Monitor USP DQI Program Activities in Ethiopia and Attend the Semi-annual PMI Partners' Meeting

Addis Ababa, Ethiopia
February 9-13, 2009

Trip Report

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About USP DQI

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00017-00), 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.
USP 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 USP DQI.

Abstract

The director of USP DQI visited Ethiopia and conducted a review of the various programmatic activities undertaken by USP DQI in the country and provided recommendations about current and future directions of USP DQI work, in consultation with USAID and the Ethiopia Drug Administration and Control Authority (DACA). At the invitation of USAID, the director also attended the semi-annual PMI partners' meeting and presented USP DQI accomplishments and progress toward FY 09 PMI objectives. While in Ethiopia, the director took the opportunity to introduce the new USP DQI consultant, Dr. Eshetu Wondemagegnehu, to USAID and DACA. Dr. Wondemagegnehu is well known at DACA, where he was the head of the DACA QC laboratory and at the World Health Organization (WHO), where he was technical advisor with oversight of national drug policies.

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Key Words

Ethiopia, DACA, DQCTL, USP DQI, quality assurance, quality control, quality management system, malaria, PMI, HIV/AIDS, PEPFAR, GLP, HPLC, dissolution, ISO/IEC 17025:2005

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I would also like to express appreciation to the USP DQI administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

Finally, I would like to thank the USAID/Ethiopia Mission, in particular Dr. Richard Reithinger, PMI Team Leader, for our useful discussions, and Mr. Anthony Boni and Veerle Coignez at USAID Washington for their guidance and support of the USP DQI program.

ACRONYMS

AED	Academy for Educational Development
CU/ICAP	Columbia University/International Center for AIDS Care and Treatment Programs
DACA	Drug Administration and Control Authority
DQCTL	Drug Quality Control and Toxicology Laboratory
DQ	Drug Quality
FIDA	Fayaa Integrated Development Association
GC	General Chapter
GLP	Good Laboratory Practices
HPLC	High Performance Liquid Chromatography
IEC/BCC	Information, Education and Communication/Behavior Change Communication
ISO	International Organization for Standardization
JSI/TO3	John Snow Inc. Task Order 3
MCDI – IMad	Medicare Development International
MSH/RPM+/SPS	Management Sciences for Health/Rational Pharmaceutical Management Plus/Strengthening Pharmaceutical Systems
ORHB	Oromia Regional Health Bureau
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PMS	Postmarketing surveillance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RTI	Research Triangle Institute
SOP	Standard Operating Procedure
SOW	Statement of Work
UNC	University of North Carolina
UNICEF	United Nations International Children's' Emergency Fund
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

USP DQI was selected by USAID/Ethiopia to provide technical, strategic, and operational support to strengthen the quality control of antimalarial medicines in Oromia. The USAID/Ethiopia Office of Health, AIDS, Population and Nutrition identified post-marketing surveillance of the quality of antimalarials as critical for effective case management of malaria under the President's Malaria Initiative (PMI). In preparation for the task, USP DQI staff provided training to DACA and Oromia Regional Health Bureau (ORHB) staff on the use of the tools and processes for conducting post-marketing surveillance in various locations in Oromia.

In July 2008, a two-day Micro-Planning Workshop on establishing a postmarketing surveillance (PMS) program to monitor the quality of antimalarial medicines in Oromia Region was conducted. During the workshop, five sentinel sites were established as monitoring zones for the quality of antimalarials in Oromia. A sentinel site team was established to conduct sampling and testing and a supervisory team was established to provide oversight of the monitoring and make recommendations to DACA for regulatory action, as necessary. Following the workshop, USP DQI staff organized training for about 30 staff in August on the use of Minilabs® for DACA DQCTL staff as well as representatives from regional health bureaus. After the training was completed, USP DQI received budgets from sentinel site teams and provided funds to DACA for sampling and testing of the antimalarials that were in scope for the monitoring program. Sampling and testing began in late 2008 and has been completed for four out of five sites. The fifth site has had staff changes, but new staff have been appointed to take over the work at the site.

Because Minilabs® used in the field are only screening tools, data are often confirmed in a quality control laboratory for a certain fraction of the results obtained in the field. In order to prepare the DACA DQCTL to conduct confirmatory testing, the capacity of the lab was assessed by USP DQI, and a training workshop for lab staff and provision of certain lab resources were recommended. USP DQI received funds from the President's Emergency Plan for AIDS Relief (PEPFAR) under a sub-contract between USP DQI and Management Sciences for Health, Strengthening Pharmaceutical Systems (MSH-SPS) program. Under this sub-contract, it was agreed that USP DQI will train DACA DQCTL on analytical methods and good laboratory practices and assist DACA DQCTL management establish an advanced quality management system to put the lab on a path to gain ISO accreditation and WHO-prequalification status.

Purpose of Trip

USP DQI staff traveled to Addis Ababa, Ethiopia to:

1. Present, discuss, and obtain USAID and DACA buy-in on the three-year implementation plan to obtain ISO-17025 and WHO prequalification for the DACA laboratory.
2. Review work done at the sentinel sites and evaluate the preliminary results obtained from the Minilab® testing in the field.
3. Participate in the semi-annual PMI partners' meeting and present USP DQI accomplishments.

Source of Funding

Funding was provided by USAID/Ethiopia-PMI, and USAID/Ethiopia-PEPFAR, under a subcontract between USP DQI and MSH-SPS.

Summary of Discussions on Trip Objectives

In order to meet the objectives for the trip, several consultative meetings were held between USP DQI and stakeholders, and recommendations were made for advancing USAID goals with respect to drug quality in Ethiopia. The following section is a summary of the discussions:

Implementation Plan for International Accreditation of the DACA QC laboratory

Prior to this trip, a USP DQI team visited Ethiopia and conducted training for the DACA laboratory staff to conduct confirmatory testing of antimalarials using compendial procedures. As part of the training, an evaluation of the laboratory systems and processes was conducted to establish the current state of the lab with respect to their quality management system and processes used to record and review data generated in the laboratory. As a result of this evaluation and at the request of USAID, USP DQI staff drafted a three-year implementation plan to obtain international accreditation for the DACA laboratory. Achieving that goal is a critical milestone that will position the lab to generate revenues by participating in testing for international organizations such as WHO and UNICEF. Also, DACA participation in an accreditation program will guide USP DQI's technical assistance for the laboratory and constitutes an exit strategy with respect to assistance for the laboratory.

USP DQI staff unveiled the implementation plan to DACA, MSH/SPS and WHO staff and discussed the details of the plans and its merits. MSH/SPS and USP DQI staff indicated that this plan is contingent on continued funding by USAID. The main facet of the plan involves the staged approach to obtaining accreditation as shown in ***Annex 1***. The main things DACA needs to do to implement the plan include:

- Appoint a staff person to head a quality assurance unit
- Manage buy-in to support the process and necessary staff changes
- Prepare staff for enhanced training and compliance with international standards

DACA management welcome the plan, and following post-meeting discussions, made the commitment to appoint a staff person responsible for QA in the lab, who will also serve as deputy to the lab director.

Based on observations by USP DQI of basic commodities that were absent in the lab and as part of the beginning process to comply with standards, USP DQI purchased the following items:

- Laboratory notebook for staff to document all work in a timely manner
- Calibration weights to be used to calibrate analytical and top load balances prior to use
- Weigh boats and weigh paper for accurate weighing and transfer of materials to analytical containers

Next steps

- Follow up with DACA management about the appointment of the deputy director and QA supervisor in the laboratory
- Work with DACA to draft the roles and responsibilities of the QA supervisor
- Work with the QA supervisor to start Phase 1 of the implementation plan, including the development of Standard Operating Procedures (SOPs), safety procedures, and a quality management system.

Visit with sentinel site team leaders and review of data from four sentinel sites in Oromia

Following the training of the sentinel site teams in August 2008, team members began collecting samples of antimalarials at their respective sites and testing them using Minilabs® provided at the sites. Preliminary results were provided by four of the five teams in January 2009 for USP DQI review. Several important observations were made that warranted a face-to-face meeting with the team leaders to review sampling protocol and format for data presentation. The preliminary data on the samples collected and initial observations from the four sites has been summarized and is presented in ***Annex 3***. Confirmation of Minilab® data and full confirmatory testing is being done at the DACA laboratory following servicing of HPLC equipment by Shimadzu.

The USP DQI staff reviewed the following points with the sentinel site team to strengthen the monitoring program and to improve sampling techniques and data gathering practices:

- Sampling should be done using the "mystery sampler" technique where locals purchase samples from pharmacies and shops instead of DACA staff posing as inspectors.
- Only one report will be produced by the focal person at the DACA laboratory. The report will include data from all sentinel sites and a summary of recommendations for regulatory action.
- All samples, including TLC plates, will be sent to the DACA QC laboratory for confirmation purposes.

USP DQI provided report templates to facilitate the reporting of sentinel site data.

Next steps

- Follow up with DACA management to appoint a focal person in the DACA laboratory to be in charge of confirmatory testing and final reporting. It was decided that the focal person will also be in charge of quality assurance.
- Disburse funds to Shimadzu to service the faulty HPLCs and IR instruments.
- DACA to conduct confirmatory testing.
- Compile all sentinel site data into the master spreadsheet provided by USP DQI and provide results to USAID.
- Prepare for the next round of sampling and testing.

Attend and present USP DQI accomplishments at PMI Partners' meeting

The PMI partners' meeting convened on February 13 at USAID/Ethiopia. The meeting was chaired by the PMI team leader, Dr. Richard Reithinger, and was opened by the mission director, Mr. Glenn Anders, who welcomed participants and congratulated them on their dedication and

assistance that they continue to provide to the people of Ethiopia. Mr. Anders also congratulated Dr. Reithinger for the recent award he received from the American Ambassador for his leadership of the PMI initiative in Ethiopia.

The PMI implementing partners include twelve (12) organizations:

Partner	Acronym	Activity
Management Sciences for Health – Strengthening Pharmaceutical Systems	MSH/SPS	Pharmaceutical management
United States Pharmacopeia Drug Quality and Information	USP DQI	Strengthening drug quality monitoring
Academy for Educational Development	AED/C Change	Information Education and Communication/Behavior Change Communication to increase access to and use of key malaria interventions
Malaria Consortium	Malaria Consortium	Operational research on Rapid Diagnostic Tests (RDTs) and malaria risk mapping in Oromia
Columbia University/International Center for AIDS Care and Treatment programs	CU/ICAP	Support for strengthening malaria laboratory diagnosis
Pathfinder International Inc.	Pathfinder	Support for malaria case management and epidemic detection and response
John Snow International Task Order 3	JSI/TO3	Procurement of RDTs, laboratory equipment and supplies
Medicare Development International	(MCDI) IMad	Support for quality assurance systems for microscopy and RDTs
University of North Carolina /MEASURE III	UNC/MEASURE III	Training zonal health officials in data management, sentinel site development, program tracking tools, and skills strengthening
Fayaa Integrated Development Association	FIDA	IEC/BCC at community level
Research Triangle Institute	RTI	Coordination of Indoor Residual Spraying
United Nations International Children's Emergency Fund	UNICEF	Distribution, procurement of ACTs and LLINs

PMI activities are limited to the Oromia region, which is the largest region with 17 million people and 38% of the malaria burden in Ethiopia. The level of funding will be $19.7 million in FY 09 with an anticipated increase in FY 10. All partners presented their workplans and progress

made. PMI activities in Oromia fall into four categories: Prevention and Control, Case Management, Monitoring and Evaluation, and Operational Research. USP DQI activities to strengthen drug quality assurance systems in Oromia fall under Case Management.

The meeting highlights are summarized below:

- Ms. Kimberly Flowers, the communication director, discussed the need to accurately display the USAID logo on all materials and work funded by USAID.
- There were calls for partners to coordinate so as to avoid duplication of work.
- The PMI team leader recommends monthly meetings with partners to get updates.
- Partners were asked to take advantage of C-Change's work in Information, Education and Communication/Behavior Change Communication (IEC/BCC). This call will be headed by USP DQI as we start the drug quality monitoring systems where we will need to inform the public about the drug quality situation in Oromia.
- Templates were distributed for workplans, technical reports, financial accruals, and TDY Statements of Work (SoW)

USP DQI accomplishments in Ethiopia are summarized in ***Annex 4***.

Next steps

- Dr. Wondemagegnehu to brief Dr. Reithinger monthly about USP DQI progress
- Obtain report templates for quarterly reports and financial accruals

Other Activities conducted during the trip

Review of the Architectural Design of DACA Administrative and Quality Control Laboratory

DACA has secured Global Fund money to build a new building to house administrative staff and the quality control laboratory. The building structure is in place and is being built by a local company; Tekleberhan Ambaye Construction P.L.C.

While in Ethiopia, USP DQI obtained the services, free of charge[1], of an independent architect. The architect, Mr. Christine Schnitzer who is the president and CEO of Dipl-Ing (TU) Architect, was accompanied by USP DQI staff, the head of DACA, the director of the QC laboratory, and the mechanical engineer and supervisor in charge of the construction. Mr. Schnitzer reviewed the architectural design of the building and identified some design flaws that would affect the smooth running of operations in the building. Some of the observations are as follows:

Observation	Corrective Action
There was no elevator access to the basement where the chemicals were stored	Change the location of the chemical storage room from basement to first floor
Animal food preparation room and the animal room are on different floors	Make the animal food preparation room and the animal room on the same floor in the basement
Some doors open inward instead of outward in the direction of escape route	All exit doors should open outward in the direction of escape route

[1] The architect is a colleague of Abdelkrim Smine (USP DQI consultant) and was visiting Ethiopia from Germany for other business.

Storage room contains flammable and non-flammable containers	Store the flammable and non-flammable as well as waste and non-waste solvent in separate rooms or in different flame resistant cupboards.
Multiple air handling units in building will make maintenance costs high	Consider a central air handling unit. The problem with a central unit is that different rooms require different environmental conditions. This may not be done
Food and pharmaceuticals laboratories slated to be on same floor	Separate food and pharmaceutical laboratories on different floors. Also consider putting toxicology, pesticide, and microbiology on separate floors.
No alarm in animal room to indicate changes in environmental conditions	Install alarm system in the animal storage rooms in case of changes in environmental conditions
Safety procedures to be validated by fire department	Consult with fire department to ensure compliance with safety guidelines

Next Steps

- DACA will consult with Mr. Schnitzer to provide specifications for furnishing the lab
- DACA will consult with the original architect to discuss what changes can be made to accommodate Mr. Schnitzer's suggestions

Debrief with USAID – February 15, 2009

Participants: Patrick Lukulay (USP DQI Director), Richard Reithinger PMI Team leader, USAID), and Eshetu Woldemedhin (USP DQI consultant)

The USP DQI team met with Dr. Richard Reithinger to brief him about their trip and provide updates about USP DQI accomplishments with respect to PMI goals and objectives in Oromia. Specifically, the USP DQI team informed Dr. Reithinger about their discussions with DACA regarding the three-year implementation plan for the DACA laboratory and their review of the drug quality monitoring data from the four sentinel sites in Oromia. Dr. Reithinger stressed the importance of the drug quality monitoring program to support PMI objectives and asked the team to produce a preliminary report on the drug quality data obtained at the sentinel sites and attach it to the trip report. With respect to the implementation plan, he suggested that USP DQI consider including the proposal in the pending Global Fund application. Dr. Reithinger will inquire about the possibility of including the DACA lab plan into the Global Fund application and will then give indication to USP DQI to proceed.

Next Steps

- Compile the drug quality monitoring data from the four sentinel sites and include in the trip report
- Dr. Reihinger will find out about the possibility of including the DACA implementation plan in the Global Fund application.

Conclusion

Progress has made on all activities undertaken by USP DQI in Ethiopia. The drug quality monitoring program has been established, and sampling and testing has begun at all five sentinel sites. Staff at the DACA laboratory and ORHB have been trained in the use of Minilabs® and have conducted their first round of sampling and testing. As part of continuous improvement in

work practices, retraining will occur for some members of the sentinel site teams in order to improve the sampling procedures.

USP DQI assistance to the DACA laboratory continues. Training of several key staff has occurred, and plans have been made to service all non-functioning HPLC and FT-IR to allow staff to conduct confirmatory testing of Minilab® results. All sentinel site results will be confirmed by May 2009 before the next round of sampling and testing.

A three-year implementation plan to obtain WHO prequalification and ISO 17025 accreditation for the DACA laboratory has been developed by USP DQI and endorsed by DACA management. Based on the availability of funding from USAID, USP DQI will work with the DACA lab toward accreditation and improved work processes.

Finally, USP DQI will continue to provide needed input into building the new DACA laboratory to ensure that the design of the lab is consistent with needed specifications and workflow. The new USP DQI consultant, Dr. Eshetu Wodemagegnehu, will follow up on all USP DQI activities and will be our point of contact for USAID and DACA.

Annex 1

Summary of DACA Implementation Plan

STAGES	TIMELINE	PRIORITY RECOMMENDATIONS TO BE IMPLEMENTED
1	January 1st – July 31st, 2009	Training in HPLC and Dissolution, Creation of Independent QA Unit and DACA to hire/appoint a staff to be QA officer, Cleaning and Organization of the lab, Implement the basics of good laboratory practices as directed by USP DQI, Draft 10 SOPs identified by USP DQI and DACA DQCTL, ii. Inventory current equipment and glassware & prioritize needs, Carry out proficiency project as agreed by USP DQI and DACA DQCTL Director
2	Aug. 1st – Dec 31st, 2009	Execute all recommendations in Stage-1, USP DQI to train on GC, UV, KF or IR and good lab practices, Draft 15 new SOPs, begin writing quality manual and continue to implement key parameters of stringent QMS. Carry out a proficiency project to continue monitoring DQCTL competency
3	Jan. 1st – Jun. 30, 2010	Execute all recommendations in Stage-2, USP DQI to provide two trainings (QC techniques & implementing stringent QMS). Draft 15 new SOPs, finalize quality manual, begin to establish internal audit program, continue implementation of key parameters of stringent QMS, and participate in inter-laboratory testing.
4	July 1st, - Dec. 31st, 2010	Execute all recommendations in Stage-3; USP DQI will support the lab on calibration and qualification of all lab equipment. Stringent QMS is established with all key parameters operational. QMS internship for one key staff member at USP headquarters. Staff are well trained, all equipment are functional and continue to participate in inter-laboratory testing. Lab to move to the new facility
5	Jan. 1st – Dec. 31st, 2011	Execute all recommendations in Stage-4. Qualify the equipment after the move to the new facility, review and update SOPs to fit the new facility and adjust work flow to new facility. USP DQI to conduct QMS mock audit. Submit expression of interest for WHO prequalification. Lab is pre-qualified by end of this stage
6	Jan 1st – Dec. 31st, 2012	Execute all recommendations in Stage-5. After WHO prequalification, USP DQI assists DACA DQCTL to prepare for an international ISO/IEC 17025:2005 accreditation. Develop uncertainty budget and conduct QMS audit. ISO/IEC 17025:2005 accreditation can be achieved by end of 2012.

Annex 2

Sentinel Site team leaders

Name	Sentinel Site	E-mail address
Mohamed Tusi	East Shoa	tmoh@yahoo.com
Anteneh Bayissa	West Wollega	Angias.forevet33@gmail.com
Daniel Yami	Jimma	Danarre2000@yahoo.com
Helawe Ketema	Borena	Helawek@gmail.com
Wassu Gedefew	Hararge	*Not provided*

Annex 3

FIRST ROUND OF SAMPLING IN SENTINEL SITES IN OROMIA-ETHIOPIA

Product	Borena	East Shoa*	Jimma	West Wallaga	Harerge**
Amodiaquine	**1** informal 1				
Primaquine	**1** private 1		**2** private 1 public 1	**2** private 2	
Coartem	**26** informal 8 public 17 private 1		**26** private 1 public 24 informal 1	**23** private 3 public 13 informal 7	
Quinine	**18** public 13 informal 5		**19** public 11 private 7 informal 1	**24** private 9 public 10 informal 5	
Chloroquine	**21** public 4 private 8 informal 9		**35** private 23 public 11 informal 1	**37** private 25 public 9 informal 3	
SP	**15** public 3 private 8 internal 4		**13** public 0 private 13 informal 0	**11** private 10 public 1 informal 0	
Total Samples	**82**	**93**	**95**	**97**	

* Data not broken down by class of medicine at the time this report was written
** Data not provided by the time this report was written

Summary of Preliminary Observations from the Sentinel Site Activities
• Sulfadoxine/Pyrimethamine (SP) found in all sectors (Public, Private and Informal) • Unregistered antimalarials found in private and informal sectors • Amodiaquine found in circulation in the private and informal sectors • Informal sector is quite active with commerce of antimalarials • After confirmatory testing at DACA (which is on-going), the full extent of failure (% failure for each drug type and at each sentinel site) against quality standards will be communicated.

Annex 4

Summary of USP DQI activities in Ethiopia

USP DQI Activity	USP DQI staff involved	Dates	Ethiopian partners involved	Number of staff participated or trained	Products
Assessment	P. Lukulay and A. Smine	March 2008	DACA, MOH, MCP, WHO, SPS, Public Hospitals	NA	▪ Assessment report ▪ Trip report
Micro-planning workshop	P. Lukulay and A. Smine	July 24-25, 2008	DACA, NMCP, RHB, PFSA, WHO	15 participated	▪ PMS program designed ▪ Trip report
Basic tests PMS training	A. Smine and S. Bradby	August 18-22	DACA, NMCP, RHB, PFSA, SPS	24 trained	▪ PMS plan finalized ▪ Trip report
GLP, HPLC, Dissolution training	A. Smine and A. Barojas	January 12-16, 2009	DACA	8 trained	▪ Trip report ▪ Implementation plan for DACA lab finalized
Monitoring of sentinel sites activities	P. Lukulay	February 9-13, 2009	DACA, ORHB	5 Sentinel site team leaders	▪ Trip report
First round PMS	Dr. Eshetu, A. Smine, P. Lukulay	Dec, 08 - present	DACA, RHB, NMCP, PFSA	24 trained sentinel sites staff involved	▪ Sampling and basic test report (not completed)