

USP Drug Quality and Information Program (USP DQI)

Second Quarter Program Report – FY 2006

January – March 2006

Common Agenda

- N. Davydova developed LC-MS and UV theoretical materials for training courses, which are designed by USP DQI for countries that seek to improve their drug quality control systems
- S. Phanouvong briefed USAID (Anthony Boni and Kama Garrison) on the status of activities regarding the Centers of Excellence in Medicines Quality Assurance in Asia
- J. Murphy and S. Phanouvong submitted an abstract for presentation at the annual APHA meeting, planned for November 2006
- A. Smine attended a meeting with USAID, MSH, DOC and others at the Drug Regulatory Authority of Nigeria
- A. Smine participated in a meeting with MSH about possible collaboration in East Africa
- N. Davydova and A. Smine updated training modules for HPLC and GC
- J. Carpenter and M. McGinnis completed the January 06 update of the *Matrix of Drug Quality Reports in USAID-assisted Countries* and disseminated it on the USP DQI website. 10 copies were disseminated at the European Federation of Pharmaceutical Industry Association meeting on March 3, 2006
- J. Carpenter peer reviewed an article on counterfeit drugs for the Lancet Infectious Diseases journal
- E. Toledo wrote GMP training modules and assessment tools

SO2 (Maternal Health)

- J. Carpenter, L. Callahan, and A. Smine met with PATH to discuss work on oxytocin for the Prevention of Postpartum Hemorrhage Initiative (POPPHI). L. Callahan gave a presentation about the oxytocin monograph at the POPPHI meeting attended by USAID, PATH, and RPM Plus
- N. Davydova, E. Toledo and M. Welsch conducted literature searches on oxytocin stability storage guidelines and identified manufacturers for the POPPHI meeting
- USP DQI document on misoprostol for PPH was included in the toolkit for providers for PPH; this toolkit contains evidence-based summary articles compiled by the POPPHI project

SO 3 (Child Survival)

- J. Carpenter finished co-drafting the zinc specification guidelines with A. Smine and M. Foster for the Zinc Task Force; A. Smine submitted the guidelines to WHO and USAID for review
- E. Toledo and A. Smine visited Nutriset to follow up on the progress of recommended actions to achieve GMP status. They discussed disintegration test results and stability studies of zinc tablets; collected samples for testing
- L. Evans revised the zinc tablet monograph to include the new data on disintegration and sent it to the USP Expert Committee for review
- A. Smine and E. Toledo visited the Rodael manufacturing plant in France; worked with Rodael and Nutriset on how to improve their GMP and prepare for the UNICEF GMP assessment
- S. Bradby, A. Barojas and A. Smine conducted disintegration tests of zinc samples collected from Nutriset in RDL lab; updated zinc monograph and submitted the changes to DSD for monograph correction

SO 4: HIV/AIDS

- B. Davani finished the Nevirapine tablet monograph and published it in the Pharmacopeial Forum (PF) 32(3) for public review; the Nevirapine oral suspension is now being edited for inclusion in PF 32(4)
- D. Seyoum reviewed abstracts for the International AIDS Society AIDS 2006 Conference
- D. Seyoum reviewed HIV/AIDS-related articles for the USP DQI website monthly update

SO 5A – Tuberculosis

- D. Seyoum reviewed TB-related articles for the USP DQI website monthly update

SO 5A: AMR/Infectious Diseases

- S. Phanouvong, jointly with national counterparts, developed and approved a plan of activities for field-testing *Ensuring the Quality of Medicines in Low-Income Countries: An Operational Guide* in Cambodia and Laos
- S. Phanouvong, K. Burimski, and E. Ushkalova organized a symposium on medicines quality at the Man and Drugs Conference in Moscow, Russia
- D. Seyoum finalized organizing a symposium on “Antimicrobial Drug Resistance” at the FIP Congress in Salvador De Bahia, Brazil
- D. Seyoum reviewed the WHO Interagency Emergency Health Kit (IEHK) on behalf of the FIP Information Section; the kit’s contents can serve 10,000 people for approximately 3 months
- D. Seyoum researched clinical information to support proposed AMR Statement of Policy for the 2006 FIP Congress
- D. Seyoum reviewed articles submitted to the WHO Bulletin related to tuberculosis and essential drugs
- E. Ushkalova reviewed AMR/Infectious Diseases-related articles for the USP DQI website monthly update
- 2 students in Russia completed the Distance Learning Continuing Education Course provided by the Smolensk Medical Academy; 16 students are currently enrolled and 258 students from Russia and the NIS have completed the course in total
- The Smolensk team presented results of the Distance Learning Course to approximately 900 people at five conferences
- On the www.antibiotic.ru website, 59 new topics were added, including six devoted to HIV infection, one to TB, six to STDs, eight to AMR and three to avian flu
- Eleven drug bulletins from www.antibiotic.ru were e-mailed to 2,337 subscribers
- The Smolensk team moderated antimicrobial therapy forums for health care professionals on the www.antibiotic.ru site
- The on-line version of the Infectious Diseases Textbook was visited 345,381 times during this quarter, bringing the total number of visits to 2,697,139
- The on-line version of the Guide to Infection Control in the Hospital was visited 24,916 times this quarter, bringing the total number of visits to 188,291
- E. Ushkalova wrote and published two articles on the rational treatment of infectious diseases in the medical journal *Pharmateca* “Josamycin role in the treatment of infections caused by intracellular pathogens” and “Roxithromycin use in pediatrics”
- E. Ushkalova participated in discussions on rational drug use in the Russian-language e-mail conference “E-lek”, a derivative of “E-drug”

Vladivostok DIC staff:

- With technical support from USP DQI, the DIC delivered the Rational Antibacterial Therapy Course for Russian Far-East health care professionals. The Course was sponsored by a \$30,000 grant from the

Academy for the Educational Development (AED) and conducted within the framework of the USAID project START

- Answered 361 requests from health care professionals, including 78 requests on antimicrobials
- Participated in the work of hospital and territorial Formulary commissions
- Conducted ABC/VEN analysis of pharmaceuticals bought by Central Regional Hospital of Primorski Krai in 2005
- Analyzed rationality of prescribing narcotic, psychotropic and antibacterial drugs in the Central Regional Hospital of Primorski Krai (43 case reports). The results of the analysis were presented to the Hospital Medical Council
- Sent 25 reports about serious adverse drug reactions not listed in the drug package insert to the Federal Adverse Drug Reactions Center
- Analyzed rationality of pharmacotherapy of 5 lethal cases
- Analyzed rationality of pharmacotherapy in gynecological department of the Central Regional Hospital of Primorski Krai (35 case reports)
- Developed a list of pharmaceuticals for urgent aid for physicians on duty
- Participated in development of medical care standards for dermatological and gastroenterological departments
- Developed, published and distributed among health care professionals one issue of Drug Bulletin
- Conducted two “Days of Clinical Pharmacologists”; topics included problems of distance learning education in the area of clinical pharmacology, antimicrobial treatment, and blood/plasma formulations
- Conducted a regional conference “Rational Antibacterial Therapy” for 80 physicians
- Conducted a course of rational pharmacotherapy for physicians in out-patient settings of Primorski Krai

Ryazan Medical University staff:

- Conducted 3 seminars for physicians on the problems of rational drug use, including antimicrobials
- Participated in the work of Ryazan Oblast Formulary Committee

Ryazan Oblast Hospital DIC staff:

- Answered 452 requests from health care professionals and consumers, including 170 requests on antimicrobials.
- Conducted ABC/VEN analysis of pharmaceuticals bought by Ryazan Oblast Hospital in 2005.
- Participated in the development of the 4th edition of Ryazan Oblast Hospital Formulary.
- Participated in the work of Ryazan Oblast Formulary Committee
- Analyzed rational pharmaceutical management for national drug supply program
- Updated 29 protocols of treatment for different diseases, including 6 protocols of antimicrobial therapy
- Sent 4 reports about serious adverse drug reactions not listed in the drug package insert to Federal Adverse Drug Reactions Center

Novgorod DIC staff:

- Answered 119 requests from health care professionals and consumers, including 39 requests on antimicrobials
- Analyzed rational pharmaceutical management for national drug supply program
- Organized and conducted twelve conferences for physicians, including Russian-Italian Conference “Actual Problems of Socially Important Infections.” Problems of rational antibiotic therapy and antimicrobial resistance were discussed at 7 conferences
- Delivered 3 presentations for physicians and pharmacists of Novgorod Oblast on problems of drug safety and 2 presentations on antibiotic resistance

Russia Far East Project

- One student completed the Distance Learning Continuing Education Course; six students are enrolled currently, twelve have completed the course in total
- Three students are currently enrolled in the Vladivostok Medical University Distance Learning Education Course

RDM/A-4: Mekong Expansion

- S. Phanouvong, E. Toledo, and S. Bradby conducted training courses in Laos (good laboratory practices, sampling and data management, GMP fundamentals application, and advanced testing methods)
- S. Phanouvong routinely provided guidance on how to manage (i.e. implement, supervise, coordinate, follow-up and report) the expansion of drug quality monitoring for ARVs, anti-TBs, antimalarials, and antibiotics in Cambodia, Laos, and Vietnam.
- S. Phanouvong met with representatives of Thai FDA, Bureau of Vector Borne Diseases – Malaria Cluster, Bureau of Narcotics and Drugs and Pharmaceutical System Research & Intelligence to further discuss and plan a survey to obtain base-line data on the quality of selected ARVs, anti-TBs, and antibiotics as part of the Mekong expansion activities
- S. Phanouvong and J. Murphy visited the Yunnan province of China to meet and discuss with provincial and local counterparts possible ways to continue and possibly expand the antimalarial medicines' quality monitoring in this province
- S. Phanouvong and N. Blum discussed with Dr. Kate Nguyen of Home Health Care the possibility of a joint conference on HIV/AIDS for Community Pharmacists: the Role of Pharmacists in the Management and Prevention of HIV/AIDS, along with the Vietnamese Pharmacists Association and Ho Chi Minh City AIDS Committee; the conference will be June 26-27, 2006 in Ho Chi Minh City
- A. Smine and S. Bradby provided the Cambodia QC lab with HPLC technical assistance
- Kirill Burimski traveled to Vietnam and Cambodia to review progress to date and discuss/plan future activities with USAID Missions and local counterparts

Cambodia

- S. Phanouvong, with national counterparts, monitored progress and planned to expand the infectious diseases medicines quality monitoring project

RDM/A-5: Centers of Excellence in Quality Assurance of Medicines

- S. Phanouvong, J. Murphy, A. Smine, and K. Burimski organized the first meeting of the candidates for the Centers of Excellence in Bangkok, Thailand. Participating institutions were Chulalongkorn University (Thailand), Mahidol University (Thailand) and University of Santo Tomas (Philippines).

E&E-1: Freedom Support Act/Moldova/NIS

Moldova DIC of the National Institute of Pharmacy:

- Answered 171 requests from pharmacists, physicians, and nurses
- Developed, published and distributed among health care professionals 3500 copies of 2 issues of Drug Bulletin devoted to rational drug use, including antimicrobials
- Sent two reports about adverse drug reactions to the Center on Clinical Trials and Pharmacovigilance of National Institute of Pharmacy
- Conducted six presentations for physicians, pharmacists and nurses of Chisinau
- Provided informational support to the Department of Pharmaceuticals Purchases of the Pharmaceutical Agency to optimize purchasing of pharmaceuticals

E&E-2: SEED

- The Drug Information Center (DIC) in Cluj, Romania printed out 3000 leaflets for distribution to schoolchildren in Cluj and neighboring counties, as part of its avian flu information campaign

LAC-1-Amazon Malaria Initiative

- A. Smine coordinated the second round of antimalarial drug collection and testing in three sentinel sites in Ecuador and the first round in Colombia, Venezuela and Brazil
- A. Barojas, S. Bradby, and A. Smine purchased and sent Minilabs to Bolivia and Peru
- A. Barojas and S. Bradby conducted a workshop on basic tests and use of Minilabs in Bolivia and Peru
- N. Davydova trained Bolivian QC laboratory technicians on analytical methods
- A. Smine, A. Barojas and N. Davydova trained the QC lab of Peru on HPLC, Dissolution, UV and GLP
- A. Smine and three WHO consultants trained the Peruvian DRA on drug registration using SIAMED
- A. Smine, with the help of A. Rodriguez and K. Conerly (QA), audited the Peruvian QC lab and recommended steps to follow to be certified ISO 17025

LAC-2- South American Infectious Diseases Initiative

- A. Smine, N. Davydova, and A. Barojas organized and conducted a training workshop on GLP, HPLC, Dissolution, and UV for the QC lab in Peru
- N. Davydova, A. Barojas, and S. Bradby organized HPLC training for the QC lab in Bolivia; N. Davydova conducted the training
- A. Barojas, N. Davydova, S. Bradby and A. Smine coordinated drug analysis with SAIDI partners. They provided technical assistance, reagents and answered questions

Madagascar, Senegal, and Ghana

- J. Murphy, A. Smine and A. Barojas traveled to Madagascar to provide technical assistance and training on the monitoring of selected medicines for drug quality. They participated in the implementation of a pharmacovigilance program, coordinating with the Agence du Medicament
- A. Smine and J. Murphy met with CDC, MSH, and JHPIEGO about the Pharmacovigilance (PV) Workshop in Madagascar and reviewed the proposed concept paper; prepared a power point presentation, and participated in conference calls and discussions with MAC partners about PV activity
- A. Smine invited speakers and coordinated the PV workshop; A. Smine and J. Murphy attended the workshop
- A. Smine arranged for two staff from DRA of Madagascar to go for training in PV center in Morocco
- A. Smine is coordinating the preparation for PV training in Madagascar by Moroccan PV experts
- A. Barojas and A. Smine conducted a training on basic tests and use of Minilabs for four selected provinces in Madagascar in collaboration with DRA of Madagascar and the Faculty of Medicine of Antananarivo
- A. Smine reviewed the proposal from the National QC lab of Senegal to conduct a large study on the quality of artesunate in the private sector in Senegal

Other activity

- J. Carpenter, M. Foster and M. McGinnis submitted "Success Stories" from USP DQI FY 05 program to USAID

Planned for Next Quarter

- Follow-up on antibiotic and anti-tuberculosis drug quality testing in Peru and Bolivia, and review the testing reports
- Submit the paper "Validation of TLC Methods for the Determination of Six Anti-retroviral Drugs" for the J. of Chromatography

- Develop training material on Bioanalytical Method Validation for Bioavailability and Bioequivalence Studies
- Upgrade training materials for TLC and GLP Modules
- Revise and disseminate the *Matrix of Drug Quality Reports in USAID-assisted Countries*
- Assist in the UNICEF audit of Nutriset in relation to zinc
- Submit the revised zinc monograph for public review
- Follow-up on progress and obtain data on quality of ARVs, anti-TBs, antibiotics and antimalarials from country counterparts
- Organize and participate in symposiums on drug quality and drug information at the Man and Drugs conference
- Take part in the operationalization of the Asian Network of Excellence in Quality Assurance of Medicines (ANE-QAM) in June, by holding a second meeting in the region to finalize a work plan and memorandum of understanding for each institution
- Organize workshops for inspectors and USP DQI project evaluation in Vietnam in July
- Organize training workshop on GMP in Cambodia - June
- Follow-up on comments on the *Operational Guide* field testing
- Obtain formal clearance to conduct a survey to obtain base-line data on quality of antibiotics, antituberculosis and antiretrovirals in Thailand
- Follow up on drug sampling and testing by SAIDI countries, analyze results obtained and make appropriate use of the information with SAIDI partners
- Work with zinc group on finalizing the papers about the specifications guideline
- Hold a panel session on zinc, addressing its safety, efficacy, quality and roll-out implementation strategies at the GHC annual conference in June
- Visit Senegal and start quality study of artesunate in private sector, meet with malaria program representatives from West Africa and study the possibility of hiring a consultant to be based in Dakar
- Participate in the publication of two peer-reviewed papers about AMI studies
- Work on clinical information on antimicrobial drug resistance
- Continue working on antituberculosis drug resistance and multidrug-resistant tuberculosis (MDR-TB)
- Conduct a round table devoted to Distance Learning Continuing Education at the “Man and Drug” conference
- Continue communications with the Russian Health Foundation and WHO/Moscow regarding possible collaboration