15)
  - Vector control (RTI/CDC) (:15)
  - Discussion (:45)
- *Coffee (:15)*
- Need for strengthening of and technical cooperation with Malaria Control Programs in the current epidemiological context:
  - BOL(:10), BRA(:10), COL(:10), ECU(:10)
  - Questions (:15)
  - GUY(:10), PER(:10) y SUR (:10)
  - Questions (:15)
  - Areas for technical cooperation in AMI versus Needs of the countries (Why the difficulties in the institutionalization?) (:10)
  - Discussion (:15)

12:30 - 14:00 *Lunch*

14:00 - 14:45 **Plan of Action in Central America**
- Conclusions of the meeting in El Salvador (PAHO)
- Discussion

14:45 - 15:45 **Incorporation of the agreements of the Meeting into the work plans of AMI 2008-2009**
Work in groups by country (:60)

15:45 - 16:00 Conclusion and closure

Iniciativa Amazónica contra la Malaria (AMI)
Red Amazónica de Vigilancia de la Resistencia a los Antimaláricos (RAVREDA)

VIII Reunión Anual de Evaluación
XIV Reunión del Comité Coordinador de AMI

Bogotá, Colombia
17 al 20 de marzo del 2009

Agenda

Martes, 17 de marzo del 2009

08:30 - 09:00 Inscripción

09:00-09:15 **Instalación de la Reunión**
(Ministerio de la Protección Social de Colombia, Misión de USAID, Representación de OPS/OMS, Área de Vigilancia y Control de Enfermedades de OPS Washington, Coordinación de AMI en USAID)

09:15 - 09:30 **Aportes de AMI y RAVREDA a los esfuerzos de control de la malaria en la Región** (K. Carter)

09:30 - 09:45 Aspectos generales de la Reunión, presentación de participantes (K. Carter)

09:45 - 10:45
- Implicaciones del cambio climático en el control de la malaria en América Latina (conferencia) (S. Connor)
- Experiencias en Colombia (V. Cerón)
- Preguntas

10:45 - 11:00 *Café*

11:00 - 12:30 **Vigilancia de la Resistencia a los Antimaláricos**
- Progresos en 2008
  - Situación de la Red de Vigilancia en 2009 (R. Montoya) (10')
  - Estudios realizados en 2008 (Perú, Suriname, Guyana) (30')
  - Uso de marcadores moleculares: Progresos 2008 y fortalecimiento a capacidad en los países (CDC) (20')
  - Discusión (30')

12:30 - 14:00 *Almuerzo*

14:00 - 15:30 **Vigilancia de la Resistencia a los Antimaláricos** (continuación)
- Actualización sobre situación de monitoreo de resistencia a ACT y recomendaciones para monitoreo en situaciones de baja transmisión (P. Ringwald) (35')
- Preguntas (20')
- Discusión sobre plan de estudios y actividades 2009-2011 (OPS) (25')

15:30 - 16:30 **Acceso y uso de antimaláricos**
- Progresos en actividades durante el periodo 2008 – 2009 (E. Barillas) (20')
- Ejemplos de actividades en los países en el periodo 2008-2009 (40')

16:30 - 16:45 *Café*

16:45 - 17:30 **Acceso y uso de antimaláricos** (Continuación)
- Problemas concretos con relación al suministro de antimaláricos en el periodo 2008-2009 (países desde su lugar en la plenaria exponen) (5' por país)
- Discusión (20')

Mércoles, 18 de marzo del 2009

08:00 - 09:00 **Calidad de antimaláricos**
- Actividades en curso y resultados parciales 2008-2009 (V. Pribluda)
- Discusión

09:00 - 10:30 **Control vectorial**
- Estrategia de focalización del control vectorial y vigilancia entomológica con parámetros estandarizados 2008-2009 (OPS-CDC) (20')
- Vigilancia de la resistencia a los insecticidas (CDC) (30')
- Discusión (30')

10:30 – 10:45 *Café*

10:45 - 12:30 **Control vectorial**
- Experiencias de implementación y monitoreo de LLIN (Brasil, Colombia y CDC) (20')
- Evaluación del efecto de LLINs con casas experimentales (Perú y CDC) (15')
- Monitoreo de la residualidad en LLINs (CDC)
- Discusión (30')

12:30 - 14:00 *Almuerzo*

14:00 - 14:30 **Acceso y calidad del diagnóstico**
- Líneas de trabajo en AMI (R. Montoya)
- Experiencias con control de calidad de lotes de pruebas rápidas (C. Murillo)
- Discusión

14:30 - 15:15 **Manejo de información epidemiológica**
- Actividades en curso y resultados parciales 2008-2009 (G. Bretas)
- Discusión

15:15 - 16:00 **La iniciativa Roll Back Malaria y los Proyectos del Fondo Global**
- Inclusión de abordajes y herramientas de AMI en los Proyectos del Fondo Global para Malaria en la Región (G. Bretas) (15')
- Iniciativa RBM y Global Malaria Action Plan (OPS) (15')
- Discusión (15')

16:00 - 16:15 *Café*

16:15 - 17:15 **Diseminación de información en AMI (links media)**
- Progresos (10')
- Necesidades de diseminación y comunicación por países (trabajo en grupos) (35')

Jueves, 19 de marzo del 2009

08:30 - 12:30 **Panel sobre abordaje estratégico de AMI para los próximos años**

- Enfoque de AMI y RAVREDA frente a los cambios epidemiológicos en la Región y la transición hacia situaciones de eliminación
  - Consideraciones generales (J. Chang) (20')
  - Vigilancia de casos, diagnóstico y tratamiento (búsqueda activa, uso racional de RDT vs. microscopía) (OPS) (15')
  - Control vectorial (RTI/CDC) (15')
  - Discusión (45')
- *Café (15')*
- Necesidades de fortalecimiento y cooperación técnica de los programas de control de malaria en el contexto epidemiológico actual :
  - BOL (10'), BRA(10'), COL(10'), ECU(10'),
  - Preguntas (15')
  - GUY(10'), PER(10') y SUR (10')
  - Preguntas (15')
  - Líneas de cooperación técnica en AMI vs. Necesidades de los países (10')
  - Discusión (15')

12:30 - 14:00 *Almuerzo*

14:00 - 14:45 **Plan de acciones en Centroamérica**

- Conclusiones reunión de El Salvador (OPS)
- Propuestas de otras líneas de trabajo
- Discusión

14:45 - 15:45 **Incorporación de los acuerdos de la Reunión en los planes de trabajo de AMI 2008-2009**

Trabajo en grupos por países (60')

15:45 - 16:00 Conclusiones y clausura

Iniciativa Amazónica contra la Malaria (AMI)
Red Amazónica de Vigilancia de la Resistencia a los Antimaláricos (RAVREDA)

VIII Reunión Anual de Evaluación
XII Reunión del Comité Coordinador de AMI
Bogotá, Colombia
17 al 20 de marzo del 2009

Henry Agudelo Tejada
Unidad Ejecutiva de Saneamiento del Valle
Calle 19 #24B 23
Cali, Colombia
Tel: (57-092) 558-0868 ext. 139
Fax: (57-092) 558-0727
E-mail: hagudelo@uesvalle.gov.co
henryagudelo@graffiti.net

Arletta Añez
OPS/OMS, Bolivia
Calle Víctor Sanjinéz No. 2678
Edificio Torre Barcelona Pisos 1, 6 y 7
Zona Sopocachi, La Paz, Bolivia
Tel: (591-2) 241-1323
Fax: (591-2) 241-2598
Cel: (591) 730-08844
E-mail: aanez@bol.ops-oms.org

Zulma Bejarano Maturama
DASALUD- Chocó
Laboratorio Dept. de Salud Pública (LDSP)
Carrera 8 # 11-109, Barrio Niño Jesús, Sector Cabí
Quibdo, Chocó, Colombia
Tel: (57-946) 720-045/ 719-805
Fax: (57-946) 671-1471
Cel: (57) 310-836-4232
E-mail: zbejarano21@yahoo.es

Edgar Barillas
Strengthening Pharmaceutical Systems (SPS)
Management Sciences for Health
4301 N. Fairfax Dr. Suite 400
Arlington, VA 22203
Tel: (1-703) 248-1611
Fax: (1-703) 524-7898
E-mail: ebarillas@msh.org

Ray Beach
Division of Parasitic Diseases
Centers for Disease Control and Prevention (CDC)
4770 Buford Hwy., NE, MS F-42
Atlanta, GA, 30341
Tel: (1-770) 488-4633
Fax: (1-770) 488-4258
E-mail: rfb1@cdc.gov

Silvia Blair
Universidad de Antioquía
Sede de Investigaciones (SIU), Lab. 610
Calle 62 #52-59
Medellín, Colombia
Tel: (57-4) 219-6487
E-mail: silviablair@gmail.com

Gustavo Bretas
PAHO/WHO Suriname
Burenstraat #33
Paramaribo, Suriname
Telf: (597) 411-892
Fax: (597) 471-568
E-mail: bretasgu@sur.paho.org

Anngie Elisa Caballero Herrera
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (1-301) 987-5495
(51-1)999-59-1827
Fax: (1-301) 987-5498
E-mail: acaballero@linksmedia.net

Florence Camus-Bablon
Drugs for Neglected Diseases *initiative* (DNDi)
15 Chemin Louis-Dunant
Geneva, 1202, Switzerland
Tel: (41-22) 906-9230
E-mail: fcamus@dndi.org

Idelfonso Cepeda
Ministerio de Protección Social
Grupo de Vectores
Carrera 13, # 32-76, Piso 12
Bogotá, Colombia
Tel: (57-1) 330-5000 ext. 1295-1296
E-mail: icepeda@minproteccionsocial.gov.co

Nicolás Cerón
PAHO/WHO, Guyana
Lot 8 Brickdam Stabroek
Georgetown, Guyana
Tel: (59) 225-3000
Fax: (59) 226-6654
E-mail: ceronnic@guy.paho.org

Viviana Cerón Rodríguez
Instituto Nacional de Salud
Subdirección Vigilancia y Control
Avenida El Dorado # 50-61
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 543
Fax: (57-1) 220-0901
E-mail: vceron@ins.gov.co

Adeline Chan
Centers for Disease Control and Prevention
Entomology Branch, Division of Parasitic Diseases
4770 Buford Highway, MS F-42
Atlanta, GA 30345
Tel: (1-770) 488-4987
Fax: (1-770) 488-4258
E-mail: AChan@cdc.gov

Jaime Chang Neyra
USAID/Perú
Oficina de Salud
Av. La Encalada cuadra 17 s/n, Lima 33, Perú
Tel: (51-1) 618-1266
Fax: (51-1) 618-1350
E-mail: jachang@usaid.gov

Pablo E. Chaparro Narváez
Instituto Nacional de Salud
Avenida El Dorado 51-20
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 308
Fax: (57-1) 220-7700 ext. 323
E-mail: pchaparro@ins.gov.co
pechaparro@yahoo.es

Stephen Connor
PAHO/WHO Collaborating Centre on Climate Sensitive Diseases.
International Research Institute for Climate and Society
The Earth Institute at Columbia University
Lamont Campus, Palisades, 10964 NY, USA
Tel: (1-845) 680-4458
Fax: (1-845) 680-4564
E-mail: sjconnor@iri.columbia.edu

Liliana Jazmín Cortés
Instituto Nacional de Salud
Departamento de Parasitología
Avenida calle 26 No. 51-20 - Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 454-455
Fax: (57-1) 220-0901
E-mail: jcortes@ins.gov.co

Freddy Córdoba Rentería
DASALUD- Chocó
Carrera 7 #26-87
Quibdo, Chocó, Colombia
Tel: (57-946) 711-410
E-mail: frecorea04@gmail.com
Freddycordoba2004@yahoo.com.mx

Andrés Cuervo Hernández
Org. Andino de Salud – Colombia
PAMAFRO
Carrera 48 #118 – 21 Alambra
Bogotá, D.C. Colombia
Tel: (57-1) 213-9675/ 609-8282
E-mail: lcuervo@conhu.org.pe
lcuervo@hotmail.com

Carmen Elizabeth Cruz Gamboa
Ministerio de Salud
Dirección General de Salud Ambiental (DIGESA)
Calle Amapolas N° 350, Urb. San Eugenio, Lince
Lima, Peru
Tel: (51-1) 442-8353 ext. 143
Fax: (51-1) 440-2333
E-mail: ccruzg@digesa.minsa.gob.pe
ccgsalud@yahoo.es

Andre Bastos Daher
Farmanguinhos/FIOCRUZ
Ensayos Clínicos
Av. Comandante Guaranis 447, Jacarapaguá
Rio de Janeiro, Brasil, 22775-610
Tel: (55-21) 3348-5019
E-mail: andredaher@gmail.com

Erico Daemon De Oliveira
Farmanguinhos/FIOCRUZ
VDOP (Vicerrectoría de Operaciones)
Av. Comandante Guaranis 447, Jacarapaguá
Rio de Janeiro, Brasil, 22775-610
Tel: (55-21) 3348-5316
E-mail: edaemon@far.fiocruz.br

Silvia P. Díaz Mosquera
DASALUD Chocó
Laboratorio Departamental de Salud Pública (LDSP)
Carrera 8 # 11-109, Barrio Niño Jesús, Sector Cabi
Quibdó, Chocó, Colombia
Tel: (57-946) 671-9805/ 672-0045
Fax: (57-946) 671-1471
Cel: (57) 3104-7025-03
E-mail: entochoco@yahoo.es
entochoco@hotmail.com

Humberto Escobar Doncel
Secretaría de Salud del Valle del Cauca
Carrera 80 #5-220
Cali, Valle del Cauca, Colombia
Tel: (57-092) 620-0000 ext. 1660
Fax: (57-092)886-0180
E-mail: hescobar@valledelcauca.gov.co

José Pablo Escobar
OPS/OMS, Colombia
Carrera 7 Nr. 74-21, Piso 9
Edificio Seguros Aurora
Bogotá, D.C., Colombia
Tel: (57-1) 314-4141
Fax: (57-1) 254-7070
Cel: (57) 315-35-65-193
E-mail: pescobar@col.ops-oms.org

Armando Galeano Marín
Gobernación Antioquia
Calle 42 B # 52-106, Piso 8
Oficina 816
Medellín, Colombia
Tel: (57-4) 389-879
E-mail: agaleano@gobant.gov.co

Nora Girón
OPS/OMS, Honduras
Oficina Sanitaria Panamericana
Edificio Imperial
6o.y 7o.piso
Avenida República de Panamá
Tegucigalpa, M.D.C., Honduras
Tel: (504) 221-6091
Fax: (504) 221-6098
E-mail: gironn@hon.ops-oms.org

Michael D. Green
Division of Parasitic Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop F12
Atlanta, GA 30333
Tel: (1-770) 488-4039
Fax: (1-770) 488-4108
E-mail: mdg4@cdc.gov

Yeni Otilia Herrera Hurtado
Ministerio de Salud
Dirección General de Salud de las Personas
Ave. Salaverry 801, Jesús Maria, Lima, Perú
Tel: (51-1) 315-6600 Ext. 2506
Fax: (51-1) 315-6600 Ext. 2553
E- mail: yherrerah@minsa.gob.pe
yherrerah@gmail.com

Yenifer Hinestroza
MSH/SPS
4301 N. Fairfax Dr.
Arlington, VA 22203
Tel: (1-703) 524-6575
Fax: (1-703) 524-7898
E-mail: yeniferhc@hotmail.com

José Lázaro de Brito Ladislau
Programa Nacional de Controle da Malária
Secretaria de Vigilancia em Saúde
Ministério da Saúde
Ed. Sede, Bloco G, sobreloja sala 151
Brasília, Brasil, 70058-900
Tel: (55- 61) 3315-3277
Fax: (55- 61) 3315-3277
E-mail: Jose.ladislau@saude.gov.br

Yolanda L. López Arango
Universidad de Antioquía
Facultad de Salud Pública
Calle 62 #52-59, Of. 315
Medellín, Colombia
Tel: (57-4) 219-6869
Fax: (57-4) 511-2506/219-6850
Cel: (57)300-787-5604
E-mail: yola@guajiros.udea.edu.co

Lisardo Osorio Quintero
Universidad de Antioquía
Facultad de Salud Pública
Calle 62 #52-59, Of. 302
Medellín, Antioquía, Colombia
Tel: (57-4) 219-6854
Fax: (57-4) 511-2506
Cel: (57) 311-723-8098
E-mail: lisardoq@guajiros.udea.edu.co

Ligia Lugo Vargas
Grupo de Entomología
Calle 26 No. 51-20 - Zona 6 CAN
Bogotá, D.C., Colombia
Tel: (57-1) 220-7700 ext. 486
Fax: (57-1) 220-0923
E-mail: llugo@ins.gov.co

Alexandre Macedo de Oliveira
Malaria Branch, Division of Parasitic Diseases
Centers for Disease Control and Prevention
4770 Buford Hwy, MS F-22
Building 102, Room 1507
Atlanta, GA 30341
Tel: (1-770) 488-7747
Fax: (1-770) 488 7761
E-mail: acq7@cdc.gov

Cynthia Malacarne Ribeiro
Farmanguinhos/FIOCRUZ
International Affairs
Av. Comandante Guaranis 447, Jacarapaguá
Rio de Janeiro, Brasil, 22775-610
Tel: (55-21) 3348-5081 / 7617-2982
E-mail: cmalacarne@far.fiocruz.br

Gilma C. Mantilla
International Research Institute for Climate and Society
The Earth Institute at Columbia University
Lamont Campus, Palisades, 10964 NY, USA
Tel: (845) 680-4501
Fax: (845) 680-4864
E-mail: mantilla@iri.columbia.edu

Peg Marshall
USAID
LAC/RSD-PHN 5.9-110
1300 Pennsylvania Ave. NW
Washington, D.C. 20523-5900, USA
Tel: (1-202) 712-4062
Fax: (1-202) 216-3262
E-mail: pemarshall@usaid.gov

Daniel Mechali
Drugs for Neglected Diseases Initiative (DNDi)
Rua Santa Heloisa 05
Rio de Janeiro, Brasil
Tel: (55-21) 2215-2941
E-mail: danimechali@hotmail.com

Oscar Martin Mesones Lapouble
Programa Nacional de Controle da Malária
Secretaria de Vigilancia em Saúde
Ministério da Saúde
Ed. Sede, Bloco G, sobreloja sala 151
Brasília, Brasil, 70058-9000
Tel: (55-61) 3315-3353/8134-6478
Fax: (55-61) 3315-3277
E-mail: oscar.lapouble@saude.gov.br
lapouble@gmail.com

Yolanda Mosquera
Instituto Nacional de Salud
Avenida calle 26 No. 51-20 - Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220 7700
Fax: (57-1) 220 0901
Webmaster: portal_ins@ins.gov.co

Claribel Murillo
Centro Int. de Entrenamiento e Inv. Médicas (CIDEIM)
Carrera 125 #19-225
Cali, Valle, Colombia
Tel: (57-2)555-2164
Cel: (57) 300-790-1057
E-mail: claribel_murillo@cideim.org.co
clarms76@gmail.com

Norma Padilla
Unidad de Malaria y Biología de Vectores
Centro de Estudios en Salud
Univiversidad del Valle de Guatemala
18 Avenida 11-95, Zona 15, Vista Hermosa III
Guatemala, Guatemala
Tel: (502) 2329-8451
Fax: (502) 2369-7539
E-mail: npadilla@gt.cdc.gov

Miriam Palomino Salcedo
Instituto Nacional de Salud
Centro Nacional de Salud Pública
Av. Defensores del Morro 2268, Chorrillos
Lima, Perú
Tel: (51-1) 251-6151/(51-1) 467-6696 Ext: 548
Fax: (51-1) 251-6151 ext. 541
E-mail: mpalomino@ins.gob.pe
mpalominosal@yahoo.es

Dayanand Panchoe
Ministry of Health
Bureau of Public Health (BOG)
Rode Kruislaan #13
Paramaribo, Suriname
Tel: (597) 033-1236
E-mail: shir.1995@hotmail.com

Angélica Pérez
Strengthening Pharmaceutical Systems (SPS)
Management Sciences for Health
4301 N. Fairfax Dr. Suite 400
Arlington, VA 22203
Tel: (703) 310-3516
Fax: (703) 524-7898
E-mail: aperez@msh.org

Pilar Pérez Cortés
Instituto Departamental de Salud -Nariño
Programa de Control de ETV
Calle del Comercio # 11-116
Tumaco, Nariño, Colombia
Tel: (57-2) 727-2363 / 727-1817
E-mail: pperez@idsn.gov.co
pilarperez37@gmail.com

Gabriel F. Ponce de León
Centers for Disease Control and Prevention
Malaria Branch
4770 Buford Highway MS F-22
Atlanta, GA 30341
Tel: (770) 488-7141
Fax: (770) 488-7761
Email: gcp1@cdc.gov

Alexandra Porras Ramírez
Fondo Global Malaria
Universidad Nacional de Colombia
Facultad de Medicina
Carrera 45 # 26-85
Bogotá, Colombia
Tel: (57-1) 316-5000 ext. 15087
Email: porras.alexandra@gmail.com

Marinete Marins Póvoa
Instituto Evandro Chagas/SVS/MS
Seção de Parasitologia
Rodovia BR-316, Km 7, s/n
67.030-000 - Levilândia
Ananindeua – Pará, Brasil, 67030-000
Tel: (55-91) 3214-2148
Fax:(5591) 3214 2043
E-mail: marinetepovoa@iec.pa.gov.br
pepovoa@amazon.com.br

Victor S. Pribluda
United States Pharmacopeia/Drug Quality and Information Program (USP/DQI)
Latin American Programs
12601 Twinbrook Parkway
Rockville, MD, 20852
Tel: (1-301) 816-8258
Fax: (1-301) 816-8374
E-mail: vsp@usp.org

Martha Lucía Quiñonez Pinzón
Universidad Nacional de Colombia
Departamento Salud Pública
Carrera 30 #45-03, Ciudadela Universitaria
Bogotá, D.C., Colombia
Tel: (57-1) 316-5000 ext. 15078
E-mail: mlquinonesp@unal.edu.co
marthalquinones@gmail.com

Maria Recio
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (1-301) 987-5495
Mov: (1-301) 875-4655
Fax: (1-301) 987-5498
E-mail: mrecio@linksmedia.net

Gabriela Rey Vega
Instituto Nacional de Salud
Calle 26# 51A-20, Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220-7700/ 220-0293 ext. 486
Fax: (57-1) 220-0293
E-mail: reyveo@hotmail.com

Célia Riera Betancourt
OPS/OMS, Ecuador
Subsede Guayaquil
Calle Chile y Olmedo
Guayaquil, Guayas, Ecuador
Tel: (593-4) 2511-707/2511-711
Cel: (593) 9888-6260
E-mail: celriera@ecu.ops-oms.org

Alejandro Rico Mendoza
Univ. Nacional de Colombia
Facultad de Medicina
Carrera 45 # 26-85
Bogotá, Colombia
Tel: (57-1) 316-5000 ext. 15086-87
E-mail: faricom@unal.edu.co
aricomendoza@gmail.com

Angel Rosas Aguirre
Organismo Andino de Salud, Convenio Hipólito Unanue (ORAS-CONHU)
Proyecto PAMAFRO
Av. Paseo de la República 3832- San Isidro, 5to Piso
Lima, Perú
Tel: (511) 611-3700 ext. 503 / (511) 221-0074
Fax: (511) 611-3700 ext. 514
Cel: (511) 989-583-436
E-mail: arosas@conhu.org.pe

Sandra Ximena Rodríguez Delgado
Departamento de Salud del Chocó
Barrio Medrano, Calle 18 # 4-46
Quibdo, Chocó, Colombia
Tel: (57-946) 711-471
Fax: (57-946) 714-460
Cel: (57) 312-268-7979
E-mail: sandraxrd@hotmail.com

Roberto Sáenz Gómez
Instituto Nacional de Salud
Subdirección de Vigilancia y Control en Salud Pública
Avenida El Dorado 51-20
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 314
Fax: (57-1) 220-7700 ext. 323
Cel: (57) 311-263-6531
E-mail: rsaenz@ins.gov.co
roberto_saenz_g@yahoo.com

Marisabel Sánchez
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (301) 987-5497
Fax: (301) 987-5498
E-mail: msanchez@linksmedia.net

Liliana Santacoloma U.
Instituto Nacional de Salud
Laboratorio de Entomología
Calle 26 # 51-20, Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 4291
E-mail: lsantacoloma@ins.gov.co

Mercy Silva Bravo
Servicio Nal. de Erradicación de la Malaria (SENM)
Calle Tarqui N.1319 entre Boyaca y Guabo
Machala, Ecuador
Tel: (593-7) 293-1239
Fax: (593-7) 293-7747
E-mail: msilvab@hotmail.com
mercysilva@hotmail.com

Ana Carolina Faria e Silva Santelli
OPS/OMS, Brasil
Setor de Embaixadas Norte, Lote 19
70800-400 - Brasilia, D.F., Brasil
Tel:(55-61) 3251-9595 / 3251-9594
Fax: (55-61) 3251-9591
E-mail: santelan@bra.ops-oms.org

Mario Valcárcel
OPS/OMS, Perú
Oficina Sanitaria Panamericana
Los Pinos 251
Urbanización Camacho
La Molina, Lima 12, Perú
Tel: (51) 319-5700
Fax: (51) 437-3640
E-mail: mvalcarc@per.ops-oms.org

Venkatachalam Udhayakumar
Genetics and Immunology Lab
Malaria Branch
Centers for Disease Control and Prevention
Malaria Branch, Division of Parasitic Diseases
4770 Buford Highway
Atlanta, GA 30341, USA
Tel: (770) 488-4047
Fax: (770) 488-4454
E-mail: vxu0@cdc.gov

Raul Veloz Pérez
Ministerio de Salud Pública
Servicio Nal. de Control de la Malaria (SNEM)
Calle José Mascote y Julián Coronel, s/n
Guayaquil, Ecuador
Telefax: (593-4) 228-9874
E-mail: rvelozpe@hotmail.com

Luz Inés Villarreal
Ministerio de la Protección Social
Carrera 13 #32-76, Piso 12
Bogotá, D.C., Colombia
Tel: (57-1) 337-0857/ 330-5000 ext. 1400
E-mail: lbichos@yahoo.com

Stephen Vreden
Academic Hospital Paramaribo
Van Brussellaan 23
Paramaribo, Suriname
Tel: (597) 430-051
Cel: (597) 880-7151
E-mail: vredpeet@cq-link.sr

Pilar Zambrano
Instituto Nacional de Salud
Avenida calle 26 No. 51-20 - Zona 6 CAN
Bogotá, Colombia
Tel: (571) 220-7700
Fax: (571) 220-0901
Webmaster: portal_ins@ins.gov.co

Secretariat

Pier Paolo Balladelli
Representante OPS/OMS, Colombia
Carrera 7 Nr. 74-21, Piso 9
Edificio Seguros Aurora
Santafé de Bogotá, D.C., Colombia
Tel: (57-1) 314-4141
Fax: (57-1) 254-7070

Keith Carter
Asesor Regional en Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel. (202) 974-3843
E-mail: carterke@paho.org

María Claure
Programa Regional de Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel: (1-202) 974-3381
E-mail: claurema@paho.org

Rainier Escalada
Programa Regional de Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel: (202) 974-3532
E-mail: escaladr@paho.org

Karim Pardo
Programa Regional de Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel: (202) 974-3678
E-mail: pardokar@paho.org

Roberto Montoya
Coordinador RAVREDA
OPS/OMS Brasil
Setor de Embaixadas Norte, Lote 19
70800-400 - Brasilia, D.F., Brasil
E-mail: montoyar@col.ops-oms.org

Zoraida Sandoval
OPS/OMS, Colombia
Carrera 7 Nr. 74-21, Piso 9
Edificio Seguros Aurora
Bogotá, D.C., Colombia
Tel: (57-1) 314-4141
Fax: (57-1) 254-7070
E-mail: zoraida@col.ops-oms.org

Iniciativa Amazónica contra la Malaria (AMI)
Red Amazónica de Vigilancia de la Resistencia a los Antimaláricos (RAVREDA)

XII Reunión del Comité Coordinador de AMI

Bogotá, Colombia
20 de marzo del 2009

Edgar Barillas
Strengthening Pharmaceutical Systems (SPS)
Management Sciences for Health
4301 N. Fairfax Dr. Suite 400
Arlington, VA 22203
Tel: (1-703) 248-1611
Fax: (1-703) 524-7898
E-mail: ebarillas@msh.org

Ray Beach
Division of Parasitic Diseases
Centers for Disease Control and Prevention (CDC)
4770 Buford Hwy., NE, MS F-42
Atlanta, GA, 30341
Tel: (1-770) 488-4633
Fax: (1-770) 488-4258
E-mail: rfb1@cdc.gov

Gustavo Bretas
PAHO/WHO Suriname
Burenstraat #33
Paramaribo, Suriname
Telf: (597) 411-892
Fax: (597) 471-568
E-mail: bretasgu@sur.paho.org

Anngie Elisa Caballero Herrera
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (1-301) 987-5495
(51-1)999-59-1827
Fax: (1-301) 987-5498
E-mail: acaballero@linksmedia.net

Idelfonso Cepeda
Ministerio de Protección Social
Grupo de Vectores
Carrera 13, # 32-76, Piso 12
Bogotá, Colombia
Tel: (57-1) 330-5000 ext. 1295-1296
E-mail: icepeda@minproteccionsocial.gov.co

Nicolás Cerón
PAHO/WHO, Guyana
Lot 8 Brickdam Stabroek
Georgetown, Guyana
Tel: (59) 225-3000
Fax: (59) 226-6654
E-mail: ceronnic@guy.paho.org

Viviana Cerón Rodríguez
Instituto Nacional de Salud
Subdirección Vigilancia y Control
Avenida El Dorado # 50-61
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 543
Fax: (57-1) 220-0901
E-mail: vceron@ins.gov.co

Adeline Chan
Centers for Disease Control and Prevention
Entomology Branch, Division of Parasitic Diseases
4770 Buford Highway, MS F-42
Atlanta, GA 30345
Tel: (1-770) 488-4987
Fax: (1-770) 488-4258
E-mail: AChan@cdc.gov

Jaime Chang Neyra
USAID/Perú
Oficina de Salud
Av. La Encalada cuadra 17 s/n, Lima 33, Perú
Tel: (51-1) 618-1266
Fax: (51-1) 618-1350
E-mail: jachang@usaid.gov

José Pablo Escobar
OPS/OMS, Colombia
Carrera 7 Nr. 74-21, Piso 9
Edificio Seguros Aurora
Bogotá, D.C., Colombia
Tel: (57-1) 314-4141
Fax: (57-1) 254-7070
Cel: (57) 315-35-65-193
E-mail: pescobar@col.ops-oms.org

Nora Girón
OPS/OMS, Honduras
Oficina Sanitaria Panamericana
Edificio Imperial
6o.y 7o.piso
Avenida República de Panamá
Tegucigalpa, M.D.C., Honduras
Tel: (504) 221-6091
Fax: (504) 221-6098
E-mail: gironn@hon.ops-oms.org

Yenifer Hinestroza
MSH/SPS
4301 N. Fairfax Dr.
Arlington, VA 22203
Tel: (1-703) 524-6575
Fax: (1-703) 524-7898
E-mail: yeniferhc@hotmail.com

José Lázaro de Brito Ladislau
Programa Nacional de Controle da Malária
Secretaria de Vigilancia em Saúde
Ministério da Saúde
Ed. Sede, Bloco G, sobreloja sala 151
Brasília, Brasil, 70058-900
Tel: (55- 61) 3315-3277
Fax: (55- 61) 3315-3277
E-mail: Jose.ladislau@saude.gov.br

Alexandre Macedo de Oliveira
Malaria Branch, Division of Parasitic Diseases
Centers for Disease Control and Prevention
4770 Buford Hwy, MS F-22
Building 102, Room 1507
Atlanta, GA 30341
Tel: (1-770) 488-7747
Fax: (1-770) 488 7761
E-mail: acq7@cdc.gov

Peg Marshall
USAID
LAC/RSD-PHN 5.9-110
1300 Pennsylvania Ave. NW
Washington, D.C. 20523-5900, USA
Tel: (1-202) 712-4062
Fax: (1-202) 216-3262
E-mail: pemarshall@usaid.gov

Oscar Martin Mesones Lapouble
Programa Nacional de Controle da Malária
Secretaria de Vigilancia em Saúde
Ministério da Saúde
Ed. Sede, Bloco G, sobreloja sala 151
Brasília, Brasil, 70058-9000
Tel: (55-61) 3315-3353/8134-6478
Fax: (55-61) 3315-3277
E-mail: oscar.lapouble@saude.gov.br
lapouble@gmail.com

Yolanda Mosquera
Instituto Nacional de Salud
Avenida calle 26 No. 51-20 - Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220 7700
Fax: (57-1) 220 0901
Webmaster: portal_ins@ins.gov.co

Claribel Murillo
Centro Int. de Entrenamiento e Inv. Médicas (CIDEIM)
Carrera 125 #19-225
Cali, Valle, Colombia
Tel: (57-2)555-2164
Cel: (57) 300-790-1057
E-mail: claribel_murillo@cideim.org.co
clarms76@gmail.com

Norma Padilla
Unidad de Malaria y Biología de Vectores
Centro de Estudios en Salud
Univiversidad del Valle de Guatemala
18 Avenida 11-95, Zona 15, Vista Hermosa III
Guatemala, Guatemala
Tel: (502) 2329-8451
Fax: (502) 2369-7539
E-mail: npadilla@gt.cdc.gov

Angélica Pérez
Strengthening Pharmaceutical Systems (SPS)
Management Sciences for Health
4301 N. Fairfax Dr. Suite 400
Arlington, VA 22203
Tel: (703) 310-3516
Fax: (703) 524-7898
E-mail: aperez@msh.org

Gabriel F. Ponce de León
Centers for Disease Control and Prevention
Malaria Branch
4770 Buford Highway MS F-22
Atlanta, GA 30341
Tel: (770) 488-7141
Fax: (770) 488-7761
Email: gcp1@cdc.gov

Victor S. Pribluda
United States Pharmacopeia/Drug Quality and Information Program (USP/DQI)
Latin American Programs
12601 Twinbrook Parkway
Rockville, MD, 20852
Tel: (1-301) 816-8258
Fax: (1-301) 816-8374
E-mail: vsp@usp.org

Maria Recio
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (1-301) 987-5495
Mov: (1-301) 875-4655
Fax: (1-301) 987-5498
E-mail: mrecio@linksmedia.net

Gabriela Rey Vega
Instituto Nacional de Salud
Calle 26# 51A-20, Zona 6 CAN
Bogotá, Colombia
Tel: (57-1) 220-7700/ 220-0293 ext. 486
Fax: (57-1) 220-0293
E-mail: reyveo@hotmail.com

Célia Riera Betancourt
OPS/OMS, Ecuador
Subsede Guayaquil
Calle Chile y Olmedo
Guayaquil, Guayas, Ecuador
Tel: (593-4) 2511-707/2511-711
Cel: (593) 9888-6260
E-mail: celriera@ecu.ops-oms.org

Sandra Ximena Rodríguez Delgado
Departamento de Salud del Chocó
Barrio Medrano, Calle 18 # 4-46
Quibdo, Chocó, Colombia
Tel: (57-946) 711-471
Fax: (57-946) 714-460
Cel: (57) 312-268-7979
E-mail: sandraxrd@hotmail.com

Roberto Sáenz Gómez
Instituto Nacional de Salud
Subdirección de Vigilancia y Control en Salud Pública
Avenida El Dorado 51-20
Bogotá, Colombia
Tel: (57-1) 220-7700 ext. 314
Fax: (57-1) 220-7700 ext. 323
Cel: (57) 311-263-6531
E-mail: rsaenz@ins.gov.co
roberto_saenz_g@yahoo.com

Marisabel Sánchez
Links Media
707 Conservation Lane, Suite 300
Gaithersburg, MD 20878
Tel: (301) 987-5497
Fax: (301) 987-5498
E-mail: msanchez@linksmedia.net

Mercy Silva Bravo
Servicio Nal. de Erradicación de la Malaria (SENM)
Calle Tarqui N.1319 entre Boyaca y Guabo
Machala, Ecuador
Tel: (593-7) 293-1239
Fax: (593-7) 293-7747
E-mail: msilvab@hotmail.com
mercysilva@hotmail.com

Ana Carolina Faria e Silva Santelli
OPS/OMS, Brasil
Setor de Embaixadas Norte, Lote 19
70800-400 - Brasilia, D.F., Brasil
Tel:(55-61) 3251-9595 / 3251-9594
Fax: (55-61) 3251-9591
E-mail: santelan@bra.ops-oms.org

Mario Valcárcel
OPS/OMS, Perú
Oficina Sanitaria Panamericana
Los Pinos 251
Urbanización Camacho
La Molina, Lima 12, Perú
Tel: (51) 319-5700
Fax: (51) 437-3640
E-mail: mvalcarc@per.ops-oms.org

Raul Veloz Pérez
Ministerio de Salud Pública
Servicio Nal. de Control de la Malaria (SNEM)
Calle José Mascote y Julián Coronel, s/n
Guayaquil, Ecuador
Telefax: (593-4) 228-9874
E-mail: rvelozpe@hotmail.com

Luz Inés Villarreal
Ministerio de la Protección Social
Carrera 13 #32-76, Piso 12
Bogotá, D.C., Colombia
Tel: (57-1) 337-0857/ 330-5000 ext. 1400
E-mail: lbichos@yahoo.com

Keith Carter
Asesor Regional en Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel. (202) 974-3843
E-mail: carterke@paho.org

María Claure
Programa Regional de Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel: (1-202) 974-3381
E-mail: claurema@paho.org

Rainier Escalada
Programa Regional de Malaria
Organización Panamericana de la Salud
Prevención y Control de Enfermedades
Transmisibles
525 23rd St. N.W.
Washington, D.C., 20037, USA
Tel: (202) 974-3532
E-mail: escaladr@paho.org

Roberto Montoya
Coordinador RAVREDA
OPS/OMS Brasil
Setor de Embaixadas Norte, Lote 19
70800-400 - Brasilia, D.F., Brasil
E-mail: montoyar@col.ops-oms.org

U.S. PHARMACOPEIA
DRUG QUALITY AND INFORMATION PROGRAM

VIII Reunión Anual de AMI / RAVREDA

Bogotá, Colombia ◆ 17 al 19 de Marzo, 2009

Acceso y Uso de Medicamentos: Aseguramiento y Control de Calidad

Víctor S. Pribluda, Ph.D.

Gestor de Programas en América Latina

Farmacopea de los Estados Unidos de América

Programa de Información y Calidad de Medicamentos

USAID
FROM THE AMERICAN PEOPLE

Resumen de la Presentación

USP Drug Quality and Information Program

- Fortalecimiento de sistemas de calidad
- Institucionalización de un enfoque de tres niveles para el control de calidad
- Resultados de MiniLabs y próximos estudios

USAID
FROM THE AMERICAN PEOPLE

Fortalecimiento de sistemas de calidad

¿Hay un enfoque diferente para aseguramiento y control de calidad (AC/CC) en condiciones de alta y baja transmisión?

El mismo enfoque con énfasis en diferentes procesos

Fortalecimiento de sistemas de calidad

USP Drug Quality and Information Program

¿Dónde es crítico el AC/CC?

- Pre-dispensación
  - Registro
  - Adquisición
  - Almacenamiento/Transporte
- Durante dispensación
  - Control y vigilancia en el mercado

¿Cómo se logra?

- 1ra Etapa: Fortalecimiento Institucional
- 2da Etapa: Asegurar sostenibilidad

USAID
FROM THE AMERICAN PEOPLE

1ra Etapa: Fortalecimiento institucional

USP Drug Quality and Information Program

- Capacitación de Recursos Humanos
- Mejoramiento de Sistemas
  - Laboratorios Oficiales de Control de Medicamentos (LOCMs)
    - Pruebas Analíticas
    - Métodos Compendiales
    - Buenas Prácticas de Laboratorio
  - Programas Nacionales de Control de Malaria
    - Metodología de muestreo
    - Pruebas básicas con Minilabs®

USAID
FROM THE AMERICAN PEOPLE

1ra Etapa: Fortalecimiento institucional

- Capacitación de Recursos Humanos
  - OPS; OPS/USP; USP DQI (AMI y SAIDI)
  - Minilabs® operan en todos los países
  - Personal de todos los OMCLs capacitados en BPL y metodologías analíticas
    - In situ: Bolivia, Colombia, Ecuador, Perú, Guyana

      Brasil: OMCL y LACENs (2009)

1ra Etapa: Fortalecimiento institucional

- Mejoramiento de Sistemas
  - OPS/USP: BPL – Normativas OMS
  - USP DQI: Normativas OMS e ISO 17025
    - OMCLs Bolivia y Perú
      - CNCC recomendación ISO 17025
    - Pasantías en USP: Perú y Colombia
      Guatemala y Guyana (2009)

2da Etapa: Asegurar sostenibilidad

USP Drug Quality and Information Program

- Implementación e institucionalización de procesos
- Colaboraciones Sur-Sur

USAID
FROM THE AMERICAN PEOPLE

2da Etapa: Asegurar sostenibilidad

- Mejoramiento de procesos y procedimientos de suministro y AC/CC
  - MSH SPS/OPS/USP DQI: Talleres en Colombia (AMI) y Guatemala (AC)
  - Colaboraciones Sur-Sur
    - OPS/USP DQI: Taller de LOCMs en AMI (2009)
- Propuesta para la Institucionalización de Pruebas Básicas

Enfoque de Tres Niveles en el Marco de AC

USP Drug Quality and Information Program

Atributos Críticos de Calidad:

- Etiquetado y Empaque
- Identidad
- Ensayo/Valoración
- Desintegración
- Impurezas
- Disolución
- Uniformidad
- Esterilidad

USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles en el Marco de AC

USP Drug Quality and Information Program

Nivel	Análisis	Pruebas	Objetivo	Sitio/Personal responsable del análisis
1	Inspección Visual y Física	Visuales: - Propiedades del etiquetado y el envase Físicas: - Aspecto, condiciónes características físicas del Medicamento	- Información insuficiente errónea y/o fraudulenta - Envase dañado - Daños y/o alteraciones del medicamento	Gerentes de CC en cada etapa del ciclo de vida del medicamento
2	Pruebas Básicas de Laboratorio	- Desintegración - Cromatografía de Capa Delgada	Cuatro atributos críticos de calidad - Identidad - Contenido - Impurezas - Desintegración	Gerente del Minilab® LOCM
3	Pruebas Compendiales	De acuerdo a: - Especificaciones del registro - Especificación farmacopeicas	Todos los atributos críticos de calidad	LOCM

Enfoque de Tres Niveles en el Marco de AC

USP Drug Quality and Information Program

Atributos Críticos de Calidad:

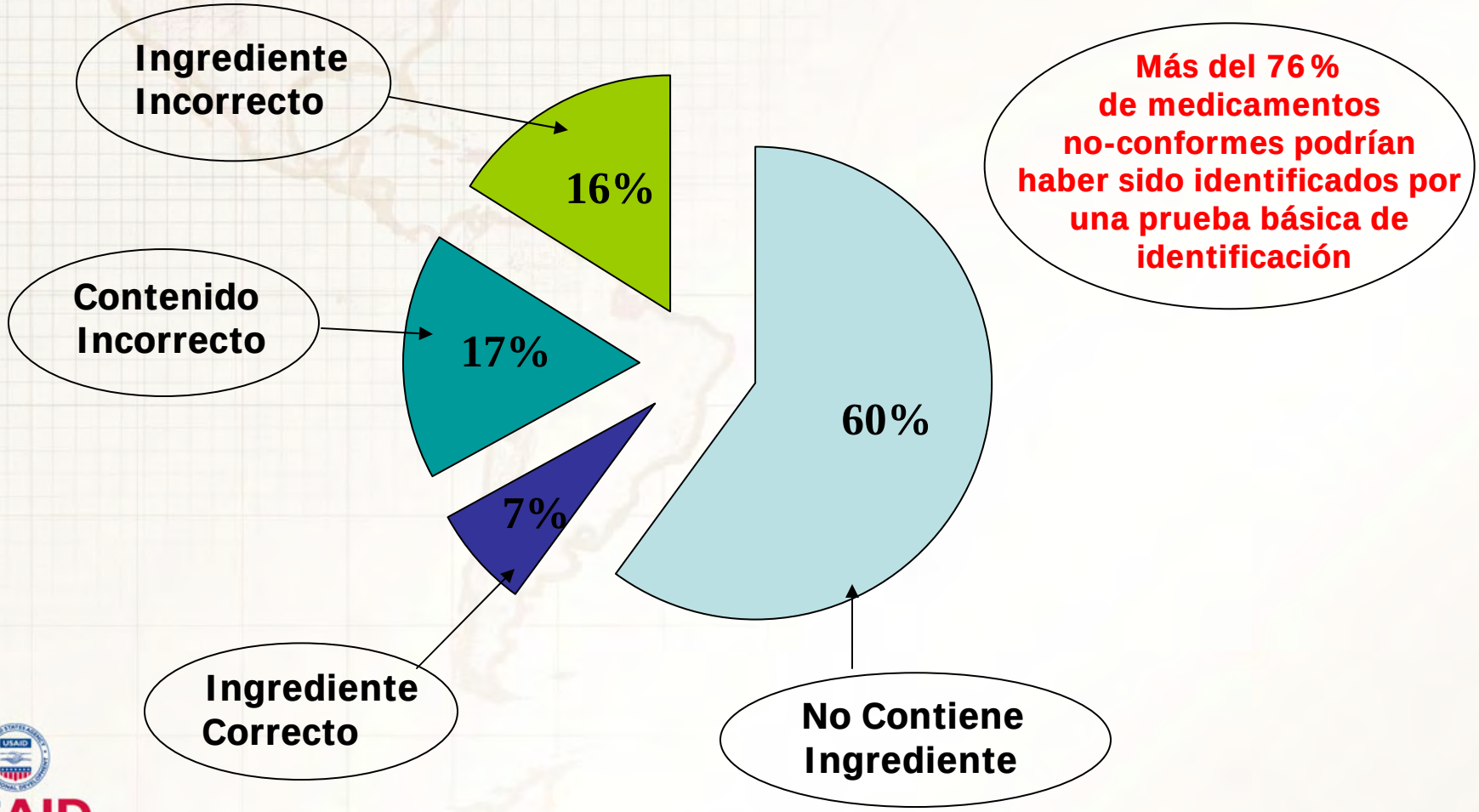
Etiquetado y Empaque	1
Identidad Ensayo/Valoración Desintegración Impurezas	2
Disolución Uniformidad Esterilidad	3

USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles en el Marco de AC

USP Drug Quality and Information Program

Causas de No-conformidades



USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles en el Marco de AC

Limitaciones de LOCMs

- Infrastructura y Equipo
- Material de Consumo
- Personal Calificado
- Recursos Financieros
- Retorno de Resultados
- Ubicación Centralizada

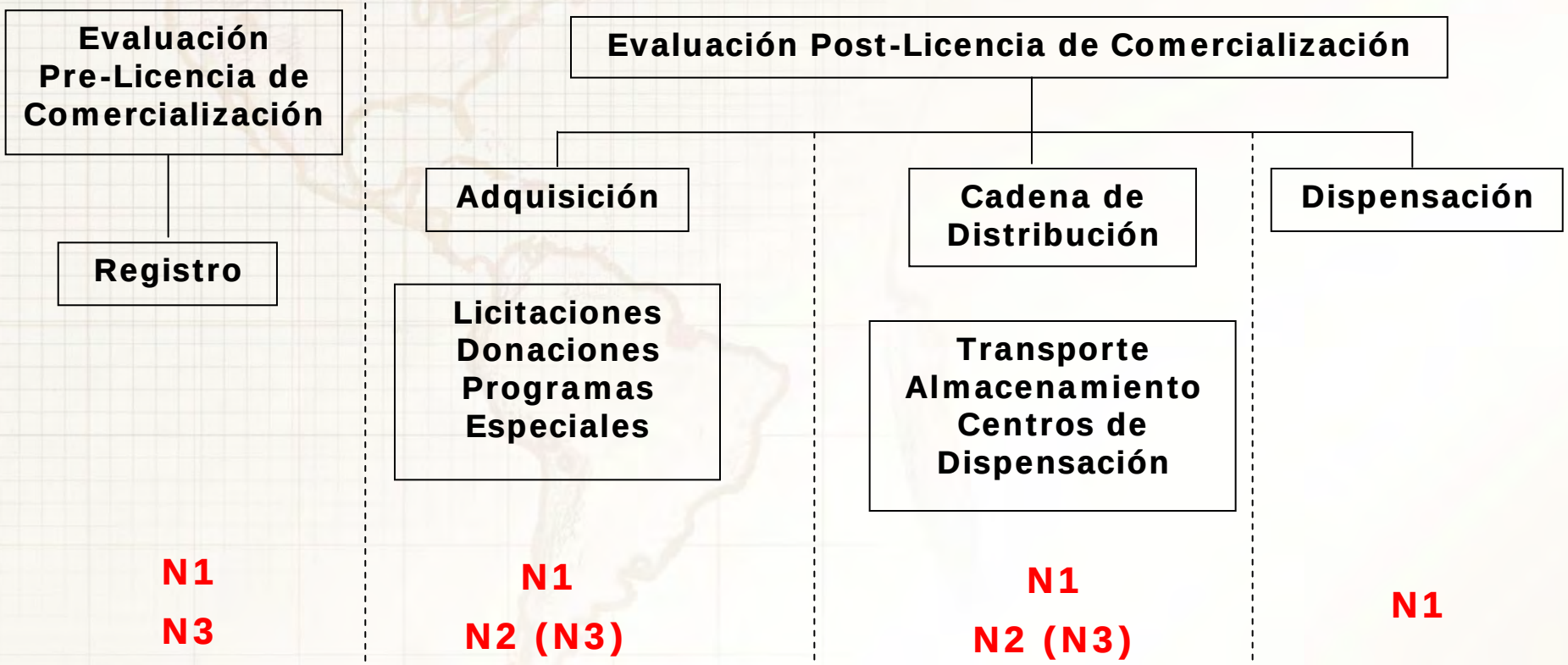
Enfoque de Tres Niveles en el Marco de AC

Ventajas de los Minilabs® – Pruebas Básicas

- Identificación de Medicamentos de Mala Calidad
- Resultados Confiables
- Ventajas de Recursos Humanos
- Alta Capacidad de Retorno de Resultados
- Mínima Infrastructura Necesaria
- Capacidad de Analizar Rango Amplio de Indicaciones Terapéuticas
- Ventajas Financieras: Bajo Costo de Adquisición y Mantenimiento

Enfoque de Tres Niveles en el Marco de AC

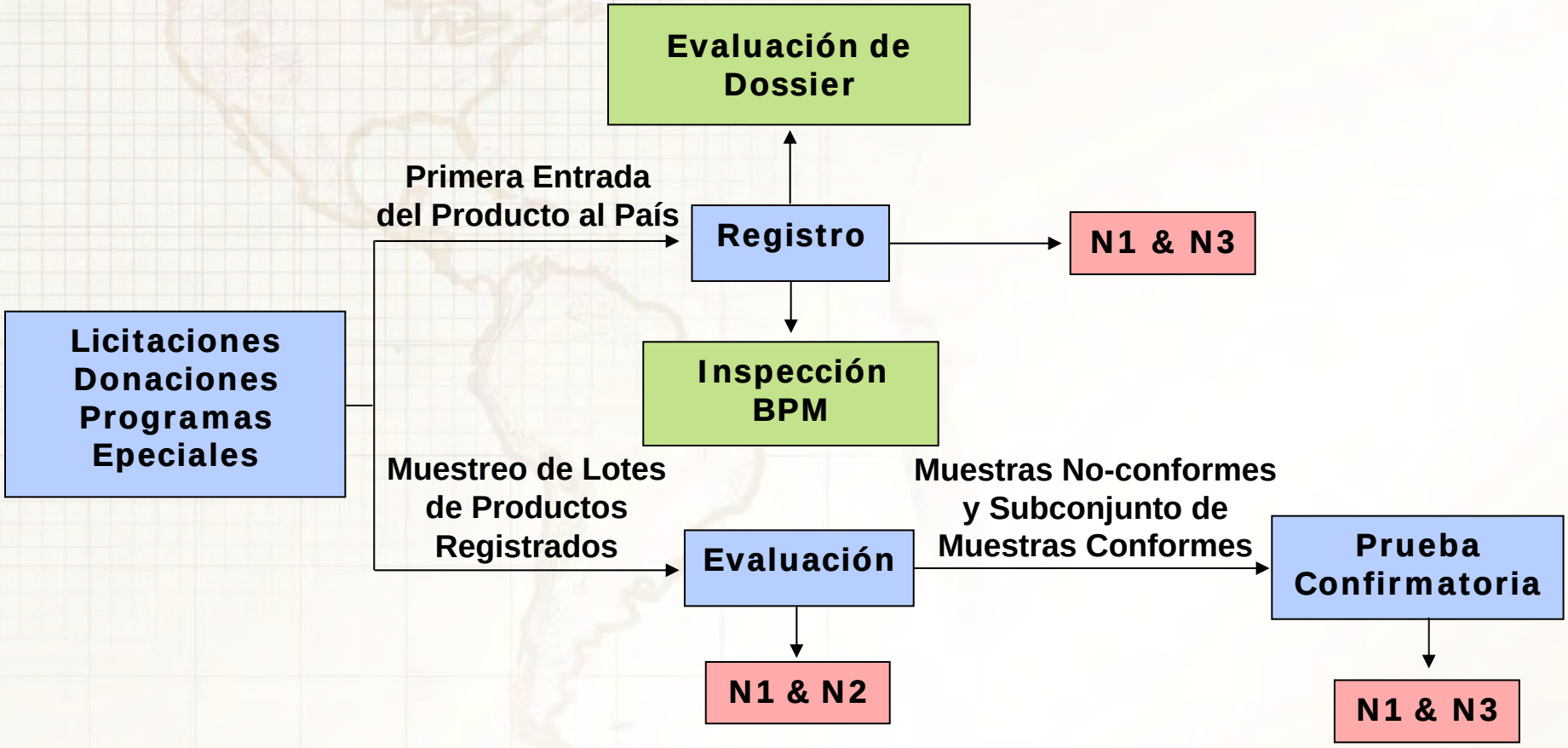
USP Drug Quality and Information Program



USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles: Adquisicion

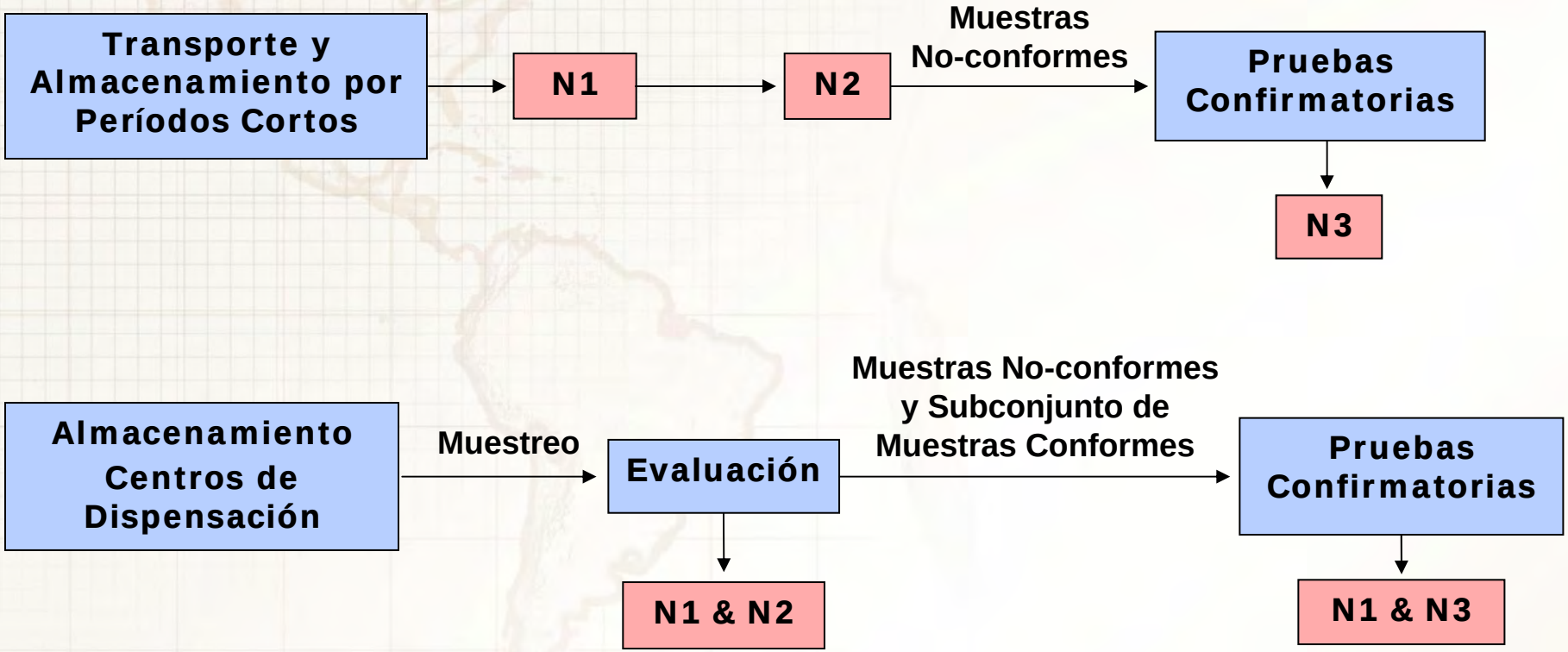
USP Drug Quality and Information Program



USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles: Cadena de Distribución

USP Drug Quality and Information Program



USAID
FROM THE AMERICAN PEOPLE

Enfoque de Tres Niveles: Conclusiones

El enfoque de tres niveles puede de un modo

- Eficiente
- Oportuno y rápido

Identificar medicamentos de mala calidad

- A través de análisis amplios
- En varias etapas de la cadena de suministro
- En actividades rutinarias de VPC

Expandir el alcance de las actividades de AC y reducir la carga impuesta al LOCM.

Control de calidad en sitios centinela

USP Drug Quality and Information Program

- ¿Qué se ha hecho?
- ¿Qué falta por hacer?
- ¿Con qué se debe continuar?

USAID
FROM THE AMERICAN PEOPLE

Resumen Parcial MiniLabs (Abril 2008)

USP Drug Quality and Information Program

Atributos de Calidad

Ingrediente Farmacéutico Activo (IPA)	Número de Muestras	Número de Lotes	Sin Registro	Vencidas	Falla Inspeccción Física/Visual	Falla Desintegración	Falla CCD
Artesunato	46	12	7	4	9	0	0
Artemether/Lumefantrina	63	8	45	0	2	0	0
Cloroquina	269	67	10	32	27	3	4
Doxociclina	42	12	0	2	0	0	30
Mefloquina	65	24	5	8	10	2	1
Primaquina	317	79	14	21	17	0	7
Quinina	74	37	4	8	0	1	14
Sulfadoxina/Pirimetamina	64	6	2	3	2	8	0
Tetraciclina	6	6	0	0	0	0	0
TOTALES	946	251	87	78	67	14	56
Percentaje del Total	100		9	8	7	1	6

USAID
FROM THE AMERICAN PEOPLE

Control de calidad en sitios centinela

USP Drug Quality and Information Program

- El porcentaje de antimálaricos de mala calidad en puestos oficiales es relativamente bajo
  - ¿Es suficiente el número de rondas realizadas?
  - ¿Se debe continuar con el monitoreo como actividad periférica o central?
  - Diseminación
- Calidad en sector privado e informal
  - Estudios on preparacion/progreso en Colombia, Guyana y Suriname
  - ¿... y después qué?

USAID
FROM THE AMERICAN PEOPLE

U.S. PHARMACOPEIA
DRUG QUALITY AND INFORMATION PROGRAM

Muchas Gracias

This presentation is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement number HRN-A-00-00-00017-00. The contents are the responsibility of the U. S. Pharmacopoeia Drug Quality and Information Program and do not necessarily reflect the views of the United States Government.

USAID
FROM THE AMERICAN PEOPLE

Annex 4

Attendants at the individual, ad-hoc USP DQI – Countries Meetings

Bolivia: Arletta Añez (PAHO/WHO, Bolivia)

Brazil: Ana Carolina Faria e Silva Santelli (PAHO/WHO, Brasil)

Colombia: José Pablo Escobar (PAHO/WHO, Colombia)

Ecuador: Raul Veloz Pérez (Servicio Nacional de Control de la Malaria (SNEM), MSP)
Célia Riera Betancourt (PAHO/WHO, Ecuador)
Mercy Silva Bravo (Servicio Nacional de Control de la Malaria (SNEM), MSP)

Guyana: Nicolás Cerón (PAHO/WHO, Guyana)

Peru: Yeni Otilia Herrera Hurtado (Dirección General de Salud de las Personas, MINSA)
Mario Valcárcel (PAHO/WHO, Peru)

Suriname: Gustavo Bretas (PAHO/WHO, Suriname)