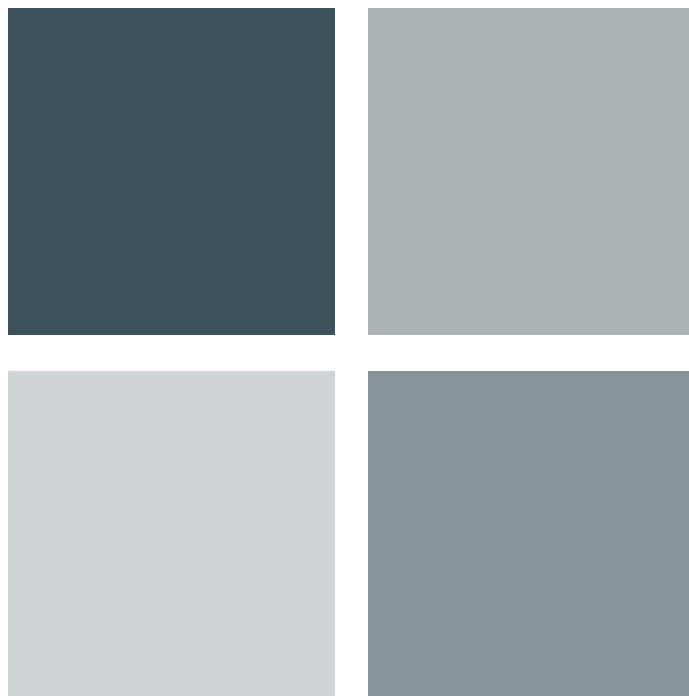


## Lessons Learned from Chiang Mai, Thailand





# Research Institute for Health Sciences Chiang Mai University

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## Introduction

Thailand is located in Southeast Asia, and is bordered by Myanmar, Laos, Cambodia and Malaysia. Out of a population of about 65 million people, approximately one million have acquired HIV since the epidemic began, with 560,000 people, or 1.5 percent of the population aged 15 to 49, living with the virus by the end of 2003. Groups that are particularly vulnerable to infection include commercial sex workers, injecting drug users, men who have sex with men, migrant and mobile populations, and young people. The “100 percent condom” policy, once widely enforced within brothels, has lost much of its momentum in recent years.

In Chiang Mai, Thailand, the Research Institute for Health Sciences (RIHES) at Chiang Mai University serves as the HIV Prevention Trials Unit (HPTU). RIHES has carried out research in various communities in northern Thailand on malnutrition, reproductive health and tropical diseases. RIHES was originally established as the Anemia and Malnutrition Research Center under the Chiang Mai University Faculty of Medicine in 1967. It served the community in the context of many projects, including pathology and treatment of protein calorie malnutrition (1967-1977) and prevention of blindness in newborn and young children by massive single dose of vitamin A (1972-1974). In 1978, the center was separated from the Faculty of Medicine and has since become the Research Institute for Health Sciences, and the RIHES has been responsible for conducting

biomedical, clinical, epidemiological and behavioral research on public health problems of high priority in the northern population of Thailand.

As the HIV epidemic surfaced in Thailand in the 1980s, RIHES began to focus its resources and efforts on identifying solutions to HIV-related problems.

## **HPTN Research Studies in Thailand**

The Research Institute for Health Sciences and its community advisory board (CAB) and sub-CAB are currently collaborating on two HIV Prevention Trials Network (HPTN) research studies, with a third study in the pipeline. HPTN 037 is a study to evaluate the efficacy of a network-oriented peer education intervention for the prevention of HIV transmission among injecting drug users and their network members. Methods used in this study included a series of six group sessions involving injecting drug users; sessions were carried out over a four-week period. Contents of the sessions include facts on HIV transmission and prevention and how to communicate these facts to their peer networks. HPTN 052 is a trial to evaluate the effectiveness of antiretroviral therapy plus HIV primary care versus HIV primary care alone to prevent the sexual transmission of HIV-1 in serodiscordant couples. The third study, HPTN 058, is a trial to evaluate the efficacy of drug treatment in prevention of HIV infection among opiate-dependent injectors. Table 1 contains additional information about these studies.

## **Community Advisory Board**

### **Establishment**

To facilitate a small HIV vaccine trial, RIHES established a CAB in 1999 in cooperation with the Ministry of Public Health Office of Disease Prevention and Control. The CAB coordinates with 30 organizations from both government and private sectors. Most of these organizations are working with communities on issues related to HIV/AIDS. RIHES brought together representatives of each organization to discuss establishing a CAB. About 20 representatives attended the initial meetings and agreed to form the CAB.

To accommodate the HPTN's HIV prevention trial among injecting drug users, the CAB, in collaboration with RIHES and the Chiang Mai Drug Treatment Center, established a sub-CAB on drug users in October 2001.

In addition to the CAB and sub-CAB, RIHES now has two subcommittees on injecting drug users and noninjecting drug users. They are smaller and deal with issues more relevant to the target populations they represent. Some study participants are also invited to become members of these committees. Regular meetings of the subcommittees on specific issues help strengthen involvement of the target community and reduce the meeting burden for the CAB and sub-CAB.

### **Members**

The initial CAB was composed of 19 people, including two representatives from nongovernmental organizations, three people living with HIV/AIDS, two monks, six local administrative officers, and six researchers. The CAB also has a full-time administrative staff person and three

**Table 1. HPTN Research Studies in Chiang Mai, Thailand**

Study #	Protocol and Purpose	Study Population in Thailand	Other Sites
HPTN 037	<p>Phase III study to evaluate the efficacy of a network-oriented peer educator intervention for the prevention of HIV transmission among injecting drug users and their network members.</p> <p>Primary objective: to determine whether the peer-educator intervention reduces the rate of HIV infection among injecting drug users and members of their HIV risk network.</p>	1,800 injecting drug users and 3,500 network members.	Philadelphia, USA
HPTN 052	<p>Phase III trial to determine the effectiveness of two treatment strategies in preventing the sexual transmission of HIV in HIV-serodiscordant couples.</p> <p>Purpose: to determine whether antiretroviral therapy can prevent the sexual transmission of HIV-1 in HIV-1-serodiscordant couples.</p>	1,750 HIV-serodiscordant couples in all study sites.	Blantyre and Lilongwe, Malawi; Chennai and Pune, India; Harare, Zimbabwe; Porto Alegre and Rio de Janeiro, Brazil; Boston, USA
HPTN 058	<p>Phase III trial to evaluate the efficacy of buprenorphine/naloxone drug treatment in prevention of HIV infection among opiate-dependent injectors.</p> <p>Primary objective: to determine whether 52 weeks of suboxone and counseling treatment in opiate-addicted participants will achieve a long-term (104 weeks) reduction in cumulative HIV incidence compared to short-term suboxone detoxification and counseling.</p>	1,460 opiate-dependent injectors in all sites.	Guangxi and Xinjiang, China

advisors (directors of RIHES, the Office of Disease Prevention and Control, and the Chiang Mai Drug Treatment Center). The CAB office was originally located at the Chiang Mai Office of Disease Prevention and Control of the Ministry of Public Health. The current CAB for the Chiang Mai HIV prevention trial was appointed in November 2003. It consists of 23 members, including three representatives from nongovernmental organizations, three RIHES staff members, three people living with HIV/AIDS, three HIV network members, two monks conducting HIV/AIDS activities, one local administration officer, three community representatives, and five other government officials. Five consultants are also affiliated with the CAB.

The initial sub-CAB on drug users included 13 members: the director of the Drug Treatment Center, the deputy director of RIHES, three drug treatment nurses, four RIHES research staff members, and four former injecting drug users. They provided a lot of useful advice on the feasibility of recruiting injecting drug users into the HIV prevention trial. The sub-CAB later developed into a continuously active committee on drug use research. The present sub-CAB on drug users,

like the main CAB, was appointed in March 2005. It has 23 members: eight representatives from nongovernmental organizations, one local administrative officer, four community representatives and ten staff members from the RIHES and other governmental organizations. The sub-CAB has changed its name to Chiang Mai University (CMU) substance abuse CAB, or “substance abuse CAB.” The directors of RIHES, the Office of Disease Prevention and Control, and the Chiang Mai Drug Treatment Center; the former chair of the old sub-CAB; and a police lieutenant general who is a liaison officer to the prime minister and ministry of interior serve as advisors. The CAB and substance abuse CAB use the same office, facilities and personnel, including a coordinator, assistant coordinator, and full-time administrative staff.

When recruiting members, the CAB and substance abuse CAB look for people with a combination of the following qualifications:

- Willing to serve on the CAB
- Engaged in a network of people living with HIV/AIDS or of former injecting drug users
- Working in nongovernmental or community-based organizations focused on HIV/AIDS
- Representative of relevant communities

Members of the CAB and substance abuse CAB are elected for a term of two years. In the CAB, six members are considered representative of direct stakeholders, while 22 represent indirect stakeholders (these numbers include CAB advisors). In the substance abuse CAB, six members represent direct stakeholders, while the remaining 22 represent indirect stakeholders.

## **Training**

Community advisory boards and substance abuse CAB members have attended several training programs organized by the RIHES and the Thai Food and Drug Administration. From 2002 to 2005, 46 CAB and substance abuse CAB members received training on research methodology, good clinical practices, protection of human subjects, and institution review board consent processes and forms.

## **Community Advisory Board Activities**

Community advisory board and substance abuse CAB members meet every two months. They attend additional local, national, and international meetings.

The first step in the studies, after development of the research protocols, was submission of the protocols to the relevant governors asking for permission to conduct the studies in the target communities. After gaining approval from the governors, RIHES and its CABs made appointments with community leaders and discussed the study details with them. RIHES solicited the permission of leaders to work in their communities and asked them to assist in identifying and meeting with members of the target population. RIHES and the CABs then provided members of the target population with general information and education about HIV/AIDS. Interested people were invited to meet the study team at the site for activities related to recruitment and screening. Those willing and eligible to participate were enrolled. RIHES and the CABs kept in touch with and listened to the needs and requests of participating communities.

Communities in the rural area of Sameong, for example, asked for vocational information about planting and cattle, how to dismiss alien laborers from the area, supplementary jobs, and land ownership certificates. They also mentioned issues related to family and community environment, solutions to various drug problems in the area; behavior improvement of family leaders, understanding among family members and people in the community, how to protect themselves from chemical substances used in agricultural activity, how to keep themselves free of disease, the appropriate role of each member of the family, and educational opportunities for children in the community (including computer skills, news channels and sports).

RIHES and CAB members also participated in additional community activities, especially those related to culture. When the communities organized traditional cultural ceremonies, RIHES and its CABs contributed resources to support activities, as well as participating in them. They led church activities, such as singing, Bible lessons, and physical and spiritual improvement activities. They organized a community meeting to discuss social and cultural roles, responsible behavior and support for others, the importance of playing sports, and the dangers of drug use, including the risk of acquiring HIV infection and other sexually transmitted infections.

Another CAB–research staff collaboration consisted of introducing one study to the community via role plays, including a puppet show that discussed information about HIV/AIDS and harm reduction related to sexual behavior and injecting drug use. A speaker living with HIV shared experiences about HIV infection and treatment, and a speaker from the Chiang Mai Drug Dependence Treatment Center provided general information about drug treatment. On National Children’s Day, the RIHES-CAB team led activities and games for children and distributed winter clothes and blankets. Community advisory board members and research staff also made routine home visits to members of the community.

*Community advisory board members inform researchers about negative rumors related to the studies and suggest ways of reacting to them.*

### **CAB and Substance Abuse CAB Roles in Research Methodology**

RIHES staff regularly submitted protocols, consent forms, brochures and leaflets for review and comment during CAB meetings. The CAB and substance abuse CAB provided comments on research materials from both the HPTN protocols and other HIV-related research conducted by RIHES. Community advisory board and substance abuse CAB members also contributed to the solution of recruitment problems. In particular, the principal investigator and coordinator of the study on reducing HIV transmission among injecting drug users contacted substance abuse CAB members who were former injecting drug users and CAB members living with HIV/AIDS to seek their views on how to adapt the recruitment plan and activities and the proper ways to help HIV-positive participants. The substance abuse CAB suggested that former injecting drug users would best understand current users and could effectively locate and persuade them to contact research staff. Community advisory board members living with HIV discussed their experiences in general self-care and offered advice to injecting drug users who tested HIV-positive about finding further assistance. RIHES, with the assistance of CAB and substance abuse CAB members, organized a seminar on these issues to improve the understanding and confidence of community educators and recruiters in the framework of their missions.

Currently, the principal investigator of the study on reducing HIV transmission among injecting drug users, the study physician, and other staff members regularly report to the CAB and substance abuse CAB about research progress and activities during regular meetings. While CAB and substance abuse CAB members have not developed a specific action plan related to research activities, they do make suggestions to researchers on how to work with the community, provide information about the research to community members, and provide assistance and facilities to researchers for mobilizing and recruiting study participants. Community advisory board members also inform researchers about negative rumors related to the studies and suggest ways of reacting to them.

For scientific research activities, there are no other formal structures or partnerships established at the site besides the CAB and substance abuse CABs. Some nongovernmental organizations are active in engaging communities in HIV prevention activities. However, they focus on providing outreach services with minimal emphasis on scientific research.

### **Community Reactions to the Research Studies**

In general, community leaders have been very willing to collaborate with RIHES because of its well-known research performance. However, responses from community leaders varied, depending on the details of each study and the target population involved. The research study on reducing HIV transmission among injecting drug users received both positive and negative responses. Most community leaders in areas such as administration and religion and others who were respected by people in the community were willing to listen to descriptions of the study. Community leaders at the administrative level were supportive, provided suggestions on how to approach target participants, and helped disseminate study details and brochures to the target group. These leaders and the study's community educator/recruiter developed trust and a good working relationship. Research staff used these interactions to better understand community needs. In the urban area of Muang, potential participants from the communities asked for a private space for their scheduled appointments at the study office. RIHES responded by outfitting a private room with newspapers, magazines, brochures on health issues, and a TV/VCR. In Sameong, a rural area, participants expressed the need for spaces devoted to sports and recreation, as well a meeting place stocked with health information materials. RIHES was able to respond to these needs by providing two sports areas, newspapers and brochures on health issues in the study office, and a local radio broadcast devoted to health-related information. Community advisory board members and research staff met with young people in church settings to provide information on how to prevent sexually transmitted infections. Research staff also contributed time and resources to community-initiated activities. The community educator, who lived in the community, actively provided affordable community services to the members of the community.

The research team conducted focus group discussions to obtain the perspectives of participants and other community members on key issues that highlighted their problems, needs and the possibility for future recruitment. The team gleaned the following information from community members:

- Positive and negative perspectives about the study
- Expected impact from participating in the study
- Expectations about the study
- What they liked about the study
- The local drug situation, which served as a data source on potential participants and new target groups
- Suggestions for conducting the study

A few leaders expressed negative feelings about the research study. They felt that it was useless and would have no direct benefit for the communities. They were not interested in listening to explanations. Some of them spoke negatively about the study and persuaded members of the target population not to participate.

## **Challenges**

RIHES, the Chiang Mai HPTN CAB and the substance abuse CAB have faced a number of challenges in conducting HIV prevention research. Examples of these challenges are listed and described below.

### **Rumors about research**

A number of rumors and myths surfaced in some communities about blood drawing and the HIV status of participants. In one community, villagers thought that study participants were HIV-infected. Some also thought that research staff collected blood samples to sell. Community advisory board members from that community were able to help the research team resolve the problem by informing research staff about the rumors and by educating community members about the facts.

### **Discrimination against injecting drug users**

RIHES also faced challenges in the form of discrimination and stigmatization against injecting drug users, sometimes exacerbated by the policy of “the war on drugs.” The research team worked with drug treatment centers, hospitals, and health centers in the area to emphasize harm-reduction principles. Team members first encouraged injecting drug users to seek treatment as the most effective way to prevent HIV and other blood-borne infections. Those unable to stop taking drugs were asked to participate in the study. To deal with the challenge of resistance from within communities, research team members disseminated information about the health benefits that would ensue if injecting drug users in the area modified their risk behaviors. To reinforce links to the community, the study recruited a community educator/recruiter of local ethnicity who could speak local dialects. The community educator approached the community in a familiar context and worked with community leaders to promote better understanding and involvement. In response to the potential problem of police opposition to the study, research staff also contacted members of the local police force and its administration, explained the potential impact of the study on the wider society, and sought cooperation. To safeguard confidentiality, the team ensured that the record system was well organized and private. Substance abuse CAB members from the drug treatment center, the local administrative office, and a former injecting drug user helped plan safe and appropriate recruitment strategies.

### **Developing and maintaining community advisory structures**

Developing and maintaining community advisory structures also presented challenges to the RIHES and the HPTN research staff. Soliciting direct representatives of the study population to become CAB members was complicated, especially when the population in question was injecting drug users. RIHES tried to approach people from sectors as close to the study population as possible. Community advisory board members living with HIV/AIDS have proven especially helpful in providing comments on research concepts and plans, based on their personal experience. Former injecting drug users on the substance abuse CAB also helped by informing the study

about their personal backgrounds. However, the format and broad nature of the committee limited the ability of the research team to address many practical problems in the field, especially the recruitment and retention of the hidden population of drug users. Sub-CABs for specific groups are in the best position to provide input on specialized issues.

It can be especially challenging, though essential, to work with people living with HIV/AIDS and with former injecting drug users on protocol development, approval and implementation. Most have limited experience in research methodology and techniques, although training may enable them to understand some basic research concepts. It is particularly important for them to learn how their experience can be helpful to protocol development and implementation.

When the Chiang Mai CAB and substance abuse CAB were first formed, researchers and government officials dominated them, with a small number of direct stakeholders invited to become members. After a period of training and developing a better working relationship, an active NGO leader was selected to become the CAB chairperson, assisted by the relevant researchers. With proper administrative support, CAB and substance abuse CAB members can maintain their functions in directing and supporting HIV prevention research.

## Lessons Learned

The work of RIHES, its CAB and substance abuse CAB has yielded lessons in the following areas.

### ***Approach the community for involvement in HIV prevention trials***

In Chiang Mai, researchers and CAB members have learned that target communities need to be clearly defined. Research teams need sufficient time to get to know target communities, learn how to access them, and establish a good relationship with them, if they hope to convince community representatives to become CAB or substance abuse CAB members. Research teams also need to explore the potential for misunderstanding — such as the rumors that study participants were HIV-positive and the blood collected from them was being sold — and arrange for opportunities to engage in open discussions with participants and their communities. Their suggestions can then become part of study-specific community education plans.

### ***Train community members involved in HIV prevention trials***

The experience in Chiang Mai showed that most CAB members did not understand research concepts, study designs and their own roles when they first joined the CAB. Regular meetings and discussion about research concepts and relevant issues, explained in simple language, have helped CAB members understand some relevant and nontechnical issues.

Research team members can explain and address relevant topics, yielding specific suggestions from CAB members. Specialized training can help familiarize CAB members with the way researchers think and work.

### ***Solicit community contributions to research methodology and design***

Due to the slow development process described above, RIHES principal investigators found it necessary and helpful to break down the studies into a few simple questions to stimulate discussion and suggestions from community representatives. Community representatives should be involved in research protocol development. However, they may not be able to contribute to the development of all protocol-related issues. Collaboration between researchers and CABs in Chiang Mai demonstrated that CAB members often do not have time or the necessary attention span to read lengthy, detailed proposals or documents. Documents should be simplified and introduced progressively during meetings. Research team members should ensure that discussions take place at a level that CAB members can understand.

### ***Develop appropriate community advisory structures***

In Chiang Mai, CAB members and researchers found that specific issues — especially sensitive issues such as injecting drug use — require small and specific sub-committees. The Chiang Mai HPTN substance abuse CAB on injecting drug users fulfilled this need. Research teams learned a great deal from the substance abuse CAB about injecting drug users, including how they function, their impact on research and community activities, and their limitations.

### ***Improve the outcome of HIV prevention trials by involving community representatives***

Community representatives help direct research teams to the proper target population. This facilitates study recruitment and enrollment and helps ensure the validity and reliability of the study. In Chiang Mai, this was particularly important in the study focused on injecting drug users, who are often difficult to access and approach. Community representatives also can provide advice on the best way to approach HIV-positive participants. This helps create a good relationship with the target community and fosters effective community education activities.

