Annual Report
2011
THE HIV NETHERLANDS AUSTRALIA THAILAND RESEARCH COLLABORATION
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We have reached the final quarter of 2011 and I am delighted to present the 15th annual report from the HIV Netherlands Australia Thailand Research Collaboration.

2011 has been a busy year for HIV-NAT staff, 86 studies were conducted and care was provided to more than a thousand patients. While HIV-NAT will continue to strive to better serve people living with HIV and the scientific community by carrying out quality research in HIV/AIDS, we would also like to highlight that some exciting happenings have taken place this year.

HIV-NAT started the year off with the ‘Art for Medical Miracles’ in January. This is HIV-NAT first auction event, organised to raise money for the Drug Fund that has supported thousands of people. Through this event, many respected artists realised the importance of creating opportunities for HIV infected patients and showed their support by having their works auctioned for charity. HIV-NAT raised THB1.6 million through the artists’ generosity and contributions.

Following, the Symposium Series training workshops took place upon request from Thai healthcare practitioners. Scheduled to take place twice a year, the Symposium Series training workshops are centred on care management, and treatment for people living with HIV/AIDS which are conducted in Thai. The purpose of the training workshop is to provide in-depth knowledge on HIV care and treatment to medical doctors, nurses, pharmacists and healthcare practitioners.

Lastly, to achieve the goal of becoming a leading centre of education and research on HIV/AIDS in Thailand, HIV-NAT has introduced two new positions: training coordinator and communication specialist. The training coordinator is responsible for organising and facilitating training sessions and workshops, and the communication specialist will help increase HIV-NAT’s visibility. More publications and newsletters are under way and HIV-NAT hopes that this will keep everyone engaged and informed about HIV-NAT’s work and community impact.

The team at HIV-NAT is strongly committed to helping people living with HIV to have better access to HIV treatment and live healthily and without stigma. I am certain that 2012 will be another productive year for HIV-NAT as it continues to drive toward excellence in HIV/AIDS research.

Phan Wannamethee
Secretary General, Thai Red Cross Society
Chairman, HIV-NAT international Advisory Board
A MESSAGE FROM OUR CO-DIRECTORS
A MESSAGE
FROM OUR CO-DIRECTORS

We are extremely pleased with HIV-NAT’s activities this year. HIV-NAT has been intensely busy conducting a total of 56 adult and 30 pediatric studies, focusing on large randomized studies that will impact the country and the field of HIV worldwide. This year, HIV-NAT announced the results of two important studies: the PREDICT and the HIV STAR studies. PREDICT is the only randomized study of when to start antiretroviral therapy in children older than one year of age that was conducted in 300 children from 7 Thai and 2 Cambodian sites. HIV STAR evaluated mono-protease inhibitor therapy compared to standard 3-drug regimen as second line treatment in 200 adults from 10 sites across Thailand. In 2011, HIV-NAT published 38 papers in peer-reviewed journals and presented 25 abstracts at major HIV conferences.

HIV-NAT is dedicated to conducting research that is relevant to Thailand and the region. One such area of research is the use of low dose antiretrovirals. This year, HIV-NAT launched the LASA study by building upon results from the initial study showing favorable pharmacokinetic profile of low dose atazanavir and comparing it to standard dose of atazanavir in a randomized clinical study. A study coordinated by the Kirby Institute of the University of New South Wales in Sydney, Australia with HIV-NAT as the country coordinator is ENCORE 1 which evaluates the clinical efficacy of low dose efavirenz compared to standard dose. Together with the Kirby Institute, HIV-NAT is coordinating a multicenter study to evaluate a novel second line regimen using an integrase inhibitor with a protease inhibitor compared to standard protease inhibitor regimen.

This year, HIV-NAT has worked closely with the Department of Disease Control (DDC), the Thai Ministry of Public Health on two studies that are equally important in influencing Thailand’s health care system. One is initiating a network of large tertiary care sites in Bangkok and its metropolitan area to evaluate best practice in diagnosing and treating tuberculosis in HIV and non-HIV population. Another is to evaluate the feasibility of Test and Treat Strategy among Men who have Sex with Men in Bangkok. This latter study is a joint effort between the DDC, Thailand Ministry of Public Health - US Centers for Disease Control and Prevention Collaboration and HIV-NAT. This is a crucial step on achieving HIV-free Bangkok, a commitment Bangkok has with UNAIDS in its “Getting to Zero” effort.

HIV-NAT faces an exciting future. We will be launching our first hepatitis C treatment trial next year and will be integrally involved in advocating for access to treatment for all Thais with hepatitis C infection.

Finally, we are grateful to our patients for their participations in our studies. We thank our collaborators for their continued support!
HIV-NAT CLINICAL TRIALS NETWORK

CHIANG MAI
- NAKORNPING HOSPITAL
- SANPATONG HOSPITAL

CHIANG RAI
- CHIANG RAI REGIONAL HOSPITAL

BANGKOK
- HIV-NAT – TRCARC
- CHULALONGKORN HOSPITAL
- SIRIRAJ HOSPITAL, MAHIDOL UNIVERSITY
- BAMRASNARADURA INSTITUTE
- RAMATHIBODHI HOSPITAL
- BANGKOK METROPOLITAN ADMINISTRATION MEDICAL COLLEGE & VAJIRA HOSPITAL
- TAKSIN HOSPITAL

KHON KAEN
- SRINAGARIND HOSPITAL, KHON KAEN UNIVERSITY
- KHON KAEN HOSPITAL

CHON BURI
- CHONBURI REGIONAL HOSPITAL
- QUEEN SAWANGWATTANA MEMORIAL HOSPITAL

CHANTABURI
- PRAPOKKLAO HOSPITAL

PHNOM PENH
- NATIONAL PEDIATRIC HOSPITAL
- SOCIAL HEALTH CLINIC
INTERNATIONAL ADVISORY BOARD 2011

1. **Mr. Phan Wannamethee (Chairman)**
The Secretary General
The Thai Red Cross Society Bangkok, Thailand

2. **Dr. Tej Bunnag**
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3. **Prof. Emeritus Praphan Phanuphak**
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4. **Prof. David A Cooper**
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Please note that this list is not exclusive nor exhaustive. Since new research studies are developed and existing studies change, it is possible that some collaborators may not be listed.
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Pakarat Sangkla

SARATHANEE
Surathanee Hospital
Songsak Serirom
OVERVIEW OF HIV-NAT STUDIES

In 2011, HIV-NAT conducted a total of 86 studies, 56 of which were conducted on adults and 30 on children. There are 56 ongoing studies. 21 studies were completed this year.

Out of nine pharmacokinetic studies conducted 2011, seven are done in adults and two are done in children. We have eight ongoing viral and co-viral studies and two studies on this subject were just opened. There are four ongoing tuberculosis studies and 11 ongoing cohorts.

HIV-NAT also conducted nine strategic studies, four of which have been completed this year. There are two ongoing strategic studies and three more were recently opened. There are nine studies on new drugs, seven of which are ongoing, one was completed and one will open in 2012. There are a total of 11 studies in other areas, seven of which are ongoing and four were completed this year.

For the pediatric studies, there are a total of 30 studies. Nine pediatric studies were completed this year. There are 18 ongoing pediatric studies and two just recently opened. One pediatric study is expected to open in 2012.
Two important strategic studies were completed in 2011. One was conducted in children and is called the PREDICT study (Pediatric Randomized to Early vs Deferred Initiation in Cambodia and Thailand) or HIV-NAT 035. This study was sponsored by the US National Institute of Health and is the only randomized trial that addresses when to start antiretroviral therapy in children older than 1 year of age. Up to 300 children from Thailand and Cambodia participated in this study. The PREDICT study showed that more than 97% of HIV-infected children in the study were alive without AIDS at three years of follow up regardless of whether ART was initiated immediately or initiated when the CD4 dropped to below 15%. However, those children in the deferred arm had a slower growth rate, more episodes of herpes zoster and thrombocytopenia. HIV viral suppression rate and immune recovery was comparable between both groups. The investigators conclude that deferred ART in children who are relatively well and have survived the first year of life without treatment is an option provided that close monitoring of CD4 can be performed and ART can be promptly initiated when CD4 declined below 15%. There are three substudies assessing neurodevelopment, impact of selenium/zinc on treatment outcomes, and immunologic substudy (this study is located under the section entitled, “LONG TERM COHORT ANALYSIS.” Based on the results from the neurodevelopment substudy, HIV-NAT will expand this further in another study.

The other study is the HIV STAR study which was sponsored by the Thai National Health Security Office, The Swiss HIV Cohort Study, and the National Research Council of Thailand. The results of this study were presented at the 18th Conference on Retrovirus and Opportunities Infections (CROI 2011) that was held in Boston, MA, USA from 27 February – 2 March 2011. The HIV STAR baseline resistance manuscript was published while the efficacy report is currently being submitted to an international, peer-reviewed journal. The HIV STAR study showed that lopinavir/ritonavir monotherapy, as a secondline regimen, was inferior to tenofovir/ lamivudine/lopinavir/ritonavir in patients who failed an NNRTI-based regimen. Therefore the investigators do not recommend the use of LPV/r monotherapy as a second-line regimen or it should be used with caution, especially in settings where close viral load monitoring is not available. This study supports the use of TDF/3TC in combination with LPV/r treatment for patients who failed 2NRTIs+NNRTI with very high rate of 3TC-resistance in settings where genotypic resistance test may not be accessible and no new class ARVs available.

This year, three important strategic studies were launched of which two are low dose studies and one is a pilot study: ENCORE-1 (Evaluation of Novel Concepts in Optimization of antiRetroviral Efficacy), LASA (Low dose Atazanavir/r vs. Standard dose Atazanavir/r) and the Test and Treat Feasibility Study. The Encore 1 study opened in September 2011 and is a randomized, double blind placebo-controlled international clinical trial. This study is designed to test for non-inferiority of lower dose (400mg) efavirenz compared to standard dose (600mg), in combination with a fixed dose backbone; if the lower dose proves to be non-inferior then
international guidelines around the world may change their recommended efavirenz dose. The potential fewer side-effects and lower cost with the lower dose mean that both patients and antiretroviral providers will benefit. The study had been recruiting well in Thailand and other sites across the world. At the time of preparing this annual report, a total of 30 patients have been enrolled in the study from the three sites: HIV-NAT, Khon Kaen and RIHES.

LASA is a multicenter, randomized control trial to find the appropriated dose of once daily atazanavir/ritonavir based HAART in Thai HIV-infected adults. The benefits of this regimen are once daily intake which may be more convenient for patients and fewer side effects of dyslipidemia compared to other PI-based regimens. LASA started enrolment since June 2011 and expected to complete the enrolment of 560 patients in December 2012. The funding agencies are the National Health Security Office and Kirby Institute for Infection and Immunity in Society, University of New South Wales, Sydney, Australia.

HIV-NAT is interested in investigating the theoretical “Test and Treat” strategy to drive the HIV epidemic towards elimination in the men having sex with men (MSM) group. Currently the MSM are a major risk group in Thailand, accounting for about one-fifth of all HIV infections. HIV infection rates among Bangkok MSM rose from 17% to 28% between 2003 and 2005 and continue to increase. The phenomenon is very similar to other high and low to middle income countries. Furthermore, Thailand has pledged its commitment to UNAIDS’s “Getting to Zero” effort. As a result of this, HIV-NAT will collaborate with the Department of Disease Control (DDC) and

Thailand Ministry of Public Health - US Centers for Disease Control and Prevention Collaboration to conduct the Test and Treat study. Unfortunately, controversial data on uptake of HIV testing among Thai MSM suggest that existing voluntary counseling and testing (VCT) services are not properly responding to the needs of MSM, in numbers, availability, confidentiality, costs and working time. Furthermore, there is limited data on the acceptability of immediate ART among HIV-positive Thai MSM which has raised some concerns on risks and benefits to implement the new strategy. Immediate ART will involve treatment of healthy HIV-positive MSM, individuals not at this time known to personally benefit from ART, therefore it is important to first assess the interest and attitudes on regular voluntary HIV counseling and testing, the acceptability of immediate antiretroviral therapy if seropositive and identify the associated factors in improving access to treatment and care. The results from this Feasibility Study will be used to design the Test and Treat Study which has been proved to reduce HIV transmission by mathematic models in several settings including Africa and North America.

Demands for HIV research are constant because there are always questions being asked. In an ever changing world, HIV-NAT will continue to conduct research and address those issues relevant to the region and worldwide. HIV-NAT’s ability to adapt and stay abreast cutting edge technology and up-to-date information has made it a formidable HIV research organization in Thailand. Nevertheless, it would not have been possible without the support from various governmental agencies, academic institutions, other research organizations, pharmaceutical partners, funding agencies and charities worldwide. HIV-NAT is grateful for everyone’s unwavering and continued support and would like to acknowledge all contributors for their resolute, steadfast financial contributions, research collaboration, transfer of knowledge, and sharing of ideas, knowledge and resources.
OVERALL THAI SUPPORT

**government agencies**
- Commission of Higher Education, Ministry of Education (CHE) 5
- Ministry of Public Health (MOPH) 3
- National Health Security Office (NHSO) 4
- National Research Council of Thailand 8
- Social Security Office (SSO) 1
- Thai Research Fund 2
- National Research University (NRU) 3
- Department of Disease Control (DDC) 2

**pharmaceutical partners**
- Government Pharmaceutical Organization 2

**academic organizations**
- Chulalongkorn University 12
- Mahidol University 1
- Chiang Mai University/PHPT 1

**funding agencies**
- The Aligning Care and Prevention of HIV/AIDS with Government Decentralization to Achieve Coverage and Impact: ACHIEVED Project (Global fund Thailand) 3

**research organizations**
- HIV-NAT 9
- Thai Red Cross AIDS Research Centre 4

**charities**
- HIV-NAT Drug Fund 1

OVERALL INTERNATIONAL SUPPORT

**governmental agencies**
- National Institute of Health (NIH) 13

**pharmaceutical partners**
- Abbott 2
- Bristol-Myers Squibb 4
- Chiron Corporation 1
- Gilead Sciences 4
- Matrix 1
- Merck & Co., Inc 2
- ROCHE Pharmaceutical 2
- Tibotec Pharmaceuticals 5
- ViIV 2
- Glaxo Smith Kline 1
- Boehringer Ingelheim 1

**academic organizations**
- Foundation for AIDS Research, United States (amfAR)/TREAT Asia 10
- The Kirby Institute for Infection and Immunity in Society was formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia 6
- University of California, San Francisco (UCSF), USA 1

**research organizations**
- Pediatric European Network for Treatment of AIDS (PENTA) 3
- Swiss HIV Cohort Study 1
- Funding agency Bill & Melinda Gates Foundation 1

**charities**
- Art AIDS Fund 3

Please note: This list is not exclusive nor exhaustive, since new research studies are developed and existing studies change, it is possible that some funders may not be listed.
NUMBER OF STUDIES IN 2010 vs 2011

Key to abbreviations:
- PK: Pharmacokinetics Studies
- Viral coinf: Clinical Research Programs in Co-Viral and Viral Infections
- TB: Clinical Research Programs in HIV/TB Co-Infections
- Cohort: Long Term Cohort Analysis
- Strategy: Strategy Studies
- New Drug: New Drug Development
- EAP: Expanded Access Programs
- Oth: Others
- Ped: Pediatric and Youth Research Programs

Number of studies for each category in 2010 and 2011, along with their corresponding abbreviations.
PHARMACOKINETIC STUDIES

We were the first to conduct low dose HIV studies in the region to show that frequently the standard doses obtained from Caucasian populations were too high for Thais, in fact sometimes 3-4 times higher in Thais than Caucasians. For countries with limited resources, this is very important as not only could it cut costs without diminishing the drug's efficacy but also reduce the number of side effects. Our studies have influenced the Thai National HIV Treatment Guidelines and led the government to change the standard doses of certain ARVs in Thais. Aside from the low dose studies, we also assess the pharmacokinetic profiles of various other drugs used in our population to ensure that there are no drug interactions leading to lower drug levels or adverse events. Sometimes, in collaboration with pharmaceutical companies and the Thai FDA, we will conduct bioequivalent and/or full pharmacokinetic studies and clinical trials for new drugs, generics and fixed dose combinations.

This year there are nine pharmacokinetic studies, two of which are in children (under the section, “PEDIATRIC AND YOUTH RESEARCH PROGRAMS”). Three studies were completed this year. There are five pharmacokinetic studies, one of which was completed this year. One of the pharmacokinetic studies, sponsored by Matrix, is large and ongoing. The two low dose studies were both completed in 2011. Most of these studies are sponsored by the Thai granting agencies.

Therapeutic Drug Monitoring (TDM) Studies
HIV-NAT 118
Therapeutic Drug Monitoring of the generic tenofovir/lamivudine/efavirenz tablets in the Thai HIV-infected Patient
This is a prospective, open-label, single arm study that assesses the efficacy and safety of fixed dose combination of TDF/3TC/EFV.
Target: 100
Status: Ongoing
Funding: Matrix Laboratory

Pharmacokinetic Studies
HIV-NAT 095
This is an open-label single arm prospective study evaluating the bioavailability of generic lopinavir/ritonavir tablets 200/50 mg in Thai HIV-infected patients.
Status: Completed 2011
Enrolled: 100 HIV-infected patients without protease inhibitor failure in the past and stable on ARV.
Funding: Government Pharmaceutical Organization
Results: The first 37 patients using generic lopinavir/ritonavir in the standard dose of 400/100 mg BID had a mean (SD) Lopinavir Cmin of 7.3 (1.8) mg/L. None of the patients had subtherapeutic levels below 1.0 mg/L.
Published: The first phase has been published, Antiviral Therapy 2009 14: 1001-1004
HIV-NAT 114
Incidence and predictor of TDF associated nephrotoxicity and pharmacokinetic of TDF in HIV-1 infected Thai patients: A sub-study of HIV-NAT 006 long term cohort.
Full PK and TDM for tenofovir are done in patients with HBV co-infection vs non HBV coinfection taking tenofovir regimen with bPI or NNRTI combination
Status: Ongoing. Waiting for analysis.
Enrolled: 300 patients for TDM; 48 patients for full PK
Collaborators: Vorasuk Shotelersuk (Division of Medical Genetics and Metabolism, Chulalongkorn), David Burger (Radboud University Nijmegen Medical Centre, Netherlands), Keakiat Praditpornsilpa and Yingyos Avihingsanon (Division of Nephrology)
Funding: Office of the National Research Council of Thailand
HIV-NAT 131
Pharmacokinetics Study of Tenofovir in
HIV-infected Thai Children using Tenofovir-
Based Regimen
This study will assess the pharmacokinetics of
Tenofovir in HIV-infected Thai children using
Tenofovir-based regimen.
Status: Ongoing
Collaborator: Pope Kosalaraksa
Site: Khon Kaen University
Funding: Ratchadaphiseksomphot Fund,
Faculty of Medicine, Chulalongkorn University

Pharmacokinetic hormonal study
HIV-NAT 147
Pharmacokinetic interactions between sex
Steroid hormones and NNRTIs in HIV-
Positive Thai Women
Status: Ongoing
Target: 60
Funding: Chulalongkorn University
(Ratchadapiseksompoch Grant) and HIV-NAT

Low Dose Studies
HIV-NAT 085
This is an open-label, two arm, randomized
pharmacokinetic study with cross-over design
of Pediatric Aluvia® (Lopinavir/Ritonavir 100/25
mg BID) and Generic Lopinavir/Ritonavir Tablet
formulation (200/50 mg BID) in clinically and
virologically stable HIV-1 infected Thai adults.
Status: Completed 2011
Enrolled: 20 Thai HIV-1 infected individuals,
stable on a PI containing HAART regimen and
virologically suppressed
Funding: Commission on Higher Education
Results: Generic Lopinavir/ritonavir tablets
were bioequivalent to the branded tablets.
Lopinavir/ritonavir 200/50 mg BID resulted in
therapeutic lopinavir plasma concentrations in
10 (50%) of the patients. All patients were
virologically suppressed after 12 weeks, and
switched to full-dose Lopinavir/ritonavir after
the end of the study.
Publications: Ramaatarsing RA, van der Lugt
J, Gorowara M, Wongsabut J, Khongpetch C,
Phanuphak P, Ananworanich J, Lange JMA,
Burger DM, Ruxrungtham K, Avihingsanon A.
Neither branded nor generic lopinavir/ritonavir
produces adequate lopinavir concentrations at
a reduced dose of 200/50 mg BID. JAIDS.
In Press.

HIV-NAT 127
Pharmacokinetics of Low Dose Raltegravir
This is an open-label, cross-over design study
investigating the pharmacokinetics profile of
low dose raltegravir (RAL) (400mg OD and
800mg OD) and standard dose of 400mg BID
in Thai HIV-infected patients.
Status: Completed 2011
Enrolled: 19
Collaborator: Lawrence Lee Soon-U (National
Healthcare Group Pte Ltd, Singapore)
Funding: Chulalongkorn University
(Ratchadapiseksompoch Grant) and the Office
of the National Research Council of Thailand
Publication: submitted to Antimicrobial Agents
and Chemotherapy
Presentation: Low-Dose RAL at 400 mg
Once Daily Achieves Adequate Plasma
Concentrations in HIV-1-infected Thai Patients.
[Abstract # 649] presented at the 18th
Conference on Retrovirus and Opportunities
Infections (CROI 2011). Boston, MA, USA.
27 February – 2 March 2011.
HIV-NAT’s initial co-viral studies focused on hepatitis B (HBV). Treatment for hepatitis C (HCV) is very expensive and currently not available through the national program for HCV which meant that up until now HIV-NAT was unable to conduct any therapeutic studies. However, HIV-NAT’s concern regarding HCV co-infected patients did not stop there and the determination in doing something for these co-infected patients has finally paid off. HIV-NAT has successfully managed to collaborate with Bangkok Metropolitan Administration, Thailand (BMA) and Ministry of Public Health (MOPH) initially to conduct a pilot HCV study examining the efficacy of short course treatment; this study will begin in 2012. HIV-NAT conducted two additional influenza studies in 2011 as the epidemic continues worldwide. HIV-NAT has made a commitment to expand its horizons and is open to other co-viral and viral infectious studies.

There are ten ongoing studies: two HBV studies, four influenza studies, two human papilloma virus (HPV) studies, one cytomegalovirus (CMV) study and one HCV study. Our large HBV study, the Cold Study, is sponsored by the Kirby Institute, GILEAD, MOPH, National Health Security Office (NHSO) and National Institute of Health (NIH). All of the influenza studies are supported by NIH. The HCV and HPV studies are supported by Thai granting agencies and funding. One of the HBV study and HCV study are sponsored by the pharmaceutical companies.

COLD Study
Longitudinal HIV/HBV Cohort
HIV-NAT 092
This is an extension of TICO/HIV-NAT 023 study. It is a prospective longitudinal cohort study on liver disease and HIV/HBV coinfection in the era of HAART in Thailand. It is assessing the risk of HAART–associated hepatotoxicity, the effect of HBV-active HAART on the magnitude and durability of HBV DNA suppression and HBeAg seroconversion, evolution and natural history of antiviral drug-resistant HBV in an HIV co-infected population, rate of liver disease progression, immune reconstitution and novel HBV epitopes associated with HBeAg seroconversion and/or disease flares.

**Status:** Ongoing
**Enrolled:** 47 patients with HIV/HBV co-infection who have completed 48 weeks of TICO/HIV-NAT 023, 147+47 subjects totally enrolment for COLD.

**Collaborators:** Gail Matthews, Sharon Lewin and Greg Dore

**Sites:** Multicenter AIDSCohort (MACS), Baltimore site, U.S.A., The Alfred Hospital, the Royal Melbourne Hospital, Melbourne, Australia and St Vincent’s Hospital, Sydney, Australia, and Johns Hopkins Center for Global Health, Division of Infectious Disease, Baltimore, USA.

**Funding:** The Kirby Institute for Infection and Immunity in Society was formerly known as the National Centre in HIV Epidemiology and Clinical Research, Gilead Sciences, MOPH, Thai National Security Office (NHSO) and supplement grant from the NIH

**Results:** TDF-containing HAART is highly successful in achieving HIV and HBV-related virological suppression in coinfected subjects initiating HAART in Thailand, irrespective of regimen. Further work is needed to understand the mechanism(s) of the high rates of HBeAg loss and HBsAg seroconversion.

**Publications:**
3) Increased hepatocyte apoptosis but reduced intrahepatic immune and stellate cell activation in HIV-HBV co-infection. AIDS. 2011 Jan 14;25(2):197-205


6) Factors associated with elevated ALT in an international HIV/HBV co-infected cohort on long-term HAART. PLOS One. In Press


Presentations:


2) Changes in Quantitative HBsAg and HBeAg Predict HBV Treatment Response in HIV/HBV Coinfected Individuals on Tenofovir based HAART in Thailand. [poster 1516] presented at The 62nd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). San Francisco, California, USA, November 4-8, 2011.
Who Are Hospitalized with Complications of Influenza. INSIGHT H1N1v Influenza Hospitalization Study.
The purpose of this observational study is to describe the characteristics and outcomes over a 60-day follow-up period of participants in geographically diverse locations who develop influenza A-pandemic H1N1 (H1N1v) and who are hospitalized with complications resulting from influenza.

**Status:** Ongoing

**Enrolled:** 13/50 Chulalongkorn site; 3 Khon Kaen site

**Collaborators:** Division of Infectious Diseases, Department of Medicine, University: Leilani Paitoonpong, Gompol Suwanpimolkul, Voraphoj Nilaratanakul, Nontalee Thongsong, Pornvimol Leethong, Paisan Techawaleekul, Suwimon Khusuwan; Khon Kaen University: Ploenchan Chetchotsak

**Enrollment** (projected): 1,000 patients in Asia, Europe, Australia, North and South America

**Sites:** Chulaolognkorn Hospital, Srinakarind Hospital and Khon Kaen University.

**Funding:** National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and carried out by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT).

**HCV**

**HIV-NAT 125**

Characteristics and clinical significances of hepatitis C genotype in HIV-and hepatitis C co-infected Thai patients.

**Status:** Ongoing

**Target Enrollment:** 100

**Funding:** Chulalongkorn University, Faculty of Medicine (Ratchadapiseksompoch Grant), and Office of the National Research Council of Thailand

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**CMV study**

**HIV-NAT 130**

Mortality and Morbidity Risk Factors of Cytomegalovirus Viremia in AIDS Patients Starting Antiretroviral Therapy in Thailand

This is a retrospective observational cohort and nested case-control study. This study will assess the possible association between CMV viremia and increased risk of mortality or the development of AIDS-defining illnesses in patients from HIV-NAT 006 long term cohort.

**Status:** Ongoing

**Funding:** Abbott

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**HPV study**

**Prevalence and 6- and 12-month incidence of cervical cytological abnormality and HR-HPV infection in a cohort of HAART naive and HAART experienced women.**

**Status:** Ongoing

**Site:** The Thai Red Cross AIDS Research Center (TRC-AC)

**Collaborators:** SEARCH, The Thai Red Cross AIDS Research Center (TRC-AC), Vanderbilt University and Amsterdam Institute for Global Health and Development (AIGHD)

**Funding:** Commission of Higher Education, National Research University, HIV-NAT


**HIV-NAT 163**

HPV genotypes present in cervical dysplasia and cervical cancer in HIV-infected women

The aim of this study is to investigate the HPV-genotype distribution in HIV-infected women with cervical dysplasia or cervical cancer compared to HIV-uninfected women. Stored tissue samples from Chulalongkorn Hospital are used for HPV genotyping.
Status: Ongoing  
Collaborators: Thai Red Cross – AIDS Research Center (TRC-ARC), Chulalongkorn University  
Funding: Chulalongkorn University (Ratchadapiseksompoch Grant)

**IRC 003**  
A Randomized Double-Blind Phase 2 Study Comparing the Efficacy, Safety, and Tolerability of Combination Antivirals Versus Standard Treatment for the Treatment of Influenza in Adults at Risk for Complications  
This is a multicentered, randomized double-blind phase 2 study that will assess the efficacy, safety, and tolerability of combination antivirals versus the standard treatment for the treatment of influenza in an at-risk outpatient population.  
Status: Will open in Dec. 2011  
Target: 50  
Sites: 4 sites in Thailand; 48 sites worldwide  
Collaborators: National Institute of Health (NIH), Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Siriraj Hospital  
Funding: National Institute of Health (NIH)

**IRC 004**  
A Randomized Double-Blind Study Comparing Standard Treatment Versus Placebo for the Treatment of Influenza in Low Risk Adults  
This is a randomized blinded study that will evaluate whether the standard treatment modifies viral shedding in an ambulatory population with uncomplicated influenza and explore the relationship between virologic effects and clinical effects, effects on proinflammatory mediators, and to start understanding if improvements to virologic shedding correlate with improvements in clinical outcomes.  
Status: Will open in Dec. 2011  
Target: 50  
Sites: 4 sites in Thailand; 48 sites worldwide  
Collaborators: National Institute of Health (NIH), Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Siriraj Hospital  
Funding: National Institute of Health (NIH)
CLINICAL RESEARCH PROGRAMS IN CO-TUBERCULOSIS INFECTIONS

Tuberculosis (TB) continues to be a worldwide problem particularly in HIV epidemic areas. The complex interactions between tuberculosis and antiretrovirals, high pill burden and overlapping side effects make it a challenge to manage patients co-infected with TB. Other problems encountered with these patients are the initial diagnosis of TB, use of boosted protease inhibitors in combination with TB therapy, and maintaining good adherence and follow-up to avoid multidrug resistance to both TB and HIV regimens. Because of all these factors, HIV-NAT has undertaken to investigate and conduct the following studies.

This year there are 4 ongoing studies. Two studies are currently funded by HIV-NAT and are seeking additional financial support. Two other studies are done through the TB network. There are a total of nine Thai university hospitals in this network aiming to improve the follow-up and treatment rates the country.

HIV-NAT 104
This is a pilot study of the pharmacokinetics and safety of lopinavir/ritonavir 400/100mg bid versus lopinavir/ritonavir 600/150 mg BID combined with nucleoside analogue reverse transcriptase inhibitors in HIV/TB co-infected patients receiving rifampicin containing anti-tuberculosis therapy.
Status: Ongoing
Collaborators: David Burger (Radboud UMC Nijmegen, The Netherlands), Kamol Kawkitinarong and Gompol Suwanpimolkul (Infectious Disease, Chulalongkorn University) and Supannee Jirajariyavet (Infectious Disease, Taksin Hospital)
Sites: TRC-ARC and Chulalongkorn Hospital
Funding: HIV-NAT (additional funds being sought)

HIV-NAT 116
A pilot study of the pharmacokinetics and safety of rifabutin 150 mg once daily versus rifabutin 150 mg thrice weekly with Lopinavir/ritonavir based HAART in HIV/TB co-infected patients
This is a randomized, open-label, 2-arm per group, parallel study that describes the pharmacokinetics of rifabutin 150 mg once daily versus rifabutin 150 mg thrice weekly in combination with LPV/r 400/100mg based HAART in HIV/TB infected patients.
Status: Proposed to start on 2012
Collaborators: David Burger (Radboud UMC Nijmegen, The Netherlands), Kamol Kawkitinarong (Chest Division, Chulalongkorn University), Kamolwan Jutivorakool and Gompol Suwanpimolkul (Infectious Disease, Chulalongkorn University), and Supannee Jirajariyavet (Infectious Disease, Taksin Hospital)
Funding: HIV-NAT (additional funds being sought)

Optimize TB Treatment outcome in Tertiary Care Hospitals
Status: Ongoing
Target: 900
Site PIs: Bamrasnaradura Infectious Disease Institute: Kamon Kawkitinarong Division of Infectious Diseases, Department of Medicine, Faculty of Medicine, Chulalongkorn University: Opass Puthacharoen Sites: Bamrasnaradura Infectious Disease Institute, Rajvethi Hospital, Chulalongkorn University (Chest Unit, Internal Medicine Department, and Division of Infectious Diseases, Department of Medicine, Chulalongkorn University Hospital)
Collaborators: Disease Department Control (DDC), Thailand
Funding: National Research University Grant (NRU)

Yield of Expert MTB Index of TB Bactermia in HIV-infected Presented with Prolong Fever
This is a TB substudy with Chulalongkorn University
Status: Ongoing
Target: 200
Sites: Chulalongkorn University, Taksin Hospital and Bamrasnaradura Infectious Disease Institute
Funding: National Research University Grant (NRU)
LONG TERM COHORT ANALYSIS

The population from the HIV-NAT 006 cohort are from a research unit and are a special population which may introduce bias in the analysis. In order to overcome this and make the 006 cohort studies more generalisable, this year we have expanded our cohort to include data from the Bamrasnaradura Infectious Disease Institute (Nonthaburi) and San Patong Hospital (Chiang Mai). Recently, more cases of syphilis have been noted in the HIV-NAT cohort. As a result, HIV-NAT will be investigating the long-term effect of syphilis (i.e. treatment outcomes, neurosyphilis rates etc.) in HIV patients. For the first time, HIV-NAT will follow HIV positive women with and without HAART using intrauterine devices (IDU) for contraception. This has never before been offered at HIV-NAT. Currently HIV-NAT is negotiating with its partner the Thai Red Cross – AIDS Research to offer reproductive health services to HIV positive women. These temporary and equally effective contraceptive methods provide many HIV-infected women alternative choices other than tubal ligation which is a permanent and irreversible procedure.

There are 11 cohorts of which 3 are pediatric cohorts with 1 pediatric substudy (which was completed this year). Two cohorts supported by Foundation for AIDS Research, United States (amfAR) and two PROGRESS cohorts by Department of Disease Control (DDC). The Syphilis Study is currently seeking funding. The rest of the studies are supported by Thai granting agencies and funding. The TNT study is partially supported by Viiv.

HIV-NAT 006
This is a long-term, post study cohort of HIV-infected patients who previously participated in HIV-NAT study protocols. Information collected from this cohort will provide further insights into the long-term safety and durability of various antiretroviral therapeutic approaches, efficacy of HIV viral load and CD4 cell counts as predictors of disease progression, mortality, resistance profiles, adherence, immune recovery syndrome, opportunistic infections or malignancies, incidence of lipodystrophy, other metabolic complications, cardiovascular, renal, hepatic, and endocrine function, skin, gastrointestinal system and urogenital tract problems and quality of life.

Status: Ongoing
Enrolled: 1600
Collaborators: David A. Cooper and Joep MA Lange


Publications:
4) Assessing adherence in Thai patients taking HAART. Int J. STD AIDS. In Press.
8) Treatment outcome and safety of zidovudine/lamivudine/nevirapine fixed-dose combination in HIV-infected Thai patients. (Submitted)
9) Long term efficacy of Low Dose Ritonavir-Boosted Atazanavir (200/100 mg) in Thai HIV-1 Infected Adults. (Submitted)

Syphilis Study
HIV-NAT 157
Serodiagnosis of syphilis and outcomes of treatment among HIV-infected patients
This objective of this study is to determine the prevalence of syphilis in the cohort HIV-NAT 006 study and the outcomes of treatment after 24 and 48 weeks using serological tests.
**Status:** Ongoing
**Enrolled:** 550
**Funding:** Chulalongkorn University (Ratchadapiseksompoj Grant)

HAND Study
HIV-NAT 166
Trial to evaluate neurocognitive functions, neuropsychiatric changes and activities of daily living among HIV infected patients in the Cohort HIV-NAT 006 study
This is an observational study among treatment naive or experienced HIV-infected adults who has been deferred, interrupted or initiated the first line antiretroviral regimens and currently on antiretroviral therapy using self assessed questionnaires about neuropsychiatric changes and daily activities and brief assessment of neurological performance with International HIV dementia scale (IHDS) and Montreal Cognitive Assessment (MoCA). Other tests such as Trial making, EIWA digit symbol task, Grooved pegboard test and block design will also be done. This study will describe the rates of neurocognitive changes among HIV-infected patients in the Cohort 006 study and determine factors related to neurocognitive changes among HIV-infected patients.
**Status:** Submitted to IRB
**Target:** HIV-NAT 006 cohort population
**Collaborators:** Pramongkutklao Hospital and SEARCH
**Funding:** Seeking funding

HIV-NAT 015
This is a long-term follow-up study of safety and efficacy of antiretroviral therapy for HIV positive children who have previously participated in HIV-NAT study protocols.
**Status:** Recruitment opened in 2002 and is still ongoing.
**Enrolled:** 303 children and 46 HIV-infected parents
**Collaborators:** Chitsanu Panchareon, David A. Cooper, Joep MA Lange
**Site:** Chulalongkorn Hospital
**Funding:** The Thai National Security Office (NHSO) and Thai Ministry of Public Health, The Aligning Care and Prevention of HIV/AIDS with Government Decentralization to Achieve Coverage and Impact: Project (Global fund Thailand)
**Publications:**

HIV-NAT 015.2
This is a pilot study comparing total brain volume and frontal lobe volume by tensor based morphometry (TBM) and corpus callosum fractional anisotropy by Diffusion Tensor Imaging (DTI) in HIV infected and healthy children.
**Status:** Completed 2011
**Enrolled:** 6 children
**Collaborator/site:** Chulalongkorn Hospital
**Funding:** HIV-NAT
PREDICT sub study- PREDICT Cohort
HIV-NAT 035.3
Extension for HIV-NAT 035
Status: Enrolling. Last follow-up will be in July 2012.
Enrolled: 180 Thai/120 Cambodian children
Site PIs in Cambodia: National Center for HIV/AIDS, Dermatology and STDs (NCHADS): Mean Chhi Vun and Vonthanak Saphonn
Collaborator: David A. Cooper
Funding: National Research Council of Thailand

TAHOD: The Treat Asia HIV Observational Database
HIV-NAT 048
This study collects observational data on HIV-infected patients from a number of sites in several Asian countries. The information gathered will help develop more effective research and treatment programs for people living with HIV/AIDS in the region.
Status: Ongoing.
Enrolled: 100
Collaborators: Mana Khongpatanayothin and David A. Cooper
Collaborator/site: Chulalongkorn Hospital
Coordinating Center: National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, Sydney, Australia
Funding: Foundation for AIDS Research, United States (amfAR)
Publications:
Presentations:
1) AIDS defining illness diagnosed within 90 days after starting HAART among TAHOD patients. Presented at the 3th IAS Conference on HIV Pathogenesis and Treatment, Rio de Janeiro, Brazil, 24-27 July 2005
2) Experience with the use of a first-line regimen of stavudine, lamivudine and nevira-pine among TAHOD patients. Presented at the 17th ASHM Conference, Hobart, Australia, 24-27 August 2005
3) Difference between Asian and Caucasian


5) Parametric models of immunological failure in HIV-infected Thais receiving antiretrovirals at HIV-NAT and validation using the TAHOD. Presented at the 18th Annual Conference of the Australasian Society for HIV Medicine, Melbourne, Australia, 11 to 14 October 2006


7) Data Collection for Antiretroviral Treatment Related Adverse Events (AEs) in TREAT Asia Observational Database. Presented at the 11th International workshop on HIV Observational Databases, Monte Carlo, 22-25 March 2007

9) Antiretroviral Treatment Related Adverse Events (AEs) in the TREAT Asia HIV Observational Database. Presented at the 9th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV, Sydney, 19-21st July 2007


11) Deferred modification of antiretroviral regimen following treatment failure in Asia: Results from the TREAT Asia HIV Observational Database (TAHOD). [Poster#: TUPE0116] Presented at the 17th International AIDS Conference, Mexico City, Mexico, 3-8 August 2008

12) HIV Disease Progression In HIV-1 Patients Initiating Combination Antiretroviral Therapy With Advanced Disease In The Asia-Pacific Region: Results From The TREAT Asia HIV Observational Database (TAHOD). Presented at the 20th Annual Australasian Society for HIV Medicine (ASHM) Conference, Perth, Australia, 17-20 September 2008


15) Short-term risk of anemia following initiation of antiretroviral treatment in HIV-infected patients in countries from sub-Saharan Africa and Asia. Presented at the 14th International Workshop on HIV Observational Databases, Lisbon, Portugal, 25th-27th March 2009


18) Non-virological criteria to predict virological failure in TAHOD and IeDEA SA. Presented at the IeDEA Satellite Meeting, San Francisco, USA, 20 February 2010

19) Trend of CD4 cell count in HIV-infected patients with HIV viral load monitoring while on combination antiretroviral treatment. Presented at the 14th International Workshop on HIV Observational Databases, Sitges, Spain, 5-27 March 2010

20) Impact of sex on long-term treatment outcomes of highly active antiretroviral therapy...
(HAART) in the TREAT Asia HIV Observational Database [Abstract #: 200736571] presented at the International AIDS Society Conference 2010, Vienna, Austria, 18-23 July 2010
21) Impact of Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Co-infections on Immunological Responses to HAART in the TREAT Asia HIV Observational Database (TAHOD) [Abstract #: 200739465] presented at the International AIDS Society Conference 2010, Vienna, Austria, 18-23 July 2010
22) High Prevalence of Anal Squamous Intraepithelial Lesions in HIV-positive and HIV-negative Men who have sex with Men in Thailand presented at the International AIDS Society Conference (IAS) 2010, Vienna, Austria, 18-23 July 2010
23) Lack of prophylaxis against Pneumocystis pneumonia and mortality: Results from the TREAT Asia HIV Observational Database (TAHOD) [Abstract #: H213] presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Boston, USA, 12-15 September 2010

TREAT Asia Pediatric HIV Observational Database
HIV-NAT 080
This study is an HIV pediatric HIV observational database collecting HIV clinical data from countries located in the Asia-Pacific region. This information will be used to develop more effective research and treatment programs for people with HIV/AIDS in the region.

Status: Ongoing.
Enrolled: 258
Funding: Foundation for AIDS Research, United States (amfAR)

Publications:

Presentations:
1) Regional survey of HIV clinical care resources and management practices in the TREAT Asia pediatric
2) Program. Presented at the Australasian Society for Infectious Diseases (ASID) Annual Scientific Conference, New South Wales, Australia, 25-28 March 2009
3) Antiretroviral Therapy Outcomes in HIV-positive Children in Asia: Data from the TREAT Asia Pediatric HIV Observational Database. Presented at the 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa.
4) Impact of antiretroviral therapy on opportunistic infections of HIV-infected children in the TREAT Asia Pediatric HIV Observational Database. Presented at the International Workshop on HIV Pediatrics, Cape Town, Africa, 19-22 July 2009
5) Antiretroviral Therapy Outcomes in HIV-positive Children in Asia: Data from the TREAT Asia Pediatric HIV Observational Database. [Poster #: MOPEB085] Presented at the International Workshop on HIV Pediatrics, Cape Town, Africa, 19-22 July 2009
7) Antiretroviral Therapy Outcomes in HIV-positive Children in Asia: Data from the TREAT Asia Pediatric HIV Observational Database. [Poster #: MOPEB085] Presented at the Australasian Society for HIV Medicine (ASHM), Cape Town, Africa, 19-22 July 2009
8) Severe adverse events in HIV-infected children in Asia after first-line HAART. [Poster #: O13] Presented at the 2nd International Workshop on HIV Pediatrics, Vienna, Austria, 16-17 July 2010
TNT-HIV 003
This is a five-year prospective cohort study that investigates the trends of morbidity and mortality among Thai HIV-infected and HIV-uninfected patients. This study has one substudy, TNT-HIV 003.1, which assesses the bone health and vitamin D status in HIV-1 infected and uninfected adults.
**Status:** Started in Oct. 2010
**Site PIs:**
- The Thai Red Cross AIDS Research Centre: Praphan Phanuphak
- Bamrasnaradura Infectious Disease Institute: Wisit Prasithisirikul
- Queen Savang Vadhana Memorial Hospital: Tanate Jadwattanakul
**Collaborators:** Peter Reiss and Ferdinand Wit, Amsterdam Institute for Global Health and Development (AIGHD)
**Funding:** The Thai Red Cross AIDS Research Centre and ViV

HIV-NAT 126.1
Intrauterine Device as a modern method of contraception in Thai HIV-positive women. This is prospective cohort study with a follow up period of six months. There will be two cohorts of subjects: cohort 1 – HIV-positive women without highly active antiretroviral therapy (HAART); cohort 2 – HIV-positive women with HAART. The main goal is to assess the acceptability and safety of intrauterine device (IUD) as a contraceptive method in Thai HIV-positive women.
**Enrolled:** 29
**Status:** Last enrolment September 2011. End of study March 2012.
**Funding:** Chulalongkorn University (Ratchadapiseksompoch Grant) and HIV-NAT

The Progress (Adult cohort)
The Thai HIV Disease Progression: An Observational Database
This is a multicenter, observational prospective cohort study – open cohort that will study the HIV disease progression in HIV-infected Thai Adult.
**Status:** Ongoing
**Enrolled:** 5000
**Site PIs:** Bamrasnaradura Infectious Disease Institute: Wisit Prasithisirikul
San Patong Hospital: Virat Klinbuayaem
**Sites:** Bamrasnaradura Infectious Disease Institute; San Patong Hospital and HIV-NAT
**Collaborators:** Department Disease Control (DDC), Thailand
**Funding:** Department Disease Control (DDC), Thailand

The Progress (Pediatric cohort)
The Thai Pediatric HIV Disease Progression: An Observational Database; Ped PROGRESS
The objective of this cohort is to describe the multicenter cohort of HIV-infected children in Thailand
**Status:** Ongoing
**Target:** 840 HIV-infected children from all sites
**Site:** Chiangrai Prachanukroh Hospital, Sanpatong Hospital, Faculty of Medicine, Siriraj Hospital, Mahidol University
**Collaborators:** Office of the National Research Council of Thailand, and Bamrasnaradura Infectious Diseases Institute, Nonthaburi
**Funding:** Department Disease Control (DDC), Thailand
STRATEGY STUDIES

HIV-NAT has participated in several clinical research strategy studies throughout the years. These innovative studies aim to impact and influence both the international and national treatment guidelines. For example, START is a large study that will inform professional health care workers when ARVs should be initiated. This year, both ENCORE and LASA were launched. ENCORE will examine the worldwide use of low dose ARV in a multicentered trial whereas LASA will focus on Thailand.

There are nine strategic studies, four of which were completed this year. Four studies are supported by the Kirby Institute. Two studies are supported by NIH. HIV STAR is supported by NHSSO and the Swiss Cohort Study group. ENCORE is supported by the Bill and Melinda Gates Foundation. HIV-NAT is currently supporting the Feasibility Study (Test and Treat).

STALWART
HIV-NAT 068

This is a randomized, open-label, international study of subcutaneous recombinant Interleukin-2 (rIL-2, Aldesleukin) with and without concomitant antiretroviral therapy in patients with HIV-1 infection and CD4+ cell counts = 300/mm3.

**Status:** completed in 2011
**Enrolled/target:** 40 at the HIV-NAT site/
Worldwide 300 subjects from 12 countries.
Target for Thailand was 60 subjects.
Regional Trials Coordinating Centre: the Kirby Institute, formerly known as the National Centre in HIV Epidemiology and Clinical Research, Sydney

**Sites:** Chulalongkorn Hospital [HIV-NAT],
Srinagarind Hospital, Khon Kaen University and Chiangrai Prachanukroh Hospital

**Funding:** National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and Chiron Corporation

**Results:** Patients on antiretroviral therapy and IL-2 had sustained increases in CD4 but did not reduce risk of opportunistic infections or death. Also, it did not improve the health outcomes for people infected with HIV.

**Publications:**
1) Interleukin 2 treatment in HIV-1 infection. Lancet. 2006 Apr 1;367(9516):1054-5

Altair
HIV-NAT 072

This is a phase IIIb/IV, international, randomized, open-label study comparing the safety and efficacy of three different regimens of combination antiretroviral therapy in treatment-naïve, HIV-infected subjects over a two-year period.

There are three substudies under Altair:
Magnetic Resonance Spectroscopy Substudy (MRS Substudy), metabolic/bone and renal.

**Status:** Completed 2011
**Enrolled:** 65

**Collaborator:** David A. Cooper

**Sites:** HIV-NAT only site in Thailand; several sites in other countries.

**Funding:** The Kirby Institute for Infection and Immunity in Society was formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia

**Results:** A novel quadruple nucleo(t)side combination demonstrated significantly less suppression of HIV replication, compared with the suppression demonstrated by standard antiretroviral therapy regimens, although it did meet the predetermined formal definition of noninferiority. Secondary analyses indicated statistically inferior virologic and safety performance. Efavirenz and ritonavir-boosted atazanavir arms were equivalent in viral suppression and safety. Also, there were greater improvements in neuronal recovery (NAA/Cr ratio) in recipients of tenofovir-emtricitabine plus efavirenz (arm 1), and greater improvements in neurocognitive function in recipients of tenofovir-emtricitabine plus zidovudine-abacavir (arm 3).

**Publications:**
3) Effects of ritonavir/atazanavir, efavirenz or zidovudine/abacavir plus tenofovir/emtricitabine on renal function; a randomized trial. (Submitted to JAIDS)
4) Dynamics of cognitive change in HIV–infected individuals commencing three different antiretroviral regimens; a randomized, controlled study. HIV Medicine. In Press...
HIV STAR (The HIV Second-line Therapy AntiRetroviral study in patients who failed NNRTI-based regimens)
HIV-NAT 079

This is a multicenter, randomized, open label, non-inferiority comparison study evaluating the efficacy and safety between two NRTIs plus lopinavir/ritonavir (LPV/r) and LPV/r monotherapy in patients failing a standard NNRTI-based treatment regimen at 48 weeks.


Status: Completed 2011
Enrolled/target: 200
Collaborators: Wisit Prasithsirikul, Ploenchan Chetchotisakd, Chureeratana Bowonwattanuwong, Patcharee Kantipong, Somnuek Sungkanuparp, Virat Klinbuayaem, Supunnee Jirajariyavej, Warangkana Munsakul and Bernard Hirschel
Sites: TRCARC, Chulalongkorn University, Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Chonburi Hospital, Chiang Rai Regional Hospital, Ramathibodi Hospital, Sanpatong Hospital, Taksin Hospital, and Vajira Hospital, University of Bangkok Metropolitan Administration

Funding: The National Health Security Office (NHSO), The Swiss HIV Cohort Study, National Research Council of Thailand (sponsored substudy for the effects of LPV/r monotherapy in central nervous system and genital secretion)


START (Strategic Timing of AntiRetroviral Treatment)
HIV-NAT 097

A Multicenter Study of the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)
The purpose of this randomized study is to determine whether immediate initiation of antiretroviral treatment (ART) is superior to deferral of ART until the CD4+ declines below 350 cells/mm3 in terms of morbidity and mortality in HIV-1 infected persons who are antiretroviral naive with a CD4+ count above 500 cells/mm3. The study will proceed in two phases: (1) a pilot phase, involving at least 900 participants; and (2) a definitive phase, expanding enrollment to an estimated 4,000 participants. Upon completion of the pilot phase, a recommendation will be made to the sponsor (DAIDS, NIAID, NIH) concerning whether the study should be expanded and prolonged into a definitive study. Successful completion of the pilot phase requires enrollment of at least 900 participants in one year by 70 designated INSIGHT sites. For Thailand, seven additional sites were included: Siriraj Hospital, San Patong Hospital, Chonburi Hospital, Chiangrai Prachanukroh Hospital, RIHES Chiang Mai University, Ramathibodi Hospital and Bamrasnaradura Infectious Disease Institute


Status: Ongoing.
Enrolled: Currently 52 from HIV-NAT; 22 from Khon Kaen. For Thailand, the plan is to enroll total 250 patients by December 2012.
Collaborators: Chulalongkorn University, Ploenchit Chuchotisakd (Srinagarind Hospital, Khon Kaen University), Chonburi Regional Hospital. Siriraj Hospital, Mahidol University, Chiangrai Prachanukroh Hospital, Sanpatong Hospital, Bamrasnaradura Infectious Disease Institute, Ramathibodi Hospital, Mahidol University, Research Institute for Health Sciences (RIHES), Chiang Mai University

Site PIs:
Srinagarind Hospital, Khon Kaen University: Ploenchit Chuchotisakd
Siriraj Hospital: Thanomsak Anekthananon
San Patong Hospital: Virat Klinbuayaem
Chonburi Hospital: Chureeratana Bowonwatanuvong
Chiangrai Prachanukroh Hospital: Pacharee Kantipong
RIHES Chiang Mai University: Khuanchai Supparatpinyo
Ramathibodi Hospital: Sasisopin Kiertiburanakul
Bamrasnaradura Infectious Disease Institute: Wisit Prasithsirikul

Sponsor: The National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) National Institutes of Health (NIH)

Publication: START; design considerations for a large simple trial to examine the time to commence antiretroviral therapy for the treatment of HIV infection. J Clin Trials 2011. In press.

ENCORE1 (Evaluation of Novel Concepts in Optimization of antiRetroviral Efficacy) HIV–NAT 128

A randomized, double-blind, placebo-controlled, clinical trial to compare the safety and efficacy of reduced dose (400mg) efavirenz (EFV) with standard dose EFV plus two nucleotide reverse transcriptase inhibitors (N(t)RTI) in antiretroviral-naïve HIV-infected individuals over 96 weeks. HIV-NAT is the Thai co-ordinating centre. There are three substudies: 1) CNS, 2) Intensive PK and 3) Neurocognitive substudy. Staff from HIV-NAT have initiated this last substudy and will be responsible for the data collection and sub-study analysis.

Status: Opened end September 2011
Enrolled/Target: 11/70 HIV-NAT, 18/20 Khon Kaen, 1/30 RIHES
Target: 120 naïve HIV positive patients from Thailand

Collaborators: Ploenchit Chuchotisakd (Srinagarind Hospital, Khon Kaen University) and Khuanchai Supparatpinyo (Research Institute for Health Sciences (RIHES), Chiang Mai University)

Sites: This study will involve 51 sites in 17 countries. Three sites in Thailand.

Sponsor: The Kirby Institute for Infection and Immunity in Society (formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia) and Bill & Melinda Gates Foundation

SECOND LINE (A randomized open-label study comparing the safety and efficacy of ritonavir boosted lopinavir and 2-3N(t)RTI backbone versus ritonavir boosted lopinavir and raltegravir in participants virologically failing first-line NNRTI/2N(t)RTI therapy: the SECOND-LINE study) HIV–NAT 119

This is a Phase IIIb/IV, international, randomized, open label study comparing two regimens of combination antiretroviral therapy in people living with HIV with confirmed virological failure of first-line NNRTI/2N(t)RTI regimens. The study will run for 96 weeks but the primary analysis will take place at the week 48. point.

Status: Closed to recruitment; patients under active study follow-up

Enrolled: HIV-NAT 25, Srinagarind Hospital 30, Khon Kaen Hospital 10 and RIHES 2 patients

Collaborators: Ploenchit Chuchotisakd (Srinagarind Hospital, Khon Kaen University), Niramon Leeratanapetch (Khon Kaen Hospital), Khuanchai Supparatpinyo (Research Institute for Health Sciences (RIHES), Chiang Mai University)
Sites: Approximately 50 sites from Australia, Africa, Asia, Latin America, and Europe. Four sites in Thailand
Sponsor: The Kirby Institute for Infection and Immunity in Society, formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia

LASA (Low dose Atazanavir/r vs. Standard dose Atazanavir/r)
HIV–NAT 110
A multicenter randomized study to compare the efficacy and safety of lower dose atazanavir/ritonavir (ATV/r 200/100 mg OD) versus standard dose (ATV/r 300/100 mg OD) in combination with 2NRTIs in well virology suppressed HIV-infected adults
This is an open-label, two arm, randomized controlled trial, multicenter sites study. This study aims to demonstrate non-inferiority of treatment with atazanavir/ritonavir (ATV/r) 200/100 mg once daily (OD) compared to the control group (ATV/r 300/100 mg OD) in regards to the proportion of virologic responders (plasma HIV RNA < 200 copies/mL) at 48 weeks in ARV-experienced HIV-1 infected subjects, with a maximum allowable difference of 10%.
Status: Ongoing
Enrolled/Target: 80/560
Collaborators: Wisit Prasithsirikul, Ploenchan Chetchotisakd, Chureeratana Bowonwattanuwong, Patcharee Kantipong, Sasisopin Kiertiburanakul, Virat Klinbuayaem, Supunnee Jirajariyavej and Warangkana Munsakul and Monica Gandhi
Sites: TRCARC, Chulalongkorn University, Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Chonburi Hospital, Chiang Rai Regional Hospital, Ramathibodi Hospital, Sanpatong Hospital, Taksin Hospital, and Vajira Hospital, University of Bangkok Metropolitan Administration
Funding: National Health Security Office (NHSO) and The Kirby Institute for Infection and Immunity in Society was formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia

LASA HAIR substudy
HIV–NAT 110.2
This study will evaluate the atazanavir/ritonavir concentration in hair
Status: Ongoing
Target: 480
Collaborators: Wisit Prasithsirikul, Ploenchan Chetchotisakd, Chureeratana Bowonwattanuwong, Patcharee Kantipong, Sasisopin Kiertiburanakul, Virat Klinbuayaem, Supunnee Jirajariyavej and Warangkana Munsakul and Monica Gandhi
Sites: TRCARC, Chulalongkorn University, Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Chonburi Hospital, Chiang Rai Prachanukroh Hospital, Ramathibodi Hospital, Sanpatong Hospital, Taksin Hospital, and Vajira Hospital, University of Bangkok Metropolitan Administration
Funding: National Health Security Office (NHSO), The Kirby Institute for Infection and Immunity in Society, University of New South Wales (UNSW), Sydney, Australia and University of California, San Francisco (UCSF), USA

Feasibility Study (Test and Treat)
HIV-NAT 162
Trial to Evaluate the Acceptability and Feasibility of “Test and Treat” and “link-to-care” to reduce HIV transmission among men having sex with men in Bangkok
This cross-sectional study will evaluate the interest and attitudes on regular voluntary HIV counseling and testing, assess the acceptability of immediate antiretroviral therapy if seropositive and identify the associated factors in improving access to treatment and care. The information from this study will be used to design the upcoming Test and Treat Study.
Status: Ongoing
Enrolled/Target: 200/400
Collaborators: Thai Red Cross Anonymous Clinic
Sites: Thai Red Cross MSM Clinic, Thai Red Cross Mobile Clinic
Funding: HIV-NAT
NEW DRUG DEVELOPMENT

Throughout the years, HIV-NAT has made a strong commitment to evaluate the safety and efficacy of new drugs. Together with the pharmaceutical companies, HIV-NAT is able to provide new drugs and new drug classes to patients who have failed all current drug classes and have limited access to new treatments. These studies provide HIV-NAT patients with an opportunity to include active agents into their regimen which would not be possible on the national program.

This year, there are a total of seven pharmaceutical initiated studies. There are four studies conducted in adults, one of which has been completed. One study is currently under IRB review and expected to start sometime next year. Two studies are supported by Tibotec, one by Gilead and one by Bristol-Myers Squibb (BMS). There are three ongoing pediatric studies: PAINT, PIANO and PRINCE 1. All of these pediatric studies are discussed under the section entitled, “PEDIATRIC AND YOUTH RESEARCH PROGRAMS.” Two of these studies are supported by Tibotec and one by BMS.

THRIVE (TMC278-C215)
HIV-NAT 091
This is a phase III, randomized, double-blind trial of TMC278 25 mg q.d. versus efavirenz 600 mg q.d. in combination with a background regimen consisting of 2 nucleoside/nucleotide reverse transcriptase inhibitors in antiretroviral-naive HIV-1 infected subjects.
Status: Closed 2011
Enrolled: 18
Funding: Tibotec Pharmaceuticals Ltd.

GS-US-216-0114
HIV-NAT 138
This is a multicenter phase 3, randomized, double-blind, active-controlled study to evaluate the safety and efficacy of a regimen containing GS-9350-boosted atazanavir (ATV/GS-9350) versus ritonavir-boosted atazanavir (ATV/r) each administered with emtricitabine/tenofovir disoproxil fumarate (Truvada®, FTC/TDF) in HIV-1 infected, antiretroviral treatment-naive adult subjects.
Status: Ongoing
Funding: Gilead

TMC278-C222
HIV-NAT 150
This is a rollover study for TMC278-C204 and TMC278-C215.
Status: Ongoing
Target: 25
Funding: Tibotec Pharmaceuticals Ltd.

BMS AI 467-003
HIV-NAT 169
BMS-986001
This is a phase 2b randomized clinical trial for BMS-986001 in HIV ARV naive.
Status: IRB submission.
Funding: Bristol-Myers Squibb (BMS)
There are six different types of studies: toxicities, asthma, questionnaire, observational, immunology and MSM. There are three ongoing toxicities studies which are funded by AmFAR and other Thai granting agencies and funding. Four studies were completed this year; two MSM, one asthma and one questionnaire studies were completed. Asthma, questionnaire, observational and one immunology study are supported by Ratchadapiseksompoch Grant, under the Chulalongkorn University. The other immunology study is supported by the Kirby Institute. All of the MSM studies are supported by the Thai Red Cross – AIDS Research Centre with some support from the ART AIDS Fund (AAF), PEPFAR and the Commission for Higher Education (CHE).

**Toxicity Studies**

**HIV-NAT 114**
This study will assess the tubular function in patients taking TDF versus non-TDF regimen from HIV-NAT 006.

- **Target:** 700
- **Status:** Ongoing
- **Funding:** Thai Research Fund and Office of the National Research Council of Thailand

**HIV-NAT 114.1**
This study will validate five different GFR measurements in Thai HIV infected population and evaluate the correlation between TDF plasma concentration and GFR.

- **Target:** 200
- **Status:** Ongoing
- **Funding:** AMFAR and Commission of Higher Education

**HIV-NAT 114.2**
This study will assess hypophosphataemia and its clinical significance.

- **Target:** 120 (60 cases; 60 controls)
- **Status:** Ongoing
- **Funding:** Chulalongkorn University (Ratchadapiseksompoch Grant)

**Asthma**

**Children with HIV and Asthma (CHIVAS)**

**HIV-NAT 102**
Allergen specific T effector and T regulatory cell response to common aeroallergens following immune restoration in HIV-infected children; Children with HIV and Asthma (CHIVAS)

This aims to study allergen specific T effector and T regulatory cell response in HIV-infected children before and after commencement of HAART.

- **Enrolled/target:** 2/20
- **Status:** Ongoing
- **Mentors:** William T. Shearer (Baylor College of Medicine, TX, USA) and Pantipa Chatchatee (Division of Allergy & Immunology, Department of Pediatrics, the King Chulalongkorn Memorial Hospital, Chulalongkorn University, Bangkok)
- **Site:** HIV-NAT, the Thai Red Cross AIDS Research Centre and the King Chulalongkorn Memorial Hospital
- **Funding:** CU Cluster Ratchadapisek Sompotch Endowment Fund, Chulalongkorn University

**Questionnaire studies**

**HIV MENQOL**

**HIV-NAT 117**
This is a cross-sectional study which evaluates the quality of life and menopausal related symptoms in Thai HIV infected women aged 40 years and older (HIV MENQOL cross sectional study).

- **Enrolled/target:** 300/300
- **Status:** Completed 2011
- **Site:** Pramongkutklao Hospital of the Royal Thai Army
- **Funding:** Chulalongkorn University (Ratchadapiseksompoch Grant)

**Presentation:** Age at Menopause and Menopausal-related Symptoms in Thai HIV-infected Women. [Poster #: P_34] presented at the 1st International Workshop on HIV & Women, from adolescent through menopause. Washington D.C., USA. 10-11 January 2011

HIV-NAT has made a commitment to always provide researchers with the highest quality in clinical research and medical care. Since medical research is continually making rapid advances, each year it is necessary to carefully select which areas to do research. Most of the studies are designed to address the current needs of HIV-NAT patients as well as the scientific community. Of note, questions addressed by these studies are clinically relevant and socially driven.
**Observational study**  
**Preventive study in reproductive health and HIV**  
**HIV-NAT 126**

Contraception and the prevention of HIV infection - conception and contraception in Thai people living with HIV

This is a cross-sectional study with two stages: stage 1 – questionnaire; stage 2 – focus group discussion. The main goal is to assess sex practices, contraceptive methods used and the desire for conception in Thai PLH via administering a questionnaire and conducting focus group discussions. There is one substudy: Intrauterine Device as a modern method of contraception in Thai HIV-positive women (for more information, please go to section, “Long Term Cohort Analysis.”

**Target:** 200

**Status:** Completed in March 2011.

**Publication:** Under review

**Funding:** Chulalongkorn University (Ratchadapiseksompoch Grant) and HIV-NAT

**Presentation:** Landolt NK, Phanuphak N, Pinyakorn S, Lakhonphon S, Khongpetch C, Chaithongwongwatthanana S, Ananworanich J.

Sexual life, intention for conception and options for contraception in HIV-positive people on successful antiretroviral therapy in Thailand. [oral presentation] presented at the 5th International Conference on Reproductive Health and Social Science Research, Bangkok, Thailand, 5 August 2011.

**Immunology studies**  
**CD4+poor response**  
**HIV-NAT 132**

Prevalence, factors and immunopathogenesis of inappropriate immune reconstitution (CD4+ below 200 cells/mm3) in Thai patients with long term viral suppression following antiretroviral therapy.

This is a retrospective, observational study that addresses why some HIV patients have CD4 <200 copies/mm3 despite being on ART and have viral load <50 copies/mL. This study will assess the factors contributing to this phenomenon and how these patients differ compared to those with CD4 <200 copies/mm3.

**Status:** Ongoing

**Funding:** Chulalongkorn University (Ratchadapiseksompoch Grant)

**Restore study**  
**HIV-NAT 136**

This is a prospective, observational study to explore reconstitution of immunity in patients with advanced HIV-1-infection commencing combination antiretroviral therapy. The protocol is designed to mirror standard of care (SOC) visits for this patient population. The main difference to SOC is the formal collection of data and the collection of extra blood volumes.

**Four-year study**

**Status:** Ongoing

**Funding:** The Kirby Institute for Infection and Immunity in Society [formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), Sydney, Australia]

**Results:** Preliminary results from initial screening for Latent TB infection demonstrated that the CD25/CD134 assay showed good agreement with QFN-GIT test for the detection of recall immune response to TB infection even in patients with advanced HIV infection. Data from one-year follow-up will be analyzed in 2012.
MSM studies MSM prevention cohort
HIV-NAT 120
HIV prevention interventions for Thai MSM
This is a study to evaluate acceptability and feasibility of standard HIV prevention package and other potential HIV prevention methods such as chemoprophylaxis, rectal microbicides, and internet social networking among MSM clients of the Thai Red Cross Anonymous Clinic.

**Status:** Completed in June 2011

**Target:** 100

**Sites:** TRC Anonymous Clinic

**Funding:** ART AIDS Fund, Thai Red Cross – AIDS Research Centre and HIV-NAT

MSM VCT
HIV-NAT 148
Multidisciplinary services to enhance HIV testing and linkage to care among MSM
This is a prospective cohort study which will determine the impact of MSM-targeted multidisciplinary services on uptake of HIV voluntary counseling and testing (VCT) and enrollment into care and retention of HIV-positive MSM.

**Status:** Ongoing

Enrolled: 350

Sites: TRC Anonymous Clinic, Sanglah Hospital, Bali, Indonesia and Cipto Mangunkusumo Hospital, Jakarta, Indonesia

**Funding:** The National Institute of Health (NIH)/President’s Emergency Fund for AIDS Relief (PEPFAR) Supplement, Thai Red Cross – AIDS Research Centre and HIV-NAT

Youth Mobile Health Clinic
HIV-NAT 151
Youth Mobile Health Clinic: service delivery model to enhance HIV testing among Thai youths
This study aims to evaluate factors associated with the acceptance of HIV testing delivered through various youth-targeted services and activities in the Mobile Health Clinic among Thai university students.

**Status:** Completed on Nov. 2011

**Enrolled:** 400

**Sites:** TRC Youth Mobile Health Clinic to three universities in Bangkok

**Funding:** Commission of Higher Education and Thai Red Cross – AIDS Research Centre

PEDiATRIC AND YOUTH RESEARCH PROGRAMS

In 2011, the pediatric team had several studies that identified the optimal regimens and appropriate treatment strategies for HIV-infected children and youths. In addition, the team also conducted vaccine trials and also neurocognitive study in these children to see the effect of antiretroviral therapy on the brain development.

There are 31 pediatric studies in 2011. Nine studies were completed this year, one of which is under the section entitled, “LONG TERM COHORT ANALYSIS,” directly beneath the HIV-NAT 015 pediatric cohort. Two studies that were completed were from NIH. Six studies are from the American Foundation for AIDS Research (amfAR), Therapeutics Research, Education, and AIDS Training in Asia (Treat Asia), three from Pediatric European Network for Treatment of AIDS (PENTA), two from TIBOTEC, two from Art AIDS Fund (AAF) and two from BMS. The rest of the studies are funded by Thai granting agencies and/or HIV-NAT. Two of the studies (HIV-NAT 90 and 152) are pharmacokinetic studies and can be found in this section.

HIV-NAT 035
This is an open label, randomized phase III study comparing early versus deferred (starting HAART when CD4+ falls below 15%) initiation of HAART in anti-retroviral-naive children aged one to 12 years with CDC paediatric clinical classification category A or B and CD4+ between 15 to 24%. (NCT 00234091)

**Status:** Completed in 2011

Enrolled: 180 Thai/120 Cambodian children

Site PIs in Thailand: Bamrasnaradura Infectious Disease Institute: Jurai Wongsawat, Khon Kaen University: Pope Kosalaraksa, Queen Savang Vadhana Memorial Hospital: Wicharn Luembrosoon, Nakornping Hospital: Suparat Kanjanavanit, Chiangrai Regional Hospital: Rawiwat Hansudewechakul, and Prapokklao Chantaburi: Chaiwat Ngampiyasakul

Site PIs in Cambodia: National Center for HIV/AIDS, Dermatology and STDs (NCHADS): Mean Chhi Vun and Vonthanak Saphonn

**PREDICT (Paediatric Randomized to Early vs Deferred Initiation in Cambodia and Thailand)**
Collaborator: David A. Cooper
Funding: National Institute of Allergy and Infectious Diseases (NIAID); Comprehensive International Program of Research on AIDS (CIPRA) grant. Antiretroviral medication is provided at no cost by GlaxoSmithKline (AZT, 3TC and Abacavir), Boehringer Ingelheim (nevirapine), Merck (efavirenz), Abbott (lopinavir/ritonavir) and Hoffmann La Roche (nelfinavir).

Publications:

Presentations:

There are substudies for PREDICT

1) HIV-NAT 035.1: This sub study assesses the effect of immediate versus deferred antiretroviral initiation on neurodevelopment in children with HIV in Cambodia and Thailand. Neurodevelopment is assessed every six months. The primary outcome is the neuro-development functions in the immediate arm compared to the deferred arm at week 144.

Status: Closed in 2011
Enrolled: 180 Thai/120 Cambodian children
Funding: National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute of Child Development (NICHD).
2) Micronutrient/HIV-NAT 035.2: This sub-study assesses the impact of selenium/zinc levels on HIV disease and treatment response in children.

**Status:** Ongoing

**Enrolled:** 180 Thai

**Funding:** National Institute of Allergy and Infectious Diseases (NIAID)

3) PREDICT Cohort/HIV-NAT 035.3: (please see section, “Long term cohort analyses”)

**Publications:**
2) CD4 Cell Count Criteria to Determine When to Initiate Antiretroviral Therapy in Human Immunodeficiency Virus-Infected Children. Pediatr Infect Dis J. Oct;29(10):966-8
3) Lymphocyte subsets in healthy, HIV-infected, and long term non-progressor Asian children through 12 years of age. JACI (In Press)

**PENTA 11**

**HIV-NAT 066**

This is a long term follow-up study assessing whether children with HIV infection undergoing planned ART interruptions are disadvantaged clinically, immunologically, virologically or neurologically from periods of time off ART.

**Status:** Ongoing until May 2013

**Enrolled:** All nine children completed their second year neurocognitive study (IQ test) in May 2010.

**Funding:** Pediatric European Network for Treatment of AIDS (PENTA)

**Publication:** Response to planned treatment interruptions in HIV infection varies across childhood. AIDS (London, England). 2010 Jan 16;24(2):231-41

**MET-THAI**

(Motivation Enhancement Therapy for Health Risk Behaviors in HIV+ Thai Youth age 16-24 years)

**HIV-NAT 078**

To assess the effectiveness of motivation enhancement therapy in reducing sexual risk behaviors in HIV-infected Thai youth by measuring their condom use

**Status:** Closed in 2011

**Enrolled/target:** 124

Project Key Personnel: Chokechai Rongkavilit, Sylvie Naar-King, Jeffrey Parsons, Pichai Saengcharnchai, and Theshinee Chuenyam

**Collaborators/sites:** Thai Red Cross AIDS Research Centre and Chulalongkorn Hospital

**Funding:** National Institute of Health (NIH)

Lopinavir/ritonavir monotherapy in virally suppressed children

**HIV-NAT 077**

Open label, multicenter observational cohort evaluating the efficacy and safety of LPV/r monotherapy maintenance in Thai children after switching from double boosted PI regimen with suppressed viral load.

**Status:** Completed in 2011

**Enrolled:** 40 children

**Collaborators:** Pope Kosalaraksa, Pagakrong Lumbiganon, Chitsanu Pancharoen

**Sites:** Chulalongkorn Hospital and Khon Kaen University

**Funding:** Global Fund for LPV/r

**Results:** 85% of the children had VL<50copies/ml at 6 months after switching from dPl to mLPV/r with no effects on clinical, CD4, lipid profiles and fasting glucose.

**Publication:** Monoboosted lopinavir/ritonavir as simplified second-line maintenance therapy in virologically suppressed children. AIDS. 2011 Jan 28;25(3):315-23.

**HIV and HBV**

**HIV-NAT 80.1**

HIV and HBV co-infection among perinatally HIV-infected adolescents participating in Treat Asia observational Database.

This is a cross sectional, substudy of TApHOD that will assess the prevalence of HBV coinfection among HIV-infected adolescents.

**Status:** Started in October 2010
Enrolled: Seven out of 80 cases were nonresponders, so a second course, double dose of HBV vaccine will be administered.

Site: Chulalongkorn Hospital

Funding: Art AIDS Fund (AAF)


T cells subsets in healthy children

HIV-NAT 108
This is a cross-sectional study assessing the cellular subsets and immunoglobulins in healthy Thai children between the ages 0 and 15 years. This study will provide normal values of lymphocytes, monocytes, natural killer cells and immunoglobulins.

Status: Closed in 2011

Enrolled: 190

Collaborator: Suwat Benjaponpitak (Ramathibodi Hospital)

Sites: Chulalongkorn Hospital and Ramathibodi Hospital

Funding: The Thailand Research Fund

Meaning of life in Thai HIV infected youth

HIV-NAT 109
This is a randomized control trial. This study will evaluate the effect of logotherapy in HIV infected youths.

Status: Ongoing

Enrolled/Target: 8/84

Collaborator: Arunya Tuicomepee (Counseling Psychology Program, Faculty of Psychology, Chulalongkorn University)

Funding: Art AIDS Fund

PIANO (TMC125-C213)

HIV-NAT 112
This is a phase II, open-label multicenter trial evaluating the safety, tolerability and antiviral activity of Etravirine (TMC 125-C213) in treatment experienced HIV-infected children and adolescents.

Status: Ongoing

Enrolled: 7

Collaborator/site: Chulalongkorn Hospital

Funding: Tibotec Pharmaceuticals

Third line HAART in HIV-infected children

HIV-NAT 113
This study will assess efficacy and safety of third line regimen in 150 Thai children.

Status: Ongoing

Enrolled/Target: 39/150

Site Pls in Thailand: Kulkanya Chokephaibulkit, Jurai Wongsawat, Rawiwan Hansudewechakul, Pope Kosalaraks, Suparat Kanjanavanit, Chaiwat Ngampiyakul, Pakarat Sangkla
Collaborators/sites: Chulalongkorn Hospital, Siriraj Hospital, Bamrasnaradura Infectious Disease Institute, Chiang Rai Regional Hospital, Srinagarind Hospital Khon Kean University, Nakornping Hospital, Prapokklao Hospital and Surin Hospital
Funding: Commission of Higher Education (CHE)

MRI brain in Children
HIV-NAT 121
This is a prospective study that will compare the total brain volume between HIV-infected and healthy children by using multimodal imaging approach such as tensor-based morphometry (TBM) and diffusion tensor imaging (DTI).
Status: Ongoing
Enrolled/Target: 105/150
Collaborators: Pope Kosalaraksa, Linda Aurpibul, Sukalaya Lerdlum, Victor Valcourt, Paul Thompson and Robert Paul
Sites: SEARCH, Khon Kaen University, Chulalongkorn University, Research Institute for Health Sciences (RIHES), Chiang Mai University, University of California at San Francisco, University of Missouri and University of California at Los Angeles
Funding: National Institutes of Health

KONCERT/PENTA 18
HIV-NAT 124
A Kaletra ONCE daily Randomized Trial of the pharmacokinetics, safety and efficacy of twice-daily versus once-daily lopinavir/ritonavir tablets dosed by weight as part of combination antiretroviral therapy in HIV-1 infected children
This study will evaluate once daily lopinavir/ritonavir-based HAART in virological suppressed children
Status: Ongoing
Target: 6/10 from HIV-NAT site
Funding: Paediatric European Network for Treatment of AIDS (PENTA)

HIV-NAT 133
The objective of this study is to determine the efficacy of TDF-based regimen in HIV-infected Thai children and assess effect of TDF on renal problem and bone mineral density.
Status: Ongoing
Enrolled/Target: 35/35
Funding: National Research Council of Thailand

PCV in HIV-infected children
HIV-NAT 135
The immunogenicity and safety of Pneumococcal conjugate vaccine in Human Immunodeficiency Virus – infected children
This is a prospective study that will evaluate immunogenicity of 7 – valent pneumococcal conjugated vaccine in HIV – infected children compared with HIV – exposed uninfected children.
Behaviorally HIV-infected adolescents, and HIV-negative adolescents.

Status: Ongoing
Target: 59
Sites: HIV-NAT, Petchburi Hospital and Chiangrai Prachanukroh Hospital
Funding: The American Foundation for AIDS Research (amfAR), Therapeutics Research, Education and AIDS Training in Asia (Treat Asia)

**BREATHER/PENTA 16**

**HIV-NAT 140**

Short-Cycle Therapy (SCT) (5 days on/2 days off) in young people with chronic HIV-infection. This study will evaluate the efficacy and safety of short cycle therapy in HIV-infected children.

Status: Ongoing
Target: 10/20 from HIV-NAT site
Funding: Paediatric European Network for Treatment of AIDS (PENTA)

**PRINCE 1**

**HIV-NAT 143**

A Prospective Single Arm, Open-label, International, Multicenter Study to Evaluate the Safety, Efficacy and Pharmacokinetics of Atazanavir (ATV) Powder Boosted with Ritonavir (RTV) Liquid with an Optimized NRTI Background Therapy, in HIV Infected Pediatric Patients Greater Than or Equal to 3 Months to Less Than 6 Years; Pediatric Atazanavir International Clinical Evaluation: the PRINCE I study (AI424397)

This study will evaluate the pharmacokinetic and efficacy data of atazanavir/rt in HIV-infected children.

Status: Ongoing
Target: 1/2 from HIV-NAT site
Funding: Bristol-Myers Squibb

**TASER-Pediatrics**

**HIV-NAT 145**

The objectives of this study is to monitor for resistance development and resistance patterns in children failing second-line ART over 72 weeks

Status: Ongoing
Target: 35/40 from HIV-NAT site
Sites: 8 sites from Thailand, Vietnam and Indonesia
Funding: The American Foundation for AIDS Research (amfAR), Therapeutics Research, Education, and AIDS Training in Asia (Treat Asia)

**HIV-NAT 146**

The study of atazanavir/ritonavir-based HAART in Thai HIV-infected children

This trial will study the pharmacokinetics of atazanavir/ritonavir (ATV/rt) in HIV-1 infected Thai children.

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**Status:** Closed in 2011

**Enrolled:** 90

**Collaborators:** Pediatric infectious diseases unit, Chulalongkorn University: Chitsanu Pancharoen, Sasithorn Likitnukul, Chareeyaa Thanee

**Sites:** Pediatric infectious diseases section, King Chulalongkorn Memorial Hospital and The Thai Red Cross AIDS Research Center (TRC-ARC)

**Funding:** Ratchadaphiseksomphot Fund, Faculty of Medicine, Chulalongkorn University


**Presentation:** The Immunogenicity and Safety of Pneumococcal Conjugate Vaccine in Human Immunodeficiency Virus-Infected Thai Children. [Poster # P_94 ] presented at the 3rd International Workshop on HIV Pediatrics. 15-16 July 2011, Rome, Italy.

**HPV Study HIV-NAT 139**

The objectives of this study is to compare the prevalence of HPV infection among perinatally HIV-infected adolescents, behaviorally HIV-infected adolescents, and HIV-negative adolescents, and compare the prevalence of intraepithelial neoplasia and presence of E6/E7 biomarker at cervical and anal sites among perinatally HIV-infected adolescents, behaviorally HIV-infected adolescents, and HIV-negative adolescents.
**Status:** Ongoing  
**Target:** 6/20 from 2 sites  
**Collaborators:** The American Foundation for AIDS Research (amfAR), Therapeutics Research, Education, and AIDS Training in Asia (Treat Asia), Thai National Health Security Office (NHSO) for antiretrovirals and certain laboratory testing, and The Thai Government Pharmaceutical Organization (GPO) for ritonavir tablet 100 mg  
**Funding:** The American Foundation for AIDS Research (amfAR), Therapeutics Research, Education, AIDS Training in Asia (Treat Asia), Thai National Health Security Office (NHSO), and Thai Government Pharmaceutical Organization (GPO)

### The PEARL study

#### HIV-NAT 152

Pediatric study for Appropriate dose of Ritonavir boosted Lopinavir in Thai HIV-infected children.  
This is a multicenter randomized study to compare the safety and efficacy of low-dose versus standard dose lopinavir/ritonavir containing HAART regimen in virologically suppressed HIV-infected Thai children  
**Status:** Ongoing. The study will be completed at the end of 2012.  
**Enrolled:** 143  
**Sites:** total 11 sites (HIV-NAT, Thai Red Cross AIDS Research Center, Bamrasnaradura Infectious Disease Institute, Khon Kaen University, Nakornping Hospital, Prapokklao Hospital, Queen Sirikit National Institute of Child Health, Surin Hospital, Sappasitthiprasong Hospital, Udonthani Hospital, Buddhachinaraj Hospital, Phrachomklao Hospital)  
**Funding:** National Research Council of Thailand  
**Results:** Treatment with low dose LPV resulted in similar pharmacokinetic profile and efficacy compared to standard dose LPV in Thai children  

#### TApHOD ACASI

#### HIV-NAT 155

The objective of this study is to collect information on adherence and behavioral risk factors in HIV-infected adolescents who are being followed in the TApHOD cohort study.  
**Status:** Ongoing  
**Target:** 10/50 (complete enrolment)  
**Site:** Chiangrai Prachanukroh Regional Hospital, Thailand; HIV-NAT, Thailand; Kuala Lumpur

### HIV-NAT 156

An open-label, multicenter, multiple-dose pharmacokinetic, safety and efficacy trial of maraviroc in combination with optimized background therapy for the treatment of antiretroviral-experienced CCR-5 tropic HIV-1 infected children 2-<18  
The study will evaluate the efficacy and safety of maraviroc in HIV-infected children.  
**Status:** Ongoing  
**Target:** 1/2 from HIV-NAT site  
**Funding:** ViiV Healthcare  

### HIV-NAT 167

Pharmacokinetics of Abacavir once daily vs. twice daily in HIV-infected Thai Children  
This study will evaluate pharmacokinetic of abacavir in Thai HIV-infected children.  
**Status:** Start in early 2012  
**Target:** 30 HIV-infected children  
**Funding:** The American Foundation for AIDS Research (amfAR), Therapeutics Research, Education and AIDS Training in Asia (Treat Asia)
HIV-NAT TEAMS

MEDICAL DEPARTMENT

Left to right:
Dr. Amanda Clarke (Adult Clinical Trial Physician), Dr. Torsak Bunupuradah (Pediatrician, Allergist and immunologist), Piraporn Ohata (Research Assistant), Dr. Anchalee Avihingsanon (Head of HIV-NAT physicians and adult infectious diseases specialist), Assoc. Prof. Thanyawee Puthanakit (Pediatric infectious diseases specialist), Assist. Prof. Wirach Maek-a-nantawat (Internist, Allergy and Immunology Specialist), Dr. Wasana Prasitsuebsai (Pediatrician, Allergist and immunologist), Dr. Reshmie Ramautarsing (Adult Clinical Trial Physician), Prof. Emer. Praphan Phanuphak (Co-director of HIV-NAT, Director of Thai Red Cross AIDS Research Centre), Prof. Kiat Ruxruntham (Deputy Director of HIV-NAT and of Thai Red Cross AIDS Research Centre), Dr. Denise Hsu (Adult Clinical Trial Physician), Assoc. Prof. Jintanat Ananworanich (Deputy Director in Scientific Affairs at HIV-NAT), Dr. Nadia Kancheva Landolt (Adult Clinical Trial Physician)

LABORATORY DEPARTMENT

Left to right:
Thatri Iampornsin (Scientist), Narukjaporn Thammajaruk (Pharmacologist), Phantipa Onsam-ang (Laboratory Secretary), Umaporn Chobkarching (Scientist), Thitiporn Somjit (Assistant Medical Technologist), Mattiga Pingthaionsong (Assistant Medical Technologist), Tanaythip Jaimulwong (Medical Technologist), Apicha Mahanontharit (Laboratory Quality Manager), Sasiwimol Uboylam (Laboratory Manager), Bunruan Sopa (Medical Technologist), Dr. Denise Hsu (Adult Clinical Trial Physician), Patcharin Eamyong (Medical Technologist), Meena Detchaiyasak (Pharmacologist), Akekalak Khadranta (Medical Technologist), Channuwat Bouko (Medical Technologist)
RESEARCH NURSE DEPARTMENT
Left to right:

RESEARCH NURSE DEPARTMENT
Left to right:
Chayapa Phasomsap (Pediatric Clinical Research Nurse), Augchara Suwannawut (Secretary for Research Nurse Department), Prachya Chaiyahong (Adult Clinical Research Nurse), Siwanart Thammasala (Assistant Research Nurse), Khuanruan Moonthong (Assistant Research Nurse), Supaporn Aunlamai (Pediatric Clinical Research Nurse), Chuleeporn Wongvoranet (Adult Clinical Research Nurse), Jaravee Jamthog (Adult Clinical Research Nurse), Oratay Butterworth (Pediatric Clinical Research Nurse), Valairat Charoenporn (Adult Clinical Research Nurse), Supalak Phophinthak (Head of Research Nurse Department), Wanida Thiansanguankul (Adult Clinical Research Nurse), Supaporn Aunlamai (Pediatric Clinical Research Nurse), Chompoonoot Sirikum (Pediatric Clinical Research Nurse), Jennisa Ahluwalia (Adult Clinical Research Nurse)

PHARMACY DEPARTMENT
Left to right:
Niti Wongthai (Stock Controller), Threepol Sattong (Pharmacist Assistant), Anuntaya Uanithirat (Pharmacist), Ratree Longharoen (Pharmacist Assistant), Plengsri Lertarom (Head of Pharmacy), Chulalak Sriheara (Pharmacist), Sarapol Tongphan (Pharmacist Assistant), Parinya Suheerasak (Pharmacist)
ADMINISTRATIVE DEPARTMENT

Left to right:
Pornwinit Sattayamongkol (Web Programmer),
Natthapa Pitayanon (Assistant HR Coordinator),
Jeerakan Janhom (HR Coordinator & Office Operation Head),
Pranee Pinklow (Training Coordinator),
Ruksina Chumchure (Administrator),
Dararin Choomsai Na Ayuthaya (Communication Specialist),
Adisak Jamrasrak (Purchaser)

Left to right:
Sommai Sattong (Housekeeper),
Yodying Kittimakorn (Housekeeper),
Apinya Phuttajitpunt (Housekeeper)

BIOSTATISTICIAN DEPARTMENT

Left to right:
Taweesak Channgam (Biostatistician),
Tanakorn Apornpong (Biostatistician),
Stephen Kerr (Head Biostatistician),
Jiratchaya Sophonphan (Biostatistician),
Suteeraporn Pinyakorn (Biostatistician)

FINANCIAL DEPARTMENT

Left to right:
Duangmanee Seedam (Assistant Financial),
Umaporn Methanggool (Accountant),
Chornarin Thangjitthanom (Accountant),
Kesdao Nanthapisal (Financial Controller)
IT & DATA MANAGEMENT DEPARTMENT
Left to right:
Tanakorn Sritha (IT Help Desk), Theeradej Boonmangum (Clinical Data Associate), Wanchai Thongsee (Data Entry), Wipada Chanthaweethip (Clinical Data Associate), Bencharat Thongpunchang (Clinical Data Associate), Chavalun Ruengpanyathip (IT & Data Management Manager), Orathai Chaiya (Clinical Data Associate), Ormrudee Rit-im (Clinical Data Associate), Kittimuk Sansuk (IT Engineer), Chowalit Phadunphon (Database Developer), Prapon Koita (Database Programmer)

CLINICAL RESEARCH ASSOCIATE
Left to right:
Jintana Intasan (Clinical Research Associate), Thidarat Jupimai (Clinical Research Associate), Kanlaya Charoentontpunban (Clinical Research Associate), Patsamon Rerkririkul (Assistant Clinical Research Associate), Purivis Chart (Clinical Research Associate), Chaladakorn Ruengprasertkit (Clinical Research Associate), Peeraporn Kaew-on (Clinical Research Associate), Tulathip Suwanlerk (Head of Clinical Research Associates), Kanitta Pussadee (Clinical Research Associate)

QUALITY MANAGEMENT DEPARTMENT
Left to right:
Aruni Tansakda (Regulatory Liaison Officer), Kanokon Sirichumpa (Regulatory Liaison Officer), Tawan Mengthaisong (Quality Management Officer), Chatsuda Auchang (Quality Management Supervisor), Gunyanee Sattong (Regulatory Liaison Officer)
PUBLICATIONS & WRITINGS

As of November 2011 a total of 38 manuscripts have been accepted for publication and six manuscripts are under review for 2011. This year, only one NIH and 12 Thai grants were submitted. Eleven Thai grants were awarded. One NIH and One Thai grant are pending review.

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2011 Publications


Kancheva Landolt NT, Lakhonphon S and Ananworanich. Contraception in HIV-positive female adolescents. AIDS Research and Therapy 2011, 8:19 (1 June 2011)


Babiker A, Emery S et al. START; desgn considerations for a large simple trial to examine the time to commence antiretroviral therapy for the treatment of HIV infection. J Clin Trials 2011. In press


ANNUAL REPORT 2011
HIV-NAT


December 2010 Publications


December 2010 Publications


This year a total of 25 posters including oral presentations were accepted. Not only has HIV-NAT expanded its field of research, but also contributed its work to other conferences outside of its typical venue. HIV-NAT participated in three conferences for the first time: the International Workshop on HIV & Women, the Reproductive Health and the Social Science Research and the International Papillomavirus Conference. For CROI, a total of seven abstracts were accepted whereas four and five were accepted for IAS and the Pediatric Workshop respectively.

**The 1st International Workshop on HIV & Women, from adolescent through menopause. Washington DC, USA. 10-11 January 2011**


**18th Conference on Retrovirus and Opportunitiies Infections (CROI 2011). Boston, MA, USA. 27 February – 2 March 2011.**


Since analysis for abstracts and manuscripts are done at the same time, fewer abstracts are submitted to international conferences in 2011 than in 2010. However, most of the abstracts submitted this year were accepted. Electronic files of the posters are, for the first time, provided at the URL located below the poster entry.


* Also presented at IAS conference
HIV-NAT RESEARCH LABORATORY

Staff:
Laboratory Director: Prof. Kiat Ruxrungtham
Laboratory Manager: Sasiwimol Ubolyam
Laboratory Quality Manager: Apicha Mahanontharit
Total number of staff: 18, consist of 7 Laboratory Medical Technologist, 2 Scientist, 2 Pharmacologist, 2 Senior Laboratory assistant, 2 laboratory assistant and 1 lab Secretary and 1 part time Medical Technologist

Auditor/Consultant:
Phillip Cunningham, senior operations manager, St. Vincent’s hospital, Australia
Mike Ussery, Division of AIDS, NIH, USA
Neal Wetherall, Division of AIDS, NIH, USA
Function:
HIV-NAT Research Laboratory is a CAP certified and DAIDS approved laboratory that provides services to all HIV-NAT clinical trials, especially studies funded by DAIDS such as ESPRIT (CPCRA), Stalwart (CPCRA), START (CPCRA) and PREDICT (CIPRA).

Since 2005, HIV-NAT Research Laboratory was assessed by DAIDS and was approved in January 2006. HIV-NAT Research Laboratory was reassessed annually on February 2007, 2008, 2009 and 2010.

HIV-NAT Research Laboratory is enrolled in the National Health Security Organization Program for Bangkok, Thailand.

The HIV-NAT Research Laboratory is located on the 7th floor of the Research Building at Chulalongkorn University Hospital which is 150 feet from the HIV-NAT main building. HIV-NAT lab serves as the central laboratory for the PREDICT study. In addition, HIV-NAT is responsible for training, quality assurance, data collection and analysis for all sites.

The HIV-NAT laboratory facility comprises approximately 2500 square feet of space. The laboratory has the capacity to perform diagnostic immuno-assays, cell phenotyping by flow cytometry, HIVRNA, DNA PCR, hepatitis and syphilis serology and molecular testing including TB Xpert Technology, haematology, chemistry and HIV pharmacokinetics.

The laboratory provides serum HIV and diagnostic serology testing for HIV, HBV and HCV, PCR for HIV proviral DNA, chlamydia, gonorrhea, and molecular quantitation of HIV by Cobas Ampliprep Taqman (Roche), Abbott Realtime PCR. The laboratory also provides 2-, 3- and 4-color flow cytometry for T-cell phenotype analysis for adult and paediatric studies.

The laboratory participates in the UKNEQAS (UK national external quality assurance scheme) and the college of American Pathologists (CAP) for flow cytometry. Viral quantitation is certified by Virology Quality Assessment Program (VQA) from Rush Presbyterian-St. Lukes Medical Center Chicago, Illinois, also from the Walter Reid Armed Forces Institute of Research and CAP. All laboratory assays has external quality assurance program with CAP or CAP approved provider. HIV-NAT laboratory has already received CAP accreditation since April 2009 (LAP Number 7197506, AU-ID : 1475967) and reaccredited in 2011.

HIV-NAT has been certified by DAIDS to perform 13 T, B, NK and monocyte subsets analyses, including CD8+DR+38+ as part of an NIAID R01-funded immunologic study (1 R01 AI075408-01) “Predictors of Immunologic Long-term Non-Progression in Children with HIV”.

The laboratory is compliant with all applicable safety and administrative requirements for GCLP and is audited annually by staff from NCHECR, St Vincent’s Hospital, Sydney, Australia and DAIDS officer, NIH USA.

Pharmacokinetic:
The pharmacology laboratory at HIV-NAT was established in 2002. Every year, HIV-NAT successfully passes the international Quality Control Program for Measurement of Antiretroviral Drugs in Plasma from the Radboud University Nijmegen Medical Center and the Dutch Association for Quality Assessment in Therapeutic Drug Monitoring and Clinical Toxicology (KKGT, see www.kkgt.nl). HIV-NAT is among other 60 laboratories worldwide that participates in this program.

HIV-NAT PK laboratory has two pharmacologists, one scientist and one assistant medical technologist who are trained by, and receive continuing technical support from, Dr. David Burger, Radboud University Nijmegen Medical Centre, Nijmegen, the Netherlands.

HIV-NAT Research Laboratory has been performing pharmacokinetics and therapeutic drug monitoring studies. HIV-NAT PK laboratory also provides services for other clinicians requesting TDM for patient management. TDM service is available for
Tenofovir (nucleotide reverse transcriptase inhibitors), Efavirenz, Nevirapine (non-nucleoside reverse transcriptase inhibitors), almost all protease inhibitors including Atazanavir, Darunavir, Indinavir, Lopinavir, Nelfinavir, Ritonavir and Saquinavir, and Raltegravir (Integrase Inhibitor). The HIV-NAT PK laboratory has also been involved in research studies that focus on issues relevant to the Asian setting such as dose reduction of several ARVs and assess the quality of many generic products. Last year dose reduction of ritonavir and boosted lopinavir in children was studied. Another study assessed the pharmacokinetics study of Darunavir and Ritonavir in children. We also explored pharmacokinetics of low dose raltegravir and standard dose tenofovir in adult patients. There are also other pharmacokinetic studies that are in line for publications. Many studies are in the pipeline and we will continue to gather more essays for future use. HIV-NAT has plans to set up PK for anti-TB drugs (rifampicin, rifabutin, moxifloxacin, and TMC207), anti-malarial drugs (artemether, lumefantrine), anti-hepatitis C drugs (boceprevir, Telaprevir) and new antiretrovirals (maraviroc, etravirine and others). Currently, we are also interested in monitoring ARVs at intracellular levels.

Our pharmacokinetic laboratory participates in an international quality control program and has met the standards required to conduct clinical work and high quality research which has been accredited by CAP in April 2009 and reaccredited in 2011

**Education and Training**

HIV-NAT Research Laboratory Manager has provided a lecture on, “Common Pitfalls in GLP” for the Workshop in Standard Course for Clinical trials, Faculty of Medicine Chulalongkorn University on March 2011.

HIV-NAT Research Laboratory Manager has provided GCLP training for participants from sites participated in low dose Lopinavir Pediatric Study (HIV-NAT 152) as part of the SEARCH Regional HIV/AIDS training which was held on March 2010.

HIV-NAT Research Laboratory Manager has provided lectures of Important of Biological transportation in Clinical Research in the World Courier’s Seminar of Role of Cold Chain Management on June 2011.

HIV-NAT Research Laboratory Manager has provided lectures of Proficiency Testing: A guide to Improve Laboratory Standard in the National Meeting for HIV/AIDS Laboratory on July 2011.

**Laboratory Network**

HIV-NAT research laboratory has expanded its lab network for the following studies: ESPRIT, Stalwart, START, and PREDICT (CIPRA) and HIV STAR.

HIV-NAT Laboratory acts as a local central lab for Peripheral Blood Mononuclear Cells (PBMC) procedure for the management of MERCK clinical research study as well as GSK clinical research study.

HIV-NAT Laboratory also offers service for the Faculty of Medicine as a Chula Clinical Research Center (Chula CRL) for non HIV studies as following

- Clinical trials
  - A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy.
  - A Phase IIIb open-label, randomised, multi-centre primary immunization study to evaluate the immunogenicity and safety of GSK Biologicals’ HPV-16/18 L1 VLP AS04 vaccine when administered intramuscularly according to alternative 2-dose schedules in 9 - 14 year old healthy females compared to the standard 3-dose schedule for GSK Biologicals’ HPV-16/18 L1 VLP AS04 vaccine in 15 - 25 year old healthy.
  - A Phase III, Multi-center, Open-label, Randomized Trial Comparing the Efficacy of GA101 (RO5072759) in combination with CHOP (G-CHOP) versus RITUXIMAB and CHOP (R-CHOP) in previously untreated patients with CD20-Positive Diffuse Large B-Cell Lymphoma (DLBCL)
  - A randomized, open-label phase II multicenter study evaluating the efficacy of oral Everolimus alone or in combination with Pasireotide LAR i.m. in advanced progressive pancreatic neuro-endocrine tumors (PNET) –The COOPERATE -2 study Authors
  - A Randomized, Open-label, Multi-center, Phase III Study to Evaluate the Efficacy and Safety of Eribulin (E7389) versus Dacarbazine in Adult Patients with Soft Tissue Sarcoma

- 5 Bioequivalent studies for safety and specimen processing lab service
Quality Management of Laboratory Network

January – February 2011, DAIDS conducted an Annual Laboratory assessment. The overall assessment of all sites indicated that everyone was compliant to GCLP practice and recommendations for improvement were provided to each site so they could reach the same level of international standard.
THE VACCINE AND CELLULAR IMMUNOLOGY LABORATORY (VCI Lab)

Chulalongkorn University Medical Research Centre (Chula-MRC) and Chula Vaccine Research Center (Chula-VRC)

Research projects

1. Construction of Asian Mosaic Subtype AE/B envelope HIV DNA Vaccine and immunogenicity testing in Balb/C mice

The mosaic subtype AE/B envelope HIV DNA has been designed from 113 CRF01_AE and 59 clade B. The DNA will be cloned into pCMVkan. The *in vitro* protein expression will be done before *in vivo* immunogenicity testing in Balb/C mice.
2. Tetravalent Dengue Vaccine Development

2.1 Research and Development of Dengue Tetravalent DNA-based Vaccine

Dengue infections caused by four antigenically related dengue virus serotypes (DENV-1, 2, 3 and 4) are a major problem in tropical and subtropical regions including Thailand. Annually, approximately 50 to 100 million people suffer from dengue infections worldwide. Natural infection with one dengue virus serotype contributes only homotypic immunity. The subsequent infection with a heterologous dengue serotype is risky to develop severe dengue. One possibility can be explained by antibody dependent enhancement (ADE). Thus an ideal dengue candidate vaccine should be a protection and should avoid the induction of ADE. Nonetheless, no licensed vaccine is currently available for dengue prevention.

A great amount effort has focused on traditional approaches to dengue vaccine development, live-attenuated vaccines (LAV). However, various degrees of reactogenicity have been reported and the dosage and multiple passage levels should be performed to induce equivalent antibody titers caused by the replication interference of four DENV serotypes. DNA vaccine is an alternative approach with several advantages; it induces both humoral and cellular immunity, is stable and easy to manufacture, and present low cost of production. Moreover, since DNA vaccines do not involve infectious process in the generation of antigens, the interference does not occur when the combined tetravalent vaccines are employed. However, the main disadvantage of DNA vaccine is the relatively poor immunogenicity in human host. Therefore, several approaches were used to improve the efficiency of naked DNA vaccines in this study including codon optimization strategies and more effective delivery approaches.

Status: study completed April 2011

Collaborators/sites: Department of Microbiology, Faculty of Medicine, Chiangmai University

Funding: The National Center for Genetic Engineering and Biotechnology (BIOTEC), Thailand

Results: In the first phase of our study, we had constructed DENV-2 DNA as a vaccine prototype. Here, we demonstrated that codon optimization of the DNA encoding target genes markedly improved their protein expression in vitro. In addition, the role of adding 20% Japanese encephalitis (JE) virus envelope (E) at the C-terminal of DEN-2 E as a chimeric (80% DEN-2 E-20% JE E) DNA was evaluated in comparison with 100% DEN-2 E. Although chimeric DNA induced higher protein expression, the neutralizing antibody response was lower (18 folds of 50% plaque reduction neutralization test (PRNT50) Geometric mean titer (GMT); pHIS-D2prME-JE20 vs pHIS-D2prME=1:40 vs 1:735). We found that pCMVkan provided a better immunogenic in vivo (3 folds of PRNT50 GMT; pCMVkan-D2 prME vs pHIS-D2 prME=1:485 vs 1:160). In term of route administration, needle free injection (NF) significantly provides a better immunogenicity than intradermal (i.d.) and showed their relative DNA dose-dependent responses (PRNT50 of pHIS-D2 prME at 100 µg =1:640 (NF) vs 1:80 (i.d.) and 10 µg =1:320 vs 1:20). Based on our preliminary study, pCMVkan encoding humanized prME of the rest serotypes were constructed and showed good protein expression. Tetravalent DNA vaccine at a total dose of 100 µg (25 µg for each serotype) induced a specific neutralizing antibody titer in comparable to monovalent DNA at a dose of 25 µg (PRNT50: DENV-1 1:160 vs 1:320, DENV-2 1:320 vs 1:320, DENV-3 1:320 vs 1:160 and DENV-4 1:40 vs 1:40). In addition, cross neutralizing antibody with other serotypes were also observed. Of note, DENV-4 DNA generates the lowest neutralizing antibody in both tetravalent and monovalent DNA vaccine. Further study, we are planning improvement of neutralizing antibody titer in DEN-4 monovalent DNA and evaluation of our vaccine strategy using non-human primates. 

Publications: Publication in preparation, first results presented at the 4th Vaccine and ISV Annual Global Congress, 2010 in Vienna, Austria.
2.2 Dengue prime-boost vaccination strategy combining the electroporation-delivered tetravalent DNA vaccines with live attenuated vaccines in mice and non-human primate

In order to prevent dengue infection, various vaccine approaches have been developed and no approved vaccine is currently available for clinical use. Although the most progressive vaccine development is live attenuated virus-based vaccine (LAV), it can potentially promote collateral side effects due to a combination of infectious viruses. A DNA-based vaccine encoding specific dengue sequences is an alternative strategy as it is noninfectious, however their efficacy needs improving. In this project, several methods are proposed to enhance the DNA-based vaccine immunogenicity that have been developed in Phase I study (supported by BIOTEC) including: using in vivo electroporation for DNA delivery and using Prime-boost vaccination strategy by combining DNA vaccine with LAV. Recently, there are two studies demonstrated that prime-boost vaccinations of DNA vaccine with LAV or infective viruses are able to induce higher antibody levels. However, no study reported the effect of LAVs prime and DNA vaccine boost.

Here, we asked whether in vivo electroporation of prime-boost vaccination, combining the two types of candidates, tetravalent live attenuated vaccine (TLAV) with tetravalent DNA vaccine (TDNA) would increase the immunogenicity of our dengue DNA vaccine. We plan to conduct this project into two phases. The first phase (first year) will be used to proof the concept of prime-boost vaccination strategy in mice. If the high titers neutralizing antibody is observed, the second phase (second and third year) will be further evaluated in non-human primate (rhesus macaque).

Status: the proposal had been determined and waiting for budget approval

Collaborators/sites: Department of Microbiology, Faculty of Medicine, Chiangmai University and Department of Veterinary Medicine, Armed Forces Research Institute of Medical Sciences (AFRIMS)

Funding: The National Center for Genetic Engineering and Biotechnology (BIOTEC), Thailand

Publications:


Abstract

6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy, July 17-20, 2011

Increasing HIV drug resistance among recently infected treatment-naïve MSM in Thailand: Results from three years of annual surveillance

Sunee Sirivichayakul1, Allison DeLong2, Rapeeporn Wongkunya2, Suwanna Mekprasan1, Annette Sohn4, Kiat Ruxrungtham1,3, Rami Kantor2, Praphan Phanuphak1,3

1 Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand
2 Division of Infectious Diseases, Brown University Alpert Medical School, RI, USA
3 The Thai Red Cross AIDS Research Centre, Bangkok, Thailand
4 TREAT Asia, amfAR, Bangkok, Thailand

Background: Prospective surveillance of transmitted HIV drug resistance among recently infected individuals can help assess the future efficacy of antiretroviral therapy in resource-limited settings. It is expected to rise with increased medication access, yet trends are unknown.

Methods: Recently diagnosed HIV-1 infected treatment-naïve individuals were consecutively recruited from the Thai Red Cross Anonymous Clinic in Bangkok in 2008 (N=130), 2009 (N=89), and 2010 (N=80). Eligible individuals had newly positive HIV antibody tests and were either 18 to 25 years old or >25 years old with a negative HIV antibody test within the last 12 months. After 2008, only males who self-identified as men who had sex with men (MSM) were included. Kruskal Wallis and Fisher exact tests were used to compare demographic and laboratory outcomes by year. Bootstrap methods were used to compare sequence diversity by year. Resistance mutations were assessed using the WHO 2009 list.

Results: Among 299 individuals recruited across all three years, 265 (89%) were MSM. The median age was 23 (range 17-47) years, median viral load was 36,860 (range 39-10,000,000) copies/ml, and median CD4 was 348 (range 9-1007) cells/mm³. Although age and CD4 count were not different by year, viral load was lower in 2008 among MSM with an increasing trend over time (p=0.03). Of 255/299 available pol sequences, 86% were CRF01_AE and 10% were subtype B. Annual resistance prevalence was 5% in 2008, 3.9% in 2009, and 6.8% in 2010 (p=0.71). Transmitted resistance to NRTI, NNRTI and PI was 0.8%, 0.8%, 4.3% in 2008; 2.6%, 1.3%, 1.3% in 2009; and 5.1%, 3.4%, 3.4% in 2010. Protease, not reverse transcriptase, sequence diversity was greater in 2010 than 2008 or 2009.

Conclusions: We report a trend of increased overall, NRTI and NNRTI resistance transmission over time warranting continued surveillance and close monitoring of treatment response.
EDUCATION AND DEVELOPMENT PROGRAM

In 2011 HIV-NAT has focused more on Education and Training programs both for HIV-NAT’s staff and for other physicians, nurses and workers who are involved in HIV care in hospitals in Thailand and South East Asia.

Education program for staff
HIV-NAT provided programs such as “HIV Medicine Staff Training” twice a year to refresh basic knowledge about HIV for staff, “Monthly In-Service Clinical Update” for staff who involved on research clinic (nurses, pharmacist, medical technologist etc.) to review and develop working skills in the research clinic and “Special Lectures” such as the Innovative Program for Living an Extraordinary Life and How and Who ensures an Organization’s Success? In addition, HIV-NAT supported one pharmacist and a medical scientist to train in the field of research at The Kirby Institute, University of New South Wales, Sydney.

Education program for other physicians and medical personnel
HIV-NAT wanted to provide in-depth training on various aspects of HIV treatment and care to professional health care workers in Thailand. So HIV-NAT designed and organized the “Bangkok Symposium Series” which take place 2 times a year in Chulalongkorn Hospital. This program will be provided in Thai unlike the Annual Bangkok International Symposium on HIV Medicine which is held every January and is in English. This program aims to cover topics such as Pediatric HIV and Co-Infection, HIV and Hepatic Disease, Long term care and PMTCT.

The Hepatic disease training was organized on 28 October 2011 with 85 participants from Thai Red Cross AIDS Research Centre, HIV-NAT and SEARCH. The Hepatic disease training is one of the trainings under the ‘In-Service Clinical Update’, organized regularly for staff working in research clinics and the Thai Red Cross AIDS Research Centre’s Anonymous Clinic. The purpose of these trainings is to update knowledge and skills for staff working in the clinics to provide a better service the patients and ensure smooth and efficient processes.
**HIV-NAT/Gilead HIV Education program**

HIV-NAT has received an educational grant from Gilead for an “HIV Medicine Education Program in Asia.” This is designed to educate and mentor key healthcare providers from selected 11 Asian countries on different aspects of HIV care. It is hoped that these trained healthcare providers will then serve as key resource persons in their countries and further train and mentor their respective colleagues in their own countries. It is also hoped to create a network of HIV experts in the region that can further cross Consult, share experience and collaborate in advocacy activities and research. The 5 initial interactive courses will be during October 2011- September 2012. The first course on October 19th – 21st focused on Pediatric HIV and Co-Infection was a great success with 35 physicians from 9 countries. The expert speakers were from HIV-NAT, Chulalongkorn Hospital, Khon Kaen University, Bamrasnaradura Infectious Disease Institute, Queen Sirikit National Institutes of Child Health and Unicef Thailand.

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**The 7th HIV Drug Resistance Workshop: Basic Principles & Clinical Implications**
on 10-11 February 2011 in Bangkok, Thailand

**Current Infectious Disease Practice**
on 14-19 March 2011 in Bangkok, Thailand

**AIDS right is human rights, Join to Protect and Respond; 13th National AIDS Conference, Thailand)**
held on 29-31 March 2011 in Nonthaburi, Thailand

**Training course in epidemiology and biostatistics, for Thai Red Cross AIDS Research Centre Campus Staff,**
al held on 22 and 29 April, 6, 13,20 and 27 May and 3 June 3 2011 in Bangkok, Thailand

**Pediatric HIV and Co infection**
on 23-24 June 2011 in Bangkok Thailand

**10th HIV/AIDS Workshop 2011 by Thai AIDS Society**
held on 31 August – 2 September 2011 in Bangkok, Thailand

**HIV and Hepatic disease workshop**
on 19-20 December 2011 in Bangkok, Thailand

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**Student Supervision HIV-NAT 2011**

**Supervisor** Anchalee Avihingsanon

**Thep Chalermmchai**
PhD
Abnormal ALT non-viral hepatitis B or C

**Supervisor** Anchalee Avihingsanon

**Surasrith Khawlaor**
Immunology Fellow
HIV Drug Resistance

**Supervisor** Anchalee Avihingsanon

**Suparat Khemnark**
GI Fellow
Comparison of fibroscan and fibrosis score between chronic hepatitis C patients with and without HIV infection

**Supervisor** Jintanat Ananworanich

**Sasiwimol Ubolyam**
PhD
Project: Investigation of specific immune response pattern in persons with active tuberculosis before and after receiving anti-tuberculous therapy
Some of the titillating topics discussed this year were human papilloma virus/anal cancer, prevention, HIV pathogenesis, hepatitis C treatment in a resource-limited setting, treatment failure, tuberculosis, vaccines, phar- ma-cokinetics/pharmacodynamics and HIV treatment in infants, children, adolescents and women, particularly in reference to pregnant women. Treatment guidelines from the US, UK and the World Health Organization (WHO) were presented and compared. Data from Thai studies were also discussed and presented as an alternative choice for those countries with limited resources and similar problems. For example, the Thai Red Cross – AIDS Research Centre has shown that by treating all pregnant women with HAART, this is not only beneficial to both the mother and child but also feasible. Along the same lines, the most debated question of the year addressed whether treatment should be used for HIV prevention or not. Initially, before the debate, there were equal numbers of people “for” and “against” universal HIV treatment with only 14% that were
unsure about their position on the matter. However, after an invigorating set of arguments from both sides, there was a dramatic shift towards “not treating everyone” with HAART. Seventy percent of the audience agreed with the opposing debaters that treating everyone was not feasible in a resource-limited setting. This is just a brief glimpse into the Symposium. For more information, you can go to the Conference Scene published in Future Virology, April 2011, Vol. 6, No. 4, Pages 409-412 (http://www.futuremedicine.com/doi/pdf/10.2217/fvl.11.18) or download the slides and/or watch the webcasts for free at www.hivnat.org.

The next Symposium has topics that are just as exciting as this one! It will be held on January 18-20, 2012 at the Queen Sirikit Convention Centre.
The Drug Fund

HIV-NAT has a policy of ensuring that clinical trial participants continue to have access to medications after the end of the trials. However, honouring this commitment in a resource-limited setting can be challenging.

To ensure that patients continue to receive antiretroviral treatment post-trial, HIV-NAT established the Drug Fund in November 2001. The Drug Fund is based on a co-payment and sliding scale system that expects patients to pay at least THB 1,500 per month and HIV-NAT to pay at most THB 5,000 per month. A patient’s ability to pay is assessed per patient by independent social workers. Income for the Drug Fund comes from revenues derived from research studies and modest profits from other activities.

Because of the Drug Fund, patients who lack the financial means no longer have to stop taking antiretroviral medication. A pioneer in providing continued care to its patients, HIV-NAT has also succeeded in influencing government agencies to include antiretroviral medication into the national health scheme and in persuading some pharmaceutical companies to provide free antiretroviral drugs to patients under the Drug Fund. From 2001-2009 HIV-NAT helped more than a hundred patients stay on ARV treatment, an undertaking that cost more than THB 4.5 million. Since 2010, there are more cases with extensive drug resistance to medications that are available through the national program; thus, the need to switch to newer, more expensive antiretrovirals such as darunavir and raltegravir. Keeping these patients on ARV costs about THB 3 millions annually.

To support the patients under the Drug Fund, HIV-NAT organised the ‘Art for Medical Miracles’ event in January 2011. Many respected artists showed their support for HIV-infected patients by having their work auctioned during this event. All proceeds, a total of THB 1.6 million, went directly to the Drug Fund. On behalf of the patients who are supported by the Drug Fund, HIV-NAT would like to thank the artists and all participants for their kind support. HIV-NAT will continue to provide care and support ranging from antiretroviral treatment and psychosocial support to tuition fees to its 2,000 patients.
PARTNERSHIP

The Ministry of Public Health, Thailand provides:
- policy direction through membership of the HIV-NAT international advisory board
- approval for the importation of study materials
- assistance with the provision of study medications

The Foundation for AIDS Research (amFAR) Establishment of the amfAR Office in Bangkok, Thailand

The amfAR office in Thailand was established with the successful completion of the application to the Ministry of Labor in April of 2006. As reported in the application, this office is intended to support the regional efforts of the TREAT Asia (Therapeutics Research, Education and AIDS Training in Asia) program (http://www.amfar.org/ treatasia). The program was launched in July 2001 and is intended to provide support for the safe and effective delivery of HIV treatments in Asia. The program is currently supporting projects in 16 economic regions in Asia Pacific including Australia, Cambodia, China, Hong Kong, India, Indonesia, Japan, Laos, Malaysia, Papua New Guinea, the Philippines, Singapore, South Korea, Taiwan, Thailand and Viet Nam. The projects focus on the four primary objectives: research, education and training, public policy and communication and strengthening civil society through treatment education and treatment literacy. The program currently employs 16 staff members.

TAHOD: The TREAT Asia HIV Observational Database (TAHOD) is a collaborative observational cohort study, which involves 19 participating sites in the Asia and Pacific region including HIV-NAT/Thai Red Cross (Bangkok), Ramathibodi Hospital (Bangkok) and Chiang Mai University - Research Institute for Health Science (Chiang Mai). The primary objectives of the TREAT Asia HIV Observational Database are to:

1. Develop capacity in HIV clinical data collection in countries of the Asia-Pacific region;
2. Assist in evaluation of new HIV treatments for the Asia-Pacific region;
3. Monitor anti-retroviral and prophylactic treatment as related to demographics and markers of HIV disease stage;
4. Monitor toxicity to anti-retroviral therapy; and
5. Examine HIV natural history, including the relationship between access to antiretroviral therapy and disease progression.

The project was established in 2003 and has enrolled 5,400 patients into prospective follow-up (as of September 2011). The program is supported in part by a grant from the US National Institutes of Health and the Ministry of Foreign Affairs of the Netherlands.

TASER: The TREAT Asia Studies to Evaluate Resistance (TASER) for HIV-1 Genotypic Anti-Retroviral Drug Testing is a comprehensive program to evaluate HIV drug resistance within TREAT Asia clinical centers and to build capacity for HIV genotypic antiretroviral (ARV) resistance testing (genotyping), surveillance of transmission of ARV resistant HIV and monitoring the development of ARV resistant HIV in persons taking ARV therapy. Currently, there are 16 participating sites in five countries in Asia, including HIV-NAT/Thai Red Cross (Bangkok), Ramathibodi Hospital (Bangkok), Siriraj Hospital (Bangkok), Chiang Rai University and Chiang Mai University. Standardization of genotyping through the TREAT Asia Quality Assessment Scheme (TAQAS) forms an integral part of this program.

TAQAS: The TREAT Asia Quality Assurance Scheme is designed to build capacity for and establish external quality assurance for HIV drug-resistance testing. Proficiency panels include HIV samples derived from HIV-1 subtype B and non-B isolates endemic in the South, East and Southeast Asia. TAQAS laboratories support HIVDR testing for the TASER clinical studies. In April 2006, TAQAS was first implemented in nine Southeast Asian laboratories. Currently, there are 15 participating sites from nine countries in the Asia-Pacific region, Africa and America, including four laboratories in Thailand: Chulalongkorn University (Bangkok), Ramathibodi Hospital (Bangkok), Siriraj Hospital (Bangkok) and Chiang Mai University (Chiang Mai).

TApHOD: The TREAT Asia Pediatric HIV Observational Database (TApHOD) is a collaborative observational cohort study, which involves 16 participating sites in five countries in Asia Pacific region including HIV-NAT/Thai Red Cross (Bangkok), Siriraj Hospital (Bangkok), Chiang Mai University - Research Institute for Health Science (Chiang Mai), Chiang Rai Regional Hospital (Chiang Rai) and Khon Kaen University (Khon Kaen). The primary objectives of the TREAT Asia Pediatric HIV Observational Database are to:
1. Develop capacity in HIV clinical data collection in countries of the Asia-Pacific region;
2. Assist in evaluation of new pediatric HIV treatments for the Asia-Pacific region;
3. Monitor anti-retroviral and prophylactic treatment as related to demographics and markers of HIV disease stage;
4. Monitor toxicity to anti-retroviral therapy; and
5. Examine HIV natural history in children, including the relationship between access to antiretroviral therapy and disease progression.

The project was established in 2006 and has, as of September 2011, enrolled 4,006 patients into prospective follow-up. The program is supported in part by a grant from the U.S. National Institutes of Health, U.S. National Institute of Child Health and Human Development and the Austrian AIDS Life Association.

**Education and Training**

**Education Program for Building Research Capacity**

TREAT Asia implemented a research capacity-building education program with support from the Australian Agency for International Development (AusAID) in 2008. The program will include research capacity site assessments, in-country trainings on good clinical research practices and provision of technical assistance awards in Cambodia, China, Indonesia, Papua New Guinea, the Philippines and Viet Nam. Training programs will utilize experts from the TREAT Asia network and The Kirby Institute for infection and immunity in society, which was formerly known as the National Centre in Epidemiology and Clinical Research at the University of New South Wales in Sydney, and other international academic centers.

**Policy and Communications**

The TREAT Asia Report includes reviews of current research activities in the TREAT Asia network and elsewhere in Asia and the Pacific. The report has featured interviews with leading figures in AIDS treatment, research, and policy. It is produced on a quarterly basis as part of TREAT Asia’s communications activities.

**Strengthening Civil Society**

To strengthen civil society and community involvement in HIV/AIDS programs in the Asia-Pacific region, TREAT Asia supports activities to provide HIV treatment literacy training, develop community advocacy and coordinate a network of men-who-have-sex-with-men (MSM) organizations.

**Regional Coordinating Secretariat for the Purple Sky Network of MSM Programs in the Greater Mekong Sub-region**

TREAT Asia serves as the Regional Coordination Secretariat (RCS) for the Purple Sky Network, a network of organizations working on HIV issues related to Men-Who-have-Sex-with-Men in the Greater Mekong Sub-region (GMS). The purpose of the RCS is to provide support, facilitate network communications and activities, monitor progress and represent the network in the international arena.

**Global Fund to fight AIDS, Tuberculosis and Malaria**

This program started in 2006 with the aim to use the Global Fund money to buy antiretroviral therapy and monitoring assays for monitoring CD4 and viral load for patients post clinical trials. HARRT has been shown to effectively reduce HIV related illnesses and mortalities, improving our patients’ quality of lives significantly. Besides providing ARV therapy to patients, we also collect long term data from each patient participating in the study. ARV drugs, CD4 and viral load tests are supported by Global Fund. Currently, 1424 adults and 321 children receive free ARV drugs, CD4 and viral load tests through the program. Because of the outstanding outcome of this year’s program, we are currently proposing to the Global Fund to continue the program via the rolling continuation channel.
**Service**

**Praphan Phanuphak** is a member of the Governing Council of the International AIDS Society (IAS), representing the Asia-Pacific Region. He is the member of Thailand National AIDS Committee and the Vice-Chair of Thailand Country Coordinating Mechanism (CCM) of Global Fund for AIDS, Tuberculosis and Malaria.

**Kiat Ruxrungtham** is the chair of the Academic Sub-committee on HIV Treatment and Care of the National AIDS Program, National Health Security Office (NHSO), elected president of The Allergy and Immunology Society, Thailand, a member of the expert panel working group on antiretroviral therapy practice policy guidelines, a member of the National AIDS Committee chaired by the Prime Minister, a member of the Thai Royal College of Physicians, chair and member of the working committee on implementing antiretroviral therapy into the universal health care system, the AIDS Division, Ministry of Public Health.

**Jintanat Ananworanich** is a member of the writing committee for the Thai Ministry of Public Health pediatric antiretroviral treatment and adjunct faculty member of Chulalongkorn University, Faculty of Medicine. She serves as an independent expert for review of PMTCT and pediatric guidelines for the World Health South East Asia Region. She serves on the DSMB for the Southeast Asia Influenza Clinical Research Network and the steering committees for the Pediatric European Network for Treatment of AIDS and Treat Asia. She is an organizing committee member of the 2009 and 2010 International Workshop on HIV Pediatrics. She serves on the Scientific Assessment Panel of the HIV Research Trust Award. She is one of the co-chairs of the TREAT Asia Pediatric HIV Observational Database (TApHOD). She is also the deputy editor for AIDS Research and Therapy, the editor for Open Virology Journal and a reviewer for various journals such as Lancet and AIDS.

**Anchalee Avihingsanon** is a member of the expert panel working group of the Thai Ministry of Public Health HIV/AIDS management guidelines, a member of the expert panel working group on antiretroviral therapy practice policy guidelines, a member of the Thai Royal College of Physicians, an external reviewer for Quality Ph.D Examination, a member of the working committee on implementing antiretroviral therapy into the universal health care system, the AIDS Division, Ministry of Public Health and

**Amanda Clarke** is a doctor mentor for the new English speaking monthly patient support group run by the TRC-ARC.

Reshmie Ramautarsing is a program coordinator for the Community[e]Education program and a trainer for the HIV[e]Education program, both for the Health[e]Foundation, Amsterdam, The Netherlands.

**Thanyawee Puthanakit** is faculty member of Department of Pediatrics, Faculty of Medicine, Chulalongkorn University, member of the expert panel working group of the Thai Ministry of Public Health HIV/AIDS on antiretroviral therapy practice policy guideline and a member of the WHO technical reference group Pediatric HIV/ART care. She is the lecturer for pediatric HIV/AIDS.

**Wasana Prasitsuebsai** is a member of the writing committee for the Thai Ministry of Public Health pediatric antiretroviral treatment and reviewer for the following journals: 1) AIDS Care and 2) Journal of Health, Population and Nutrition.

**Wirach Maek-a-nantawat** is a part-time lecturer at Division of Allergy and Clinical Immunology, Department of Medicine, Faculty of Medicine, Chulalongkorn University, and Centre of Excellence for Biomedical and Public Health Informatics (BIOPHICS), Faculty of Tropical Medicine, Mahidol University. He is also an external examiner for knowledge and thesis defense, Master/Ph.D Program at Mahidol University and Chulalongkorn University, a reviewer for various journals such as Journal of Pediatric Infectious Diseases, Southeast Asian Journal of Tropical Medicine and Public Health and Asian Pacific Journal of Allergy and Immunology.
The Thai Red Cross AIDS Research Centre (TRC-ARC)

In 2011, Thai Red Cross AIDS Research Centre (TRC-ARC), the mother organisation of HIV-NAT, had many achievements and accomplishment which build on its mission to set high standards of patient care, research and community development. There are many ongoing and newly established activities as follows.

The Thai Red Cross Anonymous Clinic (TRC-AC)

TRC-AC is the first HIV voluntary counseling and testing clinic in Asia, established in 1991. Comprehensive health care services are now provided to clients regardless of HIV status as entry points to HIV testing according to the provider initiated counseling and testing model (PICT), aiming to reduce stigma of HIV testing. These services include annual health checks, anal and cervical Pap smear, STI testing and treatment and nutritional assessment and counseling.

The Thai Red Cross Men who have Sex with Men (MSM) Sexual Health Clinic

The TRC-AC started to provide MSM sexual health services in 2008. The number of MSM clients attending the service increased rapidly in the following year which led the TRC-AC to officially establish its “Men’s Health Clinic” in June 2009 to provide health and psychosocial support specific to MSM.

Up to 13,376 MSM clients attended the Clinic during April 2008 – August 2011. Of these, 1,572 (18.7%) received anal Pap smear and 385 (24.5%) had abnormal cytology results from ASC-US and above. 63% of MSM clients who received anal Pap smear were HIV-positive MSM. Rate of the abnormal cytology results among HIV-positive MSM was around 2.0 times higher than HIV-negative MSM.

Nutrition Clinic

The Nutrition Clinic provides services every working day. Three dietitians work alternatively in the Nutrition Clinic to provide nutrition counseling for non-HIV infected and HIV-infected clients, both those have not been on antiretroviral therapy (ART) or already taking ART. The clients attending anonymous clinic to receive VCT service, health check-up service, and Men’s Health Clinic, HIV-NAT and Wednesday Friends Club will be screened for nutrition problem by healthcare workers. Those who have nutrition problem i.e. underweight or nutritional problem related to ART such as overweight, lipodystrophy abdominal obesity, diabetes mellitus, hypertension, and dyslipidemia will be referred to nutritionists for in-depth nutrition counseling.

Up to 500 clients attended the nutrition clinic in 2010. We have expanded the nutrition service to include Men who have Sex with Men (MSM) clients. The nutrition service is used as an entry point of HIV service at the anonymous clinic especially for high risk negative MSM clients who have high risk of HIV infection.

The nutritionist is counseling a patient in nutrition clinic

The Thai Nutrition Taskforce for HIV (TNT-HIV) is a national HIV nutrition committee, appointed in 2008, consisted of Thai experts in HIV and nutrition from various organisations including the Thai Ministry of Public Health, Institution of Nutrition, Mahidol University, and TACHIN. The following HIV nutrition studies are conducted under the TNT-HIV.

TNT-HIV 003 (Trends of morbidity and mortality among Thai HIV-infected and HIV-uninfected patients, a five-year multi-centre, prospective cohort)

The study aims to determine the morbidity and mortality among Thai HIV-infected participants compared to HIV-uninfected participants at the TRC-ARC and the Queen Savang Vadhana Memorial Hospital during 2010 – 2017. The study has been started the enrollment of 408 HIV-infected participants and 408 HIV-uninfected participants in November 2010. The enrollment duration has been planned to complete within 2 years. This study has currently enrolled 125 and 89 of Thai HIV-infected participants and HIV-uninfected participants. The study will complete in November 2017.
**TNT-HIV 003.1 (Bone Health and vitamin D status in Thai HIV-1 Infected and Uninfected Adults (A substudy of TNT-HIV 003: Trends of morbidity and mortality among Thai HIV-infected and HIV-uninfected patients: a five-year prospective cohort study)**

Given the recent interest in the impact of HIV infection on bone health and vitamin D levels and the association of low vitamin D status with several chronic diseases, this study will determine bone health and vitamin D levels, both in HIV-infected population and uninfected population, as a sub-study of TNT-HIV 003. The study has started the enrollment of 70 HIV-uninfected participants, 55 HIV-infected with high CD4 and 110 HIV-infected with planned to start HAART in November 2010. The enrollment duration has been planned to complete within 1.5 years. This study has now completed the enrollment of HIV-uninfected participants and HIV-infected with high CD4 group. Up to 40 participants or 36% of the total participants in HIV-infected with plan to start HAART group has currently enrolled. The study will complete in November 2017.

**Lao-Thai-Australian Collaboration in HIV-Nutrition (Lao-TACHIN) Project:**

In 2011 the Thai Red Cross AIDS Research Centre (TRCARC) has taken the lead in managing all components of project implementation in Lao PDR, with the Albion Street Centre (ASC) providing monitoring and evaluation support. Project expansion has included expanding the project activities to include VCT and PMTCT in Champasak Provincial Hospital and the provision of nutrition services and PMTCT in an additional site in Savannakhet province. A training has been provided to Lao Network of Positive People (LNP+) to integrate nutrition education into peer support groups nationally through LNP+. This activity has supported the existing capacity of Dreaming of a Brighter Future, peer support group in Champasak Province as trainer-of-trainers.

The project had three posters accepted for presenting at the 10th International Conference on AIDS in Asia and the Pacific (ICAAP 10) in Busan, Republic of Korea, in August 2011. In addition, Centre for Control HIV/AIDS/STI (CHAS) of Lao PDR and TRCARC presented the Lao-TACHIN project at the 'Global South-South Development Expo' in Rome in December 2011, where the project was awarded as an outstanding 'South-South Development Project'. The Global South-South Development Expo seeks to showcase the strongest and most successful Southern development solutions to the complex challenges facing the South today, focusing on the areas most critical to Southern development: Food Security, Social Protection, Climate Change and Environment, Nutrition, HIV/AIDS, Global Health and Agribusiness and Renewable energy. According to the Global South-South Development Expo, “The Thai-Australia HIV Nutrition Program showcases how Thailand succeeded in integrating nutrition interventions into HIV comprehensive care and transferring it to Laos through the technical support from the Australian Government. It is an excellent display and sharing of best practices through triangular cooperation, North-South-South cooperation in the area of nutrition and HIV/AIDS.”

TRCARC and ASC also support the Technical Working Group in Lao PDR to integrate nutrition into GFTAM 11 and provided support to finalise the development of HIV nutrition guidelines. Lastly, TRCARC has recently signed an additional MOU with the World Food Programme (WFP) to continue providing technical assistance in HIV nutrition and to expand the scope of activities to include the development of a collaborating centre between the TRCARC, WFP and ASC.

**ARV management and nutrition workshop for healthcare workers in Champasak Provincial Hospital, Lao PDR (June 2011)**

**National stakeholder workshop on HIV and Nutrition (March 2011) Mom Tells Mom Loved; an integrated approach of HIV disclosure for HIV-affected family**

This project is a collaboration between the Italian Red Cross and the TRC-ARC which aims to develop an HIV disclosure model for HIV-affected families in Thailand, to improve the health status.
communication skill within families, to improve the quality of life and to strengthen the knowledge and capacity, counseling skill and disclosure technique of healthcare workers regarding the Integrated Approaches of HIV Disclosure for HIV-affected Family. The project has completed the staff training for disclosure techniques by disclosure experts, the survey of the readiness and factors associated with health status communication within families, group sessions and “Healthy Camp” activities. The study will complete in December 2012.

The staff training for disclosure techniques by disclosure experts

Counseling and HIV disclosure skill building workshop Asian Red Cross and Red Crescent HIV/AIDS Network (ART)

Asian Red Cross and Red Crescent HIV/AIDS Network (ART) is a network working on HIV programming within the region, combining 15 National Societies in East and South East Asia to work together in regard to HIV and AIDS in the regional level. ART Network has been supported by International Federation of Red Cross and Red Crescent Societies (IFRC) in channeling funds from other resources such as Australian Red Cross and Norwegian Red Cross for their work in relation to HIV/AIDS program.

This year, the 23rd Annual ART Meeting was held in Busan, Republic of Korea in conjunction with the 10th International Congress on AIDS in Asia and the Pacific (ICAAP), which accepted abstracts from ART national society members had been presented oral and poster presentations in the congress. In addition, ART have been honored to receive the lecture from Dr. Praphan Phanuphak, the Director of the Thai Red Cross AIDS Research Centre, for Thai Red Cross’s expertise in HIV/AIDS programming that encourages the implementation of Red Cross’s HIV/AIDS program in the region.

The highlight of ART Network’s participation in 10th ICAAP is the ART Booth, which attracted the crowd with its interesting ideas and IEC materials to raise HIV/AIDS awareness in the region. Furthermore, this year’s Annual ART Meeting marked the important event for the selection of new ART Chair and ART Management Team. The new ART Chair is from Cambodian Red Cross; the ART Management Team consists of members from the Japanese Red Cross Society, the Red Cross Society of China and the Thai Red Cross Society.

The collaboration with the European Red Cross and Red Crescent Network on HIV/AIDS and TB (ERNA) continues. It has led ART to explore the new area of working in HIV/AIDS programming, as the training for ‘Harm Reduction’ for ART members has been successfully operated this year. ART has been invited by ERNAs president and Villa Mariani, a renowned drug rehabilitation centre in Italy for their intensive training for Harm Reduction program. The staff from ART national society members from Red Cross Society of China, Cambodian Red Cross, Lao Red Cross and Thai Red Cross Society have gained valuable experience and knowledge for further development of their harm reduction programs.

Strengthening the network is still a priority, and its aim to be recognised more in the international level still runs high. Updates, news and interesting articles can be found at ART website; www.art-hivaidsnetwork.com. The website is a resource for exchange of useful information among ART members.

Particpants visited the ART booth at ICAAP 10.

IEC Materials from ART national society members were displayed at the booth.
THAI RED CROSS
AIDS RESEARCH CENTRE PERSONNEL

ADMINISTRATIVE DEPARTMENT

Front (Left to right): Somchai Wuttiworakul (Administration Official), Vijitra Pradubkaew (Chief of Administration Department), Suphavadee Wongnohoi (Financial), Somchart Thakaeng (Administrative Officer), Sugunya Kaivikaigosol (Housekeeper), Patinya Suriwong (Administrative Officer), Nion Pakawa (Financial), Suwalee Aunjaiyai (Financial)

Back (Left to right): Mongkol Nuckapun (Electrician), Likhit Khongsra (Technical), Ruthairat Pruksasri (Purchasing Officer), Thanachai Luddrood (Information Technology), Sunanta Intarasuk (Administrative Officer), Kalayaporn Panthawong (Administrative Officer), Sumitra Techapolokul (Administrative Officer)

Missing: Songsri Wiriyawong (Administrative Officer), Adisak Chaipanna (Administration Official), Somjai Kokapant (Housekeeper)

ANONYMOUS CLINIC

Left to right: Ekkapon Manmon (Project Coordinator), Orawan Panichob (Receptionist), Sureerat Ittichai (Project Coordinator), Charnwit Pakam (Administrative Officer), Prapaipan Podgratoko (Psychologist), Somjai Kokapant (Janitor), Patchalee Suttapintu (Educator), Radda Pannun (Administrative Officer), Suttithipong Ployngam (Receptionist), Methaewee Metheesart (Project Coordinator), Prapakorn Koomwan (Receptionist), Siripen Areeprayunkit (Finance and Accounting Officer), Sugunya Kaivikaigosol (Housekeeper)

Missing: Songsri Tantipaibulvut (Chief, Group of social psychology and behavior), Wasana Sathanthammawit (Clinic Manager), Tanunjit Rakphan (Psychologist), Pailin Suwanmala (Nurse)

LABORATORY

Left to right: Namfon Sawatwong (Medical Technic Assistant), Amonrat Unyanam (Medical Technologist), Aucharapun Simputtanasan (Medical Technologist), Watchara Deepum (Medical Technic Assistant), Kannapat Phanjaroen (Medical Technologist), Pakaymard Apiwatwarawong (Medical Technologist), Supanit Pattanachaithit (Medical Technologist), Patsawadee Paqjinda (Medical Technologist)

Missing: Tippawan Pankam (Medical Technologist), Apidech Thaisamsen (Blood Collector), Rapeepong Wongkanya (Medical Technologist), Jiranuwat Barisri (Medical Technologist), Napat Sookmai (Medical Technic Assistant)
THAI RED CROSS
AIDS RESEARCH CENTRE PERSONNEL

SOCIAL PSYCHOLOGY AND BEHAVIOR TEAM

Left to right: Rangsit Sanguansak (ART Secretariat Programme Officer), Panisa Kaisakulket (Administration Staff), Wannee Khaiwkhaoapho (Project Coordinator), Tippawan Sutthikiri (Project Manager), Kamolset Kanggarruer (Senior Professional Level (K 3) Social Work), and Thaneth Kanteeranon (Research Assistant)

Missing: Somsri Tantipaibulvut (Chief Group of Social Psychology and Behavior), Thaedsak Jumnugsin (Project Coordinator), Sutep Onkumpung (Project Coordinator), Kittapol Thumdee (Project Coordinator) and Jutamart Rojwisatsap (Administration Staff)

SPECIAL TASK FORCE TEAM

Left to right: Banchob Thanomphon (Clinical Trial Nurse), Somsong Teeratakulpisarn (Chief of STFT and Program Coordinator), Piyanee Rodbamrung (Clinical Trial Nurse), Piranun Hongchookiat (Clinical Trial Nurse), Supabhorn Pengnonyang (Research Dietician, Clinical Trial Nurse and Program Coordinator), Natchaya Kongkaruek (Team Secretary Assistant), Sukanda Sutamkittiwut (Research Dietician), Umaphorn Pranitphonprang (Clinical Trial Nurse), Napasawan Thippimol (Team Secretary), Chayaporn Tasai (Financial Controller and Team Manager), Amornrat Sukjitpaiboonphol (Clinical Trial Nurse), Jureeporn Jantarapakde (Research Dietician and Clinical Trial Program Coordinator), Waraporn Sirisakyot (Clinical Trial Assistant), Rosalin Kriengsinyot (Senior Social Worker)

Missing: Dr. Nipat Teeratakulpisarn (Clinical Trial Physician), Dr. Nittaya Phanuphak (Senior Clinical Trial Physician), Khonchaya Kunacheeva (Pharmacist), Supaporn Jaieok (Pharmacist Assistant), Jiravut Keeratikongsakul (Peer supporter group leader MSM project), Kanokwan Jitrach (Data Manager), Kanyarat Punmongkon (Data Entry Staff), Sumit Tongmuang (Clinical Trial Assistant), Sirichai Jarupittaya (Clinical Trial Assistant), Pravit Mingkwanrungrueng (Clinical Trial Assistant and Data Entry Staff)
South East Asia Research Collaboration with Hawaii (SEARCH)

SEARCH is a partnership that began in 2005 with the goal of accomplishing mutual objectives in HIV/AIDS research and training in the South East Asia region between 3 partners: the Thai Red Cross AIDS Research Centre (TRCARC) and HIV-NAT in Bangkok, the Hawaii Center for AIDS of the John A. Burns School of Medicine, University of Hawaii (UH) at Manoa in Honolulu, and the Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok. SEARCH has 3 co-directors: Professor Praphan Phanuphak (TRCARC), Professor Cecilia Shikuma (UH), and COL. Jerome Kim (AFRIMS). SEARCH is headed by Dr. Jintanat Ananworanich with Dr. Nittaya Phanuphak occupying the role of Deputy Chief.

ONGOING CLINICAL STUDIES

SEARCH 002: Establishing normal values for neuropsychological testing in Thais.
This study has currently enrolled 450 of 500 HIV-negative Thais to establish normal values for neuropsychological testing panels. The public can request use of this data via the SEARCH website (www.searchthailand.org). Subjects are enrolled at Phramongkutklao Hospital and at SEARCH. The study will complete in 2012.

SEARCH 003: Comparing the toxicity profile of a d4T-based regimen as lead-in for the first 6 months versus AZT-based and TDF-based first line regimens.
This year, the study completed its 72-week follow up in 150 participants from the TRCARC and Queen Savang Vadhana Memorial Hospital. The clinical outcomes revealed that short-term d4T use before introducing AZT caused less anemia and peripheral neuropathic signs compared to initiating treatment with AZT. Initial rise in CD4 was greatest with d4T. However, peripheral fat reduction by DEXA could be observed at 1 year after d4T discontinuation. The study concluded that a 6-month d4T lead-in therapy could be considered in participants with anemia or low baseline CD4. Analyses on stored samples to decipher the pathogenesis of mitochondrial toxicity and neuropathy are ongoing. The study is funded by the Thai Government Pharmaceutical Organization and the US NIH (R01 AI074554-01A1 and R01 NS063932-01).

SEARCH 007: HIV-1 specific immune responses in Thai individuals with HIV dementia.
This study is enrolling 60 participants over 4 years to assess the HIV-1 specific CD4+ T helper cell and CD8+ CTL responses, and monocyte/macrophage activation and/or dysregulation in individuals with and without HIV-associated dementia prior to and after HAART. Participants are enrolled at Phramongkutklao Hospital and at SEARCH. The study is funded by the US NIH (R01 NS053359-01A1) and will complete in 2012.

SEARCH 010: Establish and characterize an acute HIV infection cohort in a Thai high risk population.
This study has now enrolled 64 out of 75 participants with acute HIV infection (HIV antibody negative, nucleic acid positive) who will be followed for 4 years. Investigations of the immune response and HIV subtypes/sequences in the peripheral blood, gut, genital secretions and central nervous system are done. Participants are offered 5 vs. 3-drug HAART under a separated protocol. The study is funded by the US Military HIV Research Program (MHRP) and by the US NIH (R21MH086341). A parallel study to evaluate the use of therapeutic HIV vaccine in addition to HAART in controlling HIV viremia following treatment interruption in this acutely treated population is in development.

SEARCH 011: Peripheral reservoir of HIV DNA in monocytes pivotal to cognition in HIV.
This study is enrolling 60 subjects at Phramongkutklao Hospital and at SEARCH. It will determine the long-term relationship between cognition and HIV DNA in circulating monocytes and define the longitudinal relationships between HIV DNA in monocytes and cerebrospinal fluid biomarkers and MRS findings. The study is funded by US NIH (R01 AI075408-01) and will complete in 2013.

SEARCH 013: Characteristics of immune cells in gut mucosa of HIV-negative and HIV-positive Thais.
This is to study immunophenotyping of the gut mucosa in HIV-negative and non-acute HIV-infected adults and compare them to findings from subjects with acute HIV infection in the SEARCH 010 study. The study is funded by US MHRP and will conclude in 2013.
SEARCH 014: Study of epidermal nerve fiber density, subcutaneous fat and mitochondrial parameters in Thai HIV-positive patients on long-term stavudine treatment and in Thai HIV-negative patients.
This study is to compare the number of nerves in the skin and the markers of mitochondrial oxidation in fat tissue and peripheral blood in people who are currently taking d4T and develop numbness with those who do not have numbness and those without HIV infection. The study is funded by the US NIH (5 R01 NS063932-02 revised). This study will conclude in 2012.

SEARCH 015: A cohort observational study evaluating predictors, incidence and immunopathogenesis of immune reconstitution syndrome (IRIS) in HIV-1 infected patients with a CD4 count <100 cells/µL who are initiating antiretroviral therapy.
This study is to characterize IRIS and investigate the pathogenesis and the outcomes of IRIS. The study will begin enrolment in 2012 at TRCARC and Bamrasnaradura Infectious Diseases Institute. The study is funded by the US NIH and the US MHRP.

Improving the diagnosis and management of latent TB in Thai children.
This study enrolled 158 children with a history of TB contact to assess the sensitivity and specificity of the interferon-gamma release assays and tuberculin skin test in screening for latent TB in HIV-positive and -negative children. The study is a collaboration between SEARCH, HIV-NAT, Siriraj Hospital, Queen Sirikit National Institute of Child Health and Columbia University. The study is funded by the REACH Initiative Award and will complete in 2012.

Identifying biomarkers to detect anal intraepithelial neoplasia among Thai men who have sex with men.
This study enrolled 246 subjects at the Thai Red Cross Anonymous Clinic to identify biomarkers (HPV subtype, p16, MCM proteins, E6 and E7 mRNA) that can be used as adjuncts to anal cytology in the detection of high risk anal intraepithelial neoplasia. The study is funded by amfAR and will complete in 2013. An additional component to assess HPV infection in the oral cavity is being implemented.

HIV vaccine studies in collaboration with AFRIMS and the US Military HIV Research Program:
SEARCH will be involved in mucosal compartments investigations for three follow up studies from the RV144 phase III prime-boost ALVAC® and AIDSVAX® B/E vaccines trial.
SEARCH PERSONNEL

Left to right: Dr. James Fletcher (Physician), Michittra Boonchan (Laboratory Coordinator), Patcharawee Rungrojrat (Monitor), Somporn Tipsuk (Research Nurse), Nitiya Chomchey (Clinical Trials Manager), Siriporn Sangthong (General Assistant), Dr. Nittaya Phanuphak (Deputy Chief of SEARCH), Putthachard Sangtawan (Research Nurse), Chayanin Suttichom (Data Entry), Peeriya Mungyu (Research Nurse), Duanghathai Suttichom (Monitor), Ratchapong Kanaprach (IT/Database Manager)

Left to right: Assoc. Prof. Jintanat Ananworanich (Chief of SEARCH), Varaporn Pethipala (Business Manager), Somprarthana Ratanamanee (Research Nurse), Siriporn Nonenoy (MSM Manager)
COMMUNITY OUTREACH PROGRAMS

Summary report of the activities for HIV-infected children and parents at the Thai Red Cross AIDS Research Centre

Period: October 2010 to September 2011

Background

The Children and Youth Program is a community outreach program under the Thai Red Cross AIDS Research Centre (TRCARC) and conducted by HIV-NAT and SEARCH, which are subunits within the TRCARC in Bangkok, Thailand. HIV-NAT and SEARCH have almost 2000 adults and 300 children with HIV in active follow-up. This program was initiated in 2004 because we recognized that the children and their families faced social stigma and poverty as well as limited access to education and health care. The Program’s core mission is to provide psychosocial and financial support to help the children and their families cope and live with HIV. The Program has grown from supporting 50 children at our center to supporting 333 children from 11 hospitals and health care centers from 6 provinces in Thailand in 2010. The program is supported by the three following charities: The Born to Live Charity, The ART AIDS Fund and Living and Loving.

The Born to Live Charity was founded by Father Sean Smith of the Missionaries of The Sacred Heart Development Centre in Adelaide, Australia. This charity was started in 2004 and has helped more than 100 children with HIV and their families by providing financial support for family living costs, school fees, school uniforms, textbooks, transportation costs to clinic visits, laboratory tests and HIV medications.

The ART AIDS Fund is supported by Mr. Han Nefkens from the Netherlands. This charity was started in August 2005 with the goal to provide HIV-infected and affected children additional opportunities to improve their health and quality of life. As of June 2011, the ART AIDS Fund has helped 171 children and their families; of these, 145 children were HIV-infected, while 26 were directly affected by the disease as the siblings of HIV-infected children. These children are from many places, including HIV-NAT, Chulalongkorn Hospital, Siriraj Hospital, Queen Sirikit National Institute of Child Hospital, Phrachomklao Hospital in Petchburi province, Bumrasnaradura Hospital and AIDS Access Foundation. This charity provides salvage antiretroviral therapy, laboratory testing, educational costs, costs for the social workers’ trips to the children’s homes as well as funds to hold informal camps for the children and their families to learn how to cope and live with HIV.

Living and Loving is a charity from the United Kingdom. This charity was started in 2006 with the goal of providing an opportunity for children with HIV to live a healthier life by subsidizing their living costs, educational fees and emergency medical funding for conditions not covered under the governmental health care program. Currently, the Living and Loving charity is helping over 150 HIV families from HIV-NAT and Khon Kaen University Hospital.

Assessment of the children’s psychosocial problems and psychosocial support

are provided every Monday at the HIV-NAT clinic, Tower 1 of The Thai Red Cross AIDS Research Centre and Tuesday on the 9th floor in the OPD building of the Chulalongkorn Hospital. Analysis and assessment of environmental and psychosocial factors allows us to identify the barriers to treatment adherence and helps the patients and their families to integrate anti-HIV treatment into their daily lives. This allows us to identify the specific needs and difficulties within each family. Problems can be handled by appropriate counseling or referral for tailored interventions or support.
Home Visits 2-3 days per week.

Home visits allow a holistic assessment of the patient’s household’s ability to cope with the practical difficulties of living with HIV, including treatment adherence, economic support and disease disclosure. Problems that might not be apparent during clinic visits often emerge during home visits because the patients feel more at ease and discussions are more frank when interviewed within their home environment. Home visits allow us to tackle sensitive issues such as lack of social contacts or discrimination with appropriate positive interventions.

School Visits

In addition, we provide educational scholarships as shown in Table 1. Educational support is not only practical, but also a confidence booster. For some families, it is important to reinforce the fact that any HIV-infected child with an education has the potential to become an important, functioning member of society.

<table>
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<th>Table 1</th>
<th>HIV-NAT</th>
<th>Siriraj H.</th>
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<th>PCK H.</th>
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<tr>
<td>All</td>
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<td>10</td>
<td>6</td>
<td>10</td>
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</tbody>
</table>

\* Siriraj Hospital (Siriraj H.) \* Queen Sirikit National Institute of Child Hospital (Child H.) \* Phrachomklao Hospital (PCK H.) \* AIDS Access Foundation (Chiang Rai)

Remedial classes are offered to the students during their school vacations in March, April and October two times per week

Our youth volunteers teach basic Thai language to preteens who cannot read or can read a bit.
Reforestation Camp held on 19-20 October 2010 supported by Unicef

Eight youth volunteers arrange the camp for 20 younger children. From the survey, the youth volunteers designed the program all by themselves. This camp is supported by Unicef for strengthen the Youth (Living with HIV) Volunteer Group (YVG) to carry out several activities: HIV and sex education and community work such as mangrove forest planting.

Exchange forum for youths from the South held on 27-28 November 2010

The exchange forum in Bangkok was such a success that we wanted to replicate this in the Southern region of Thailand. 48 participants (three from YVG – Bangkok, 19 from Yala, Songkhla, Trang and Phatalung, 19 from Thai Network of People Living with HIV (TNP+), and seven from AIDS Access Foundation (AC-CESS)) came together in the South to learn how to handle life with HIV. Since there are no youth groups in the southern region of Thailand, the youth members from YVG - Bangkok were there to exchange and share their experiences. This experience has encouraged the local youths to get together and seek help from the Southern TNP+. After the exchange, some youth representatives from Songkhla had the opportunity to work together with YVG’s in Bangkok and Khon Kaen.

Teenager Camp in Kao Yai National Park held on 23-25 March 2011

A total of 27 children and 5 staff attended this camp. Children of all ages, especially adolescents, struggle with the stigma of living with HIV and often worry about their future health and social acceptance. Because HIV treatment is life-long, many adolescents also suffer from HIV treatment fatigue. During this camp, the children brainstormed on how to deal with adherence problems. Other activities included comprehensive sex education, sexual health, sexual desire, sexual behavior, social and cultural dimensions that affect one's sexuality as well as HIV/AIDS. The participants discussed issues common among couples such as negotiation for condom use, impact of HIV on their relationships and family planning.
Preteen camp in Kanchanaburi held on 5-7 April 2011

Thirty-four children, 16 caretakers, 16 youth volunteers and 6 staff attended the preteen camp. The youth volunteers shared their experiences on how to live with HIV. They also provided accurate information about HIV through special performances. Training on adherence, sex education, relationships and communication was provided to the preteens. The activities for the caretakers provided understanding the development of teenagers because they lacked the knowledge on how to promote self-esteem and provide support to the teenagers.

Camp in Rayong for children between the ages 4-7 years held on 11-13 May 2011

This camp was attended by 23 children, 6 mothers, 1 father, 2 aunts, 2 grandmothers, 10 youth volunteers and 6 staffs. The objectives were to relay the information about HIV and to create a positive attitude about HIV-infected children growing up to be adults. The caretakers shared their problems on how to communicate with others on HIV/AIDS. They were educated in child development and HIV disclosure.

One day activities at Tower 2, The Thai Red Cross AIDS Research Centre

One day activities were held on 2 March, 16 March, 5 May, and 15 July 2011.

On the 27th of April 2011, a one day activity, 27 children went to SuanSiam Park while their caretakers had their own activities at Tower 1.

On 2 March, 16 March, 27 April, 5 May, and 15 July 2011, we prepared the children and their caretakers for pre- and post-disclosure. The message at the event is that AIDS can be treated and HIV can be suppressed by ARV. The children learned to distinguish between a person who has HIV and a person who has AIDS. They also learned about HIV transmission, how it can be transmitted through unprotected sex and how it can be transmitted from mother to child. They know how to take care of themselves and how to be healthy with HIV.
Activities for Caretakers held on 2 and 15 February 2011

Seed fund to support the families

Families with HIV are disproportionately socioeconomically disadvantaged and also have increased expenditures as the result of HIV disease. In many of these households, the primary difficulties of living with HIV are practical. Money is often diverted from other areas of the family monthly budget such as school fees or clothing to meet the costs of medications and transportation to the clinic. The program currently supports 47 families to help cover these costs.

Exhibitions and lessons learned from the campaign of the Youth (Living with HIV) Volunteer Group (YVG) held on 27-29 October 2010 at the Bangkok Palace Hotel

A total of 108 people attended, including staff members from four project sites (Bangkok, Phetchaburi, Khon Kaen and Chiangrai) and representatives from agencies handling children policies (MOPH, NHSO, NAMC, TUC, MSDHS, TNCA, TNP+, Youthnet, and UNICEF). There were 84 participants and 24 members from the YVG.

Lessons learned discussed at the event were:
   a. Holistic work with children living with HIV
   b. Provisions for HIV-infected teen friendly services
   c. Art as a healing tool for children and youths living with HIV
   d. How to reduce HIV labeling and protect the rights of children
Psychosocial Support Training for Health Care Providers dealing with Children and Adolescents Living with HIV

Round 1 at the Thai Red Cross AIDS Research Centre, Bangkok held on 20-22 June 2011
Round 2 at the Hatyai Paradise Hotel & Resort, Songkhla held on 24 – 26 August 2011

Objectives:
1. To learn about the different interventions used for psychosocial support and promote treatment success and quality of life for children and adolescents living with HIV
2. To promote pediatric HIV psychosocial support network from various regions

There were 23 participants from 16 organizations: 9 nurses, 1 psychologist, 2 technicians, 2 officers from HIV orphanage homes, 3 officers from an NGO, 6 volunteers and staff from a PLHIV group and network.

The book entitled, “My World,” is published and supported by TREAT Asia

A picture book entitled, “My World,” is made to support caregivers in reading or telling stories to children. This book will help children learn about HIV and how to live with the infection. The following excerpts are from the book.

At the moment, there is no treatment to completely eliminate HIV from the body. However, the medicine will put the virus to sleep and stop it from replicating so we can live together with HIV.
Community Advisory Board (CAB)
CAB is comprised of representatives from the affected population, community leaders, people from the wider community, activists, relevant HIV networks and organizations, and academics in society who have played active roles in the field of HIV medicine and civic movements.

The CAB meets once a month at TRCARC

National Health Security Office (NHSO)
Aside from doing research, HIV-NAT’s physicians serve as HIV consultants/HIV experts for Regional National AIDS Program and Bangkok Metropolitan National AIDS Program. Our physicians are part of the writing committee and assist in writing the national programs for HIV.
ACKNOWLEDGEMENTS

We would like to express our sincere gratitude and heartfelt appreciation to the following Institutional Review Boards (IRBs), without whom these studies would not be possible:

THAILAND
1. Institutional Review Board of the Faculty of Medicine, Chulalongkorn University
2. The Ethical Review Committee for Research in Human Subjects, Ministry of Public Health (MOPH)
3. The Institute for the Development of Human Research Protections (IHRP)
4. Internal Ethics committee, Chiangrai Prachanukroh Hospital
5. The Siriraj Institutional Review Board (SIRB)
6. Institutional Review Board of Bamrasnaraduru Infectious Diseases Institute
7. Committee on Human Rights Related to Researches Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital
8. Research and Ethic Committee Chonburi Regional Hospital
9. Research and Ethic Committee Queen Savang Vadhana Memorial Hospital
10. Research and Ethic Committee Prapokklao Hospital
11. Khon Kaen University Ethics Committee for Human
12. Ethics Committee Researches Involving Human Subjects, The Bangkok Metropolitan Administration
13. The Ethics Committee Rajavithi Hospital
14. The Ethics Committee Suratthanee Hospital

CAMBODIA
1. Ministry of Health, National Ethics Committee for Health Research

INDONESIA
1. The Kerti Praja Foundation Institutional Review Board, Denpasar, Bali, Indonesia
2. The Ethical Committee of the Faculty of Medicine, University of Indonesia, Jakarta, Indonesia

Please note that this list is not exclusive nor exhaustive. Since new research studies are developed and existing studies change, it is possible that some IRBs may not be listed.
SPONSORS

International Support

Pharmaceutical Partners
Abbott
Bristol-Myers Squibb
Chiron Corporation
Gilead Sciences
Matrix
Merck & Co., Inc
ROCHE Pharmaceutical
Tibotec Pharmaceuticals
Viv
Glaxo Smith Kline
Boehringer Ingelheim

Academic Organizations
AMC Amsterdam Institute for Global Health Development (AIGHD) Diseases, University of Amsterdam
Foundation for AIDS Research, United States (amfAR)
The Kirby Institute for Infection and Immunity in Society was formerly known as the National Centre in HIV Epidemiology and Clinical Research, University of New South Wales (UNSW), (Sydney, Australia)

Research Organizations
Pediatric European Network for Treatment of AIDS
Swiss HIV Cohort Study

Funding Agencies
Bill & Melinda Gates Foundation
National Institute of Allergy & Infectious Diseases (NIAID), Division of AIDS (DAIDS), National Institute of Health (NIH)

Charities
Art AIDS Fund
Born to Live Charity
Living & Loving Charity

Note:
Bristol-Myers Squibb provides life-time ATV for some patients.
Gilead-Sciences provides Truvada for some patients.
ROCHE Pharmaceutical provides life-time SQV for all patients from HIV-NAT 001.4, STACCATO, HIV-NAT 019, T-20, GEMINI, HIV-NAT 017 and HIV-NAT 096.
The Aligning Care and Prevention of HIV/AIDS with Government Decentralization to Achieve Coverage and Impact: Project (Global fund Thailand) supports ARV and some CD4 and viral load testing.

Please note that this list is not exclusive nor exhaustive. Since new research studies are developed and existing studies change, it is possible that some sponsors may not be listed.

Domestic Support

Governmental Agencies
Commission of Higher Education, Ministry of Education (CHE)
Governmental Pharmaceutical Organization (GPO)
Ministry of Public Health (MOPH)
National Health Security Office (NHSO)
Office of the National Research Council of Thailand (NRCT)
Social Security Office (SSO)
Thai Research Fund (TRF)
Department of Disease Control (DDC)
National Research University (NRU)

Academic Organizations
Ratchadaphiseksomphot Fund, Faculty of Medicine, Chulalongkorn University

Research Organizations
HIV-NAT
Thai Red Cross AIDS Research Centre

Funding Agency
The Aligning Care and Prevention of HIV/AIDS with Government Decentralization to Achieve Coverage and Impact: Project (Global fund Thailand)
Cover Design: Alan Maleesatharn
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