

Exploring Collaboration between USP DQI and the ACTWatch Study in Cambodia: Sentinel Site Visit to Oddar Meanchey and Meetings with Key Partners

Phnom Penh, Cambodia, September 15, 18 – 20, 2008

Oddar Meanchey Province, Cambodia September 16 – 18, 2008

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 the U.S. Agency for International Development (USAID). It may be reproduced if credit is given to USP DQI.

Abstract

Ms. Krech (USP DQI), Mr. Raymond (USP DQI) and Dr. Lawrence Evans (USP International Technical Alliances Program (ITAP)) traveled to Cambodia to meet with key partners and determine how the ACTWatch Drug Quality Study can be carried out in conjunction with ongoing USP DQI medicine quality monitoring activities without creating overlap or duplication. USP staff conducted a supervisory visit to the remote sentinel site of Samrong in the province of Oddar Meanchey, which is part of the Thai-Cambodia cross border study on antimalarial medicine quality. The team also traveled to the nearby border town of O'smach to collect antimalarial samples from formal and informal outlets.

USP staff met with key partners from the Department of Drugs and Food (DDF), National Laboratory for Drug Quality Control (NLDQC), Population Services International (PSI), the World Health Organization (WHO), Global Fund (GF), National Malaria Center (CNM) and USAID to discuss all ongoing medicine sampling and testing activities in Cambodia. The goal of these meetings was to discuss how the partners can best work together to report and share results as well as take action when poor quality and counterfeit medicines are found.

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Key Words

Cambodia, Oddar Meanchey, O'smach, antimalarials, ACTs, PSI, Thai-Cambodia Cross Border Study, medicine quality monitoring, Department of Drugs and Food, pharmacovigilance, ISO 17025, ACTWatch, Global Fund Round 6, National Laboratory for Drug Quality Control.

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Dr. Lawrence Evans from USP ITAP should also be thanked for his dedication to explore how USP DQI and PSI can collaborate on specific activities in Cambodia. Through the PSI grant to ITAP, Dr. Evans provided funding for two USP DQI staff and Ms. Boravann to visit O'smach as well as providing for USP DQI staff expenses while in Phnom Penh.

The author would also like to acknowledge the support and guidance from Dr. William Mfuko of the WHO Cambodia office, H.E. Yim Yann, and Dr. Sokhan on how USP DQI and Global Fund activities and funding can be coordinated and optimized.

The author would also like to thank the USAID Mission in Cambodia, in particular Mr. Jonathan Ross, for his participation in the partners' meeting on September 19, 2008 and for his feedback regarding USP DQI's current and future activities.

It is important to express sincere appreciation to all administrative staff and editors of the USP DQI Program for assistance in logistical arrangements and editing of this trip report.

Lastly, thank you to Mr. Anthony Boni, USAID CTO based in Washington, D.C. and Ms. Veerle Coigneux for their support and advice.

ACRONYMS

ACT	Artemisinin-based Combination Therapy
CNM	National Malaria Center
DDF	Department of Drugs and Food
GF or Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
HPLC	High Performance Liquid Chromatography
ITAP	International Technical Alliances Program
JPMA	Japanese Pharmaceutical Manufacturers Association
LSHTM	London School of Hygiene and Tropical Medicine
MOH	Ministry of Health
NLDQC	National Laboratory for Drug Quality Control
PAC	Pharmacists Association of Cambodia
PSI	Population Services International
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization
WPRO	WHO Western Pacific Regional Office

Background

USP, PSI, London School of Hygiene and Tropical Medicine (LSHTM), and AC Nielson – through a grant from the Bill and Melinda Gates Foundation – are partners in a study called ACTwatch. The goal of ACTwatch is to increase effective treatment rates of malaria by generating and disseminating evidence and recommendations to policymakers on methods to increase availability and decrease the consumer price of quality assured Artemisinin-based combination therapy (ACT). This study is a five-year project across eight countries: Benin, Nigeria, Uganda, The Democratic Republic of the Congo, Zambia, Madagascar, Cambodia and tentatively, Myanmar. USP is leading the antimalarial drug quality study in each country.

The objectives of ACTWatch are to provide policy makers with evidence and actionable recommendations in the following areas:

- levels and trends in the availability, price, quality, volume, retailer perceptions, and knowledge information about antimalarial medicines at different points of sale;
- wholesaler and retailer volumes and the components of the consumer price of antimalarials, as well as current policy influences on the market, and specifically, on mark-ups from import to outlet; and
- consumer treatment-seeking behavior and volumes of specific antimalarials consumed, to support the development and monitoring of policies and other interventions to increase rates of effective malaria treatment.
- country-specific advocacy plans and international dissemination activities to ensure that evidence is effectively translated into policy.

The studies through which these objectives will be met include the:

- Outlet Survey: will evaluate availability, price, and affordability of antimalarials in the public and private sectors.
- Supply Chain Research: will determine price and availability of antimalarials.
- Antimalarial Drug Quality Assurance and Control: will measure quality and purity of antimalarials in the market.
- Household Survey: will measure levels and trends in the use of effective and ineffective antimalarials and determinants of use.

Purpose of Trip

- Determine how the ACTWatch Drug Quality Study can be carried out in conjunction with ongoing USP DQI activities without creating overlap or duplication.
- Visit O'smach sentinel site and evaluate staff performance on basic testing and TLC
- Meet with the USAID Mission and WHO to discuss Cambodian activities.
- Meet with key partners from the DDF, NLDQC, and USAID to discuss USP DQI's three-year work plan proposal.
- Visit the NLDQC to determine what next steps the lab should take in terms of WHO prequalification to ultimately attain ISO 17025 accreditation.

Source of Funding

This trip was supported with funds from PSI, as well as by USAID/Cambodia.

Overview of Activities

September 15, 2008 - morning

Meeting with the Department of Drugs and Food

Participants: Dr. Choeng Sokhan, Vice-Director DDF

Ms. Mam Boravann, Deputy-Chief of the Essential Drugs Bureau

Ms. Sar Kuy Heang, Chief of Registration

Dr. William Mfuko, WHO DDF Advisor

USP Staff (Mr. Christopher Raymond, Ms. Laura Krech, and Dr. Lawrence Evans)

Dr. Choeng Sokhan welcomed the USP ITAP team. Dr. Evans gave a brief overview of the ACTWatch Drug Quality Study and summarized the study design provided earlier via email. The DDF indicated that they currently have a post-marketing surveillance system in place that is collecting data on antimalarials as well as other medicine products, and the Cross-Border study will provide data specifically on antimalarials. Dr. Evans was asked to revise the proposed work plan to: 1) focus on Cambodia; 2) add a summary section of current and recent drug quality studies in the country; and 3) indicate how an unmet need is being addressed. Dr. Sokhan requested that USP provide a 1-2 page summary letter of the study so the DDF can obtain the waiver for any type of ethical clearance. This is consistent with how USP and DDF have handled this issue in the past.

The point was made that the ACTWatch study addresses geographical areas covered by the Cross-Border study and the current medicine post-marketing surveillance program; however, in the latter, sampling is done only at the outlet level. Data sharing was recommended because of overlap and to reduce the burden on local staff. Mam Boravann, USP's focal point in the DDF.

NOTE: Cambodia is divided into 20 provinces and 4 urban municipalities. The post-marketing surveillance program collects data on anti-infective medicines – antibiotics, antimalarials, anti-tuberculosis agents (ATBs), antiretrovirals (ARVs), and oseltamivir – in 11 provinces. The Cross-Border Study focuses on antimalarials in 6 provinces, 5 of which are part of the post-marketing surveillance program (the exception is Oddar Meanchey, only participating in the Cross-Border Study). There are no sentinel sites in some central Cambodian provinces but these are areas where malaria exists but Artesunate-tolerant parasites are not suspected (see Annexes 1 and 2).

September 15, 2008 afternoon

Meeting with the Department of Drugs and Food and WHO

Participants: Dr. Choeng Sokhan, Vice-Director DDF

Ms. Mam Boravann, Deputy-Chief of the Essential Drugs Bureau

Ms. Sar Kuy Heang, Chief of Registration

Dr. William Mfuko, WHO DDF Advisor

Dr. Mam Dathara, Cambodian Pharmacovigilance Center

Mr. Bunso Sok, Cambodian Pharmacovigilance Center

USP Staff: Mr. Christopher Raymond and Ms. Laura Krech

Ms. Mam Boravann and Ms. Krech presented an overview of the 9-day training course they attended in Manila, Philippines, in September, entitled “Introductory Training Course in Pharmacovigilance”. The course was sponsored by WHO HQ and WPRO, and 14 countries were

represented. The attending countries either a) had no pharmacovigilance (PV) infrastructure or activities ongoing; b) had only recently commenced PV activities; or c) have a PV center, activities, and a reporting system but face many challenges, and therefore the program is not fully functioning.

Two DDF staff (Ms. Boravann and Mr. Huot Sengthong) were selected by the Cambodian Ministry of Health (MOH) to represent the country. Efforts were made to include the two PV staff (Dr. Dathara and Mr. Sok) already working at the Cambodian Pharmacovigilance Center, but unfortunately it was not possible. In order to share the knowledge of the training, DDF staff will spend on average one hour each day going over the different training topics from the course with the PV staff.

Ms. Krech and Ms. Boravann also presented and discussed the Cambodian PV action plan which was formulated at the training in Manila (see Annex 4). The plan lists five activities to be accomplished in FY 09.

September 15, 2008

Meeting with Population Services International (PSI)

Participants: Dr. Lawrence Evans, USP

Ms. Diane Freeman, International Fellow, Malaria Advisor, PSI

Dr. Evans met with Diane Freeman, Country Program Coordinator for ACTWatch in Cambodia. Dr. Kate O'Connell was scheduled to be included in the meeting via teleconference but was unavailable. In the proposed study design, during phase 2, a single product would be targeted. Ms. Freeman indicated that neither Malarine nor A+M, need to be tested in this phase because both undergo testing by the NLDQC. The PSI developed zones/stratum for Cambodia were compared with the sentinel sites for the Cross-Border study and were found to overlap, thus suggesting that the sentinel sites are optimal locations for sample collection. (See annex 3)

Site Visit to Oddar Meanchey Province, September 16-17, 2008

September 16, 2008 arrival in Samrong

Meeting with the Vice Provincial Health Director of Oddar Meanchey (OMC)

Participants: Dr. Ploug Thom, Vice Provincial Health Director and Hospital Chief

Mr. Hien Kimseat, Pharmacist, OMC Operational District

Mr. Bun Channa, Pharmacist, OMC Operational District

Ms. Mam Boravann, DDF and USP focal Point

USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

The Deputy Director of Oddar Meanchey, Dr. Ploug Thom, welcomed the USP team. He was pleased to have had two pharmacists from his operational district recently complete sample collection and Minilab[®] training. He has been active in removing medicine from private outlets that are banned by the MOH or not registered. However, he pointed out that in some cases, medicines that do not have a registration sticker are of good quality and that the registration sticker is easily counterfeited.

He indicated that with Minilab[®] results and coordinating with the NLDQC, he will now have the drug quality data needed for enforcement, including the removal of poor quality drugs from the market. He was interested in testing medicines besides antimalarials in the future, especially when he and his staff find suspicious products. In addition, he requested the testing results be made available to the MOH to assist in forming policy.

September 16, 2008

Visit to the OMC Operational District Warehouse

Participants: Mr. Hien Kimseat, Pharmacist, OMC Operational District

Mr. Bun Channa, Pharmacist, OMC Operational District

Ms. Mam Boravann, DDF and USP focal Point

USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

Oddar Meanchey Province has only one operational district compared and is part of the USP Cross-Border Study. Mr. Kimseat and Mr. Channa are pharmacists at the Operational District Warehouse. Both are responsible for sample collection, performing Minilab[®] testing, and distributing medicines to provincial facilities. The facility houses public sector drugs including antimalarials that are distributed to hospitals, health centers, and other health posts. Both pharmacists recently completed the USP DQI training (July 2008) on the use of the Minilab[®], thus this visit was used to evaluate and reinforce skills obtained during the training. The individuals were evaluated for their basic testing and TLC skills for two chloroquine samples. Their technique was good, and no issues were observed. USP DQI should budget for a larger table and sufficient quantities of water for testing.

September 17, 2008

Visit to the O'smach Health Center and O'smach Market (on the Thai-Cambodia border)

Participants: Mr. Hien Kimseat, Pharmacist, OMC Operational District

Mr. Bun Channa, Pharmacist, OMC Operational District

Ms. Mam Boravann, DDF and USP focal Point

USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

USP staff shadowed Mr. Kimseat and Mr. Channa to observe their sample collection technique. The group visited one public facility, the O'smach Health Center, and seven private outlets. Four of the private outlets were located in a market; two of the outlets were legal, and two were illegal.

Sample availability was an issue. An adequate number of units to comprise a sample were available at only a few locations. This raised the issue of whether a sample should be collected for testing or left for potential treatment against malaria. The "mystery shopper" approach was not used because the town is small and all the pharmacy staff know Mr. Kimseat and Mr. Channa personally.

September 18, 2008

Meeting with the PSI, DDF, CNM, NLDQC, and WHO

Participants: Dr. Chroeng Sokhan, Vice Director, DDF

Ms. Mam Boravann, Deputy Chief of the Essential Drugs Bureau, DDF

Mr. Samuth Oeurn, TLC and Cross Border Study supervisor, DDF

Dr. William Mfuko, Technical Officer – Essential Medicines, WHO
Mr. Ouk Rada, Senior Officer, CNM
Prof. Nam Nivanna, Director, NLDQC
H.E. Yim Yann, Global Fund-DDF Medicine Quality Project Coordinator
Mr. Long Sameth, Global Fund-DDF Medicine Quality Project Asssistant
Mr. Tey Sovannarith, Deputy Chief of Technical Laboratory, NLDQC
Ms. Diane Freeman, International Fellow, Malaria Advisor, PSI
USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

The USP team met with the DDF, CNM, and the NLDQC. The objective of the meeting was to present the ACTWatch drug quality study to the key stakeholders as a group. Ms. Krech and Mr. Raymond gave brief overviews of their USP sponsored activities. Dr. Evans gave an overview of the ACTWatch Drug Quality Study, which included the objectives, methodology, and timeline and names of USP's partners in the study. Dr. Evans also updated the stakeholders of the low availability of antimalarials in the province visited earlier in the week. Therefore, where the study designs allow, data sharing will be required to not cause stock outs. Data on samples collected per province will be requested from the DDF to establish whether this is common to only this province. Dr. Evans indicated that in addition to testing antimalarials, the study also includes a survey of the Medicine Regulatory Authority in each country.

Dr. William Mfuko, the WHO DDF Advisor, indicated that a document is available that describes the functions of the Medicine Regulatory Authority in Cambodia and provided Dr. Evans with this information. Ms. Freeman of PSI spoke about the other components of ACTWatch, the Supply Chain study, and Household and Outlet Surveys.

Mr. Sovannarith of the NLDQC mentioned that antimalarials not specified in the study design are also found in the market. He also indicated that he needed access to methods in the Chinese Pharmacopeia to perform some of the confirmatory testing. Dr. Evans asked the NLDQC for a schedule of testing for the upcoming year to identify high volume testing periods. A schedule is not available, but the NLDQC indicated that the projected period when confirmatory testing is to be performed for ACTWatch is a low volume period. The presentation was well received by all stakeholders and no implementation issues were indicated.

Dr. Evans requested the following lists from Ms. Borvann:

- registered antimalarial drug manufacturers, importers, and wholesalers
- registered antimalarials
- antimalarials collected per province from the most recent round of USP activities

NOTE:

The antimalarial drugs in the ACTWatch study design and the Cross Border study were selected because of available methodology for Minilab[®] and confirmatory testing.

Artekin is an ACT containing dihydroartemisinin and piperazine phosphate and is commonly found in the Cambodian market. A method for the Minilab[®] does not exist, and there are no pharmacopeial methods available for the FDC.

September 19, 2008

Meeting with the NLDQC to discuss 3-year work plan proposal submitted to USP DQI

Participants: Prof. Nam Nivanna, Director, NLDQC

Mr. Tey Sovannarith, Deputy Chief of Technical Laboratory, NLDQC

USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

Dr. Evans, Ms. Krech, and Mr. Raymond met with the NLDQC to review the capacity of the national lab, discuss supply requests to USP DQI, and determine what impact the ACTWatch study could have on the lab's output.

- The NLDQC is equipped with several HPLC instruments (7) that are up and running
- The NLDQC had recently received 2 additional HPLC instruments from the Japanese Pharmaceutical Manufacturers Association (JPMA) which are waiting to be installed.
- Plans are underway for the lab to move to a new building in 3 years. Construction will begin in 2009-2010. USP DQI can help NLDQC find an expert in lab design, which is very important if the NLDQC wants to attain ISO 17025 accreditation in the future. The World Bank is funding construction of the new lab, and the NLDQC will budget for a design expert.
- NLDQC and USP DQI staff agreed that a technical assessment visit from the Centers of Excellence QA/QC experts (Chulalongkorn University) is not necessary at the present time. Ms. Krech and Dr. Evans will meet with the QA department at USP to organize a packet of information about how the lab can start preparing for ISO 17025 accreditation. Once these steps have been put in place a technical assessment visit will be scheduled.
- The lab needs a new dissolution machine. USP DQI will see if a used dissolution machine – in good condition – with an autosampler can be donated to the NLDQC.
- NLDQC requested training on the potentiometry titration method. USP will see if the Pharmacopeial Education department has plans to offer their titration course in Asia.

September 19, 2008

Meeting with USAID, PSI, DDF, CNM, NLDQC, and WHO

Participants: Dr. Chroeng Sokhan, Vice Director, DDF

Ms. Mam Boravann, Deputy Chief of the Essential Drugs Bureau, DDF

Mr. Samuth Oeurn, TLC and Cross Border Study supervisor, DDF

Dr. William Mfuko, Technical Officer – Essential Medicines, WHO

Mr. Ouk Rada, Senior Officer, CNM

Prof. Nam Nivanna, Director, NLDQC

H.E. Yim Yann, Global Fund-DDF Medicine Quality Project Coordinator

Mr. Long Sameth, Global Fund-DDF Medicine Quality Project Assistant

Mr. Tey Sovannarith, Deputy Chief of Technical Laboratory, NLDQC

Ms. Diane Freeman, International Fellow, Malaria Advisor, PSI

Mr. Jonathan Ross, Deputy Director, Office of Public Health, USAID

USP Staff: Dr. Lawrence Evans, Ms. Laura Krech, and Mr. Christopher Raymond

The primary objective of the meeting was to have stakeholders describe their current drug quality monitoring programs and activities in the country. After the meeting, Mr. Ross spoke with Ms. Krech and Mr. Raymond regarding feedback from USP DQI's 3-year work plan proposal and offered advice regarding the annual portfolio review in October. Mr. Raymond provided Mr.

Ross with a DVD of the Public Service Announcements on the dangers of counterfeit medicines that USP DQI has been working on for the past 8 months with Cambodia Mission funding. There are versions of the PSA with Khmer subtitles and voiceovers.

September 20, 2008

Meeting with DDF and WHO

Participants: Dr. Chroeng Sokhan, Vice Director, DDF

Ms. Mam Boravann, Deputy Chief of the Essential Drugs Bureau, DDF

Dr. William Mfuko, Technical Officer – Essential Medicines, WHO

H.E. Yim Yann, Global Fund-DDF Medicine Quality Project Coordinator

USP Staff: Dr. Lawrence Evans and Ms. Laura Krech

Ms. Krech and Dr. Evans met with the DDF and WHO to discuss budget issues for upcoming USP projects and the initiation of Global Fund Round 6. Ms. Krech went over the Round 6 budget line-by-line with the DDF and WHO staff members to determine which agency will cover which activities. The goal is to eliminate overlaps in funding.

For the ACTWatch study, the DDF suggested that the ACTwatch budget supplement were needed to cover per diem for sampling and Minilab[®] testing as well as the cost for samples. Confirmatory testing costs will be obtained from Mr. Sovannarith of the NLDQC. It was indicated that the current rate the NLDQC charges for confirmatory testing may be adjusted. Dr. Evans will request the current rate for confirmatory testing from the NLDQC.

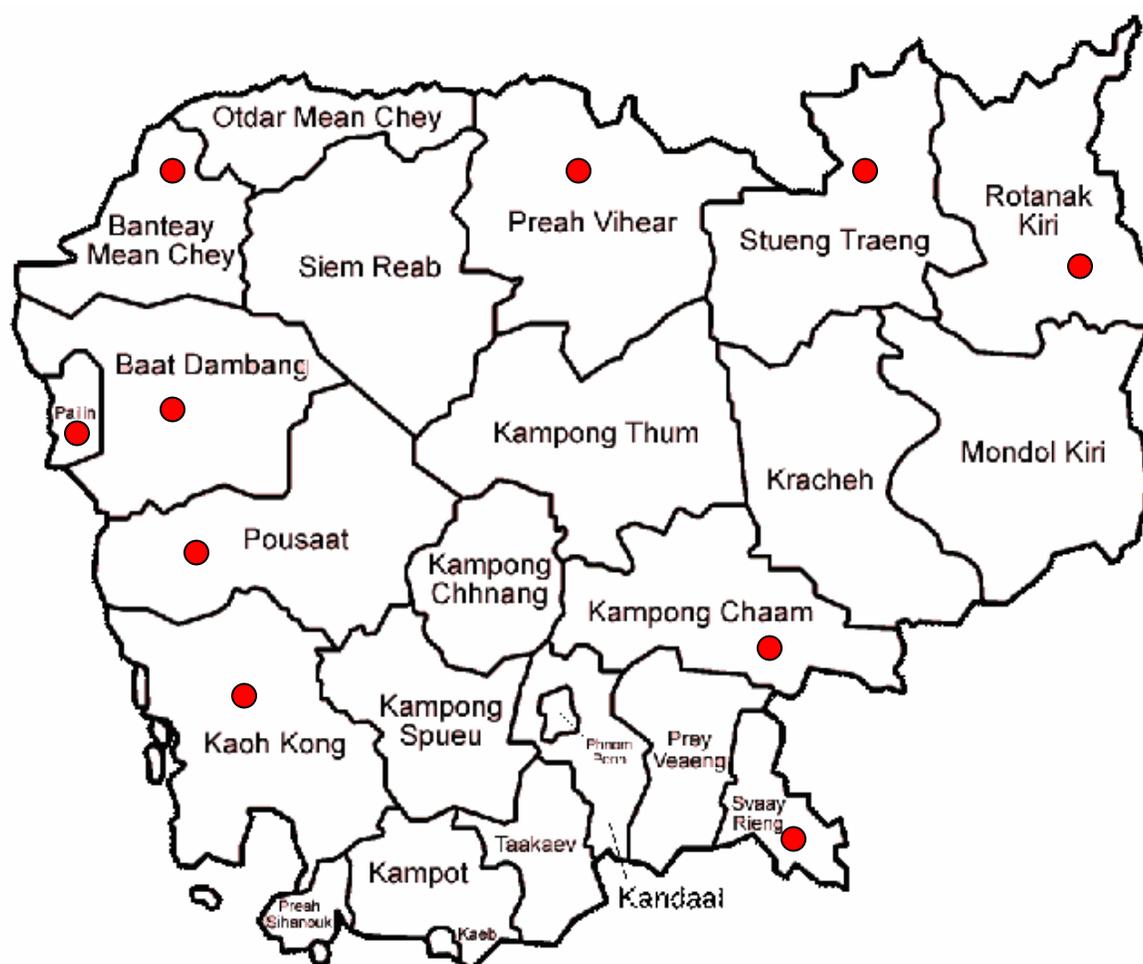
Next Steps

- Communicate regularly with Dr. Evans and PSI to determine how and when the ACTWatch study will begin in Cambodia
- Dr. Evans will add a section to the ACTWatch proposal/workplan summarizing current and recent drug quality studies in Cambodia and will also indicate how an unmet need is being addressed through this study.
- Ms. Krech and Dr. Evans will meet with Dr. Keith Conerly of QA at USP to organize a packet of information about how the NLDQC can start preparing to obtain ISO 17025 accreditation.
- Order and send all supplies, reagents, and reference standards requested by NLDQC for the sentinel sites, and the National Lab to continue sampling and testing activities for the Cross Border Study and the regular medicine quality monitoring project without delays.
- Send the two PV staff (Dr. Dathara and Mr. Sok) to a fully-functioning PV center for hands-on training.
- Follow up with Dr. Sokhan from the DDF to write a letter to WHO HQ so Cambodia can become an official member of the WHO Programme for International Drug Monitoring
- Ms. Boravann (DDF) and Dr. Mfuko (WHO) will teach the Cambodian PV staff the training materials from the WPRO “Introductory Course in Pharmacovigilance.”

SENTINEL SITES IN CAMBODIA¹

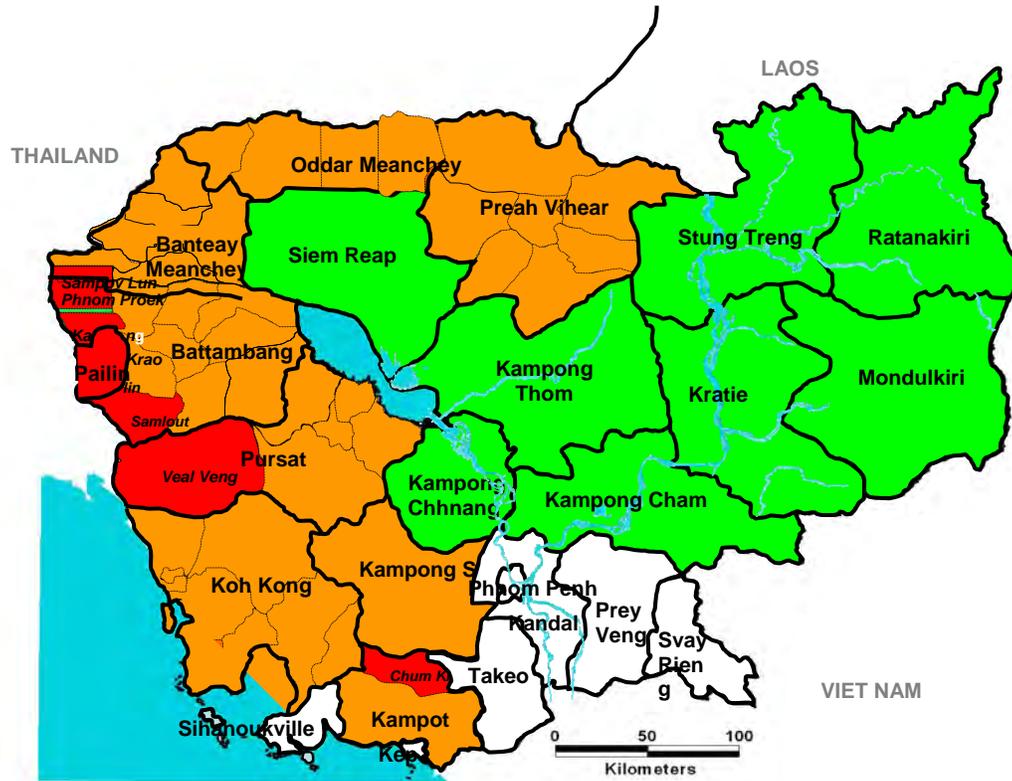
Cambodia has 10 sentinel sites, each equipped with a Minilab[®]

1. Battambang (<i>borders Thailand</i>)
2. Banteay Meanchey (<i>borders Thailand</i>)
3. Koh Kong (<i>borders the ocean</i>)
4. Pailin (<i>borders Thailand</i>)
5. Preah Vihear (<i>borders Thailand and Lao PDR</i>)
6. Pursat (<i>borders Thailand</i>)
7. Svay Rieng (<i>borders Vietnam</i>)
8. Stung Treng (<i>borders Lao PDR</i>)
9. Ratanakiri (<i>borders Vietnam and Lao PDR</i>)
10. Kampong Cham (<i>borders Vietnam</i>)



¹ Spelling of the provinces in English is phonetic; therefore some of the spelling of the sentinel sites differs from what is found in the map. USP uses the spelling of our partners from the Cambodian Department of Food and Drugs.

PSI Map of Malaria Containment Zones in Cambodia



- Zone 1 red
- Zone 2 orange
- Zone 3 green
- Zone 4 white

Map diagram prepared and provided by PSI.

Photographs of Oddar Meanchey site visit

Dr. Lawrence Evans (USP ITAP) presenting the ACTWatch study to partners from the DDF, CNM, WHO, PAC and NLDQC.



USP, DDF and Oddar Meanchey colleagues wait to see if the road will re-open – heavy rains washed away a large part of the road leaving a gaping hole, and the only way to pass through was with the help of 20 people pushing the vehicle. Here, Mr. Chris Raymond and Dr. Lawrence Evans wonder if the team will make it through.



Still waiting to see if the road is passable, Ms. Krech stands in front of the car to show that the bumper fell off during the trip due to the rough road conditions.



Mr. Raymond and Ms. Krech show DDF Vice-Director Dr. Chroeng Sokhan and His Excellency Yim Yann, President of the Pharmacists Association of Cambodia, the Public Service Announcements USP DQI created about the dangers of counterfeit medicines. An interview that USP DQI filmed with H.E. Yim Yann was also shown.

