NATIONAL CENTRE IN HIV EPIDEMIOLOGY AND CLINICAL RESEARCH

ANNUAL REPORT 2005
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The National Centre in HIV Epidemiology and Clinical Research (NCHECR) was established in 1986 by the Australian Government to fulfil a number of key roles in Australia's fight against HIV/AIDS.

Located on the campus of St Vincent's Hospital in Sydney, the Centre is directly affiliated with the Faculty of Medicine at the University of New South Wales, and receives its core funding through the Australian Government Department of Health and Ageing.

Program Management Committee
Back row: Annie Tong, Anthony Kelleher, Andrew Grulich, Sean Emery, Bronwen Turner, Matthew Law
Front row: John Kaldor, David Cooper, Greg Dore, Lisa Maher

NCHECR's primary functions relate to the coordination of national surveillance programs, clinical research and clinical trials. While its original focus was exclusively on HIV/AIDS, NCHECR's work has expanded to encompass hepatitis B and C, and sexually transmissible infections. NCHECR also conducts research into the transmission, prevention and natural history of these infections. NCHECR's research program has increasingly taken on a regional focus, with major collaborative programs in Thailand and Cambodia. Other functions of NCHECR include the training of health professionals, and input into the development and implementation of health policy and programs.

NCHECR carries out its functions by working with an extensive range of collaborators, including State and Territory Health Departments, public and private clinical units, national and international organisations, and the corporate sector including the pharmaceutical industry. It also works closely with the other national HIV research centres.

Dissemination of NCHECR's research output is undertaken through publication in scientific journals and a range of surveillance reports.
NCHECR is funded by the Australian Government Department of Health and Ageing, through a grant to the University of New South Wales, where it is affiliated with the Faculty of Medicine. Its primary role is to coordinate national surveillance and carry out clinical and epidemiological research related to HIV/AIDS, viral hepatitis and sexually transmissible infections.

At the start of 2005, NCHECR changed its program structure in some important ways. The Viral Hepatitis Program was divided into two, with Lisa Maher leading the Viral Hepatitis Epidemiology and Prevention Program, and Greg Dore taking responsibility for the Viral Hepatitis Clinical Research Program. These changes show the emergence of research into viral hepatitis as a stronger theme of NCHECR's work. At the same time, the Primary HIV Infection Research Program merged with the Laboratory Support Program to form the Immunovirology and Pathogenesis Program under Anthony Kelleher. Basil Donovan also joined NCHECR on a fractional basis to strengthen research activities related to sexually transmissible infections.

Several major research programs were initiated in calendar year 2005. In the clinical trials area, major planning was carried out for the ESPRIT group to merge with CPCRA (Community Programs for Clinical Research on AIDS), two of the US National Institutes of Health (NIH), Division of AIDS (DAIDS) major clinical trials networks. The planning resulted in the formation of the INSIGHT network whose mission is to carry out large clinical endpoint strategic trials in HIV disease that would contribute to important advances in HIV disease management. The new network, with over 300 sites in over 30 countries, applied for the 2006 recompetition with NCHECR being one of the four international coordinating centres. A decision on the application is expected in 2006. Moreover, NCHECR submitted a complementary application to be a clinical trials unit of the DAIDS networks. This outcome will be known subsequent to the successful network leadership applicants being funded in 2006. This is a very exciting development for NCHECR which should enable us to be in the forefront on the international clinical trials research agenda.

With the official closure of the Australian-Thai HIV Vaccine Consortium in 2005, following the completion of the NIH-supported vaccine contract, it was decided to finish some of the work plan to complete a phase I trial of the subtype A/E HIV DNA and fowlpox prime-boost construct with our partners at HIV-NAT in Bangkok. Extensive planning was carried out in 2005 to enable a trial start date in 2006. The Therapeutic and Vaccine Research Program, together with the Immunovirology and Pathogenesis Program, under Sean Emery’s and Anthony Kelleher’s joint leadership, have been instrumental in advancing the planning of this trial. NCHECR was able to institute technology transfer of both data management and laboratory immunogenicity assays for the vaccine to our Thai partners at HIV-NAT. The trial is slated to commence in 2006.

The advent of new dual nucleoside fixed dose combinations as standard backbones for combination antiretroviral therapy has enabled the Therapeutic and Vaccine Research Program to institute a randomised comparative study called STEAL, with the aim of comparing toxicity outcomes of these backbones which has long been an important leadership area for NCHECR. All sites in the network were most enthusiastic in signing up for the STEAL study and will commence enrolment in 2006 as the largest fully independent trial ever carried out by NCHECR in its own home base network.

In intensive planning during 2005 was the first efficacy study of a candidate preventive vaccine developed by Merck against HIV infection to be implemented in Australia. A series of procedural developments and regulatory approval steps were negotiated under the supervision of a collaborative mechanism involving the industry sponsor of the candidate vaccine, community based organisations, the trial site and NCHECR.

Internationally, NCHECR continued to work with research partners in a number of countries in the Asia-Pacific region and elsewhere. Through in-country staff placements, the involvement was particularly strong in Thailand and Cambodia. The Treat Asia network sponsored by amfAR, the American Foundation for AIDS Research, has gone from strength to strength with the technical support of Matthew Law and his team in the Biostatistics and Databases Program at NCHECR. With this scientific leadership from NCHECR, amfAR was successful in applying to be the Asian-Pacific regional cohort in the NIH-sponsored program of international cohorts for the
epidemiological evaluation of HIV disease outcomes globally known as IeDEA. This support will also enable the Australian HIV Observational Database (AHOD) to continue with renewed enthusiasm for another five years.

A new grants scheme developed by Australia’s National Health and Medical Research Council (NHMRC) and its counterparts in Canada and New Zealand made its first award to a collaborative group involving NCHECR, to undertake a research program aimed at enhancing the resilience of Indigenous people to sexually transmissible and blood-borne viral infections. This program is being conducted in Australia through collaboration with three large Aboriginal community controlled health services. Another new direction in 2005 was represented by a very substantial award by NIH for the development of a vaginal microbicide by a consortium in which NCHECR is one of four partners.

Several other projects entered new phases during 2005. NCHECR undertook new responsibilities in the ongoing evaluation of the Sydney Medically Supervised Injecting Centre in King Cross, including the establishment of a longitudinal cohort of clients. The HIM study of HIV negative gay men, which has proven over the past five years to be an extremely rich source of information on behavioural risk and the transmission of HIV and other sexually transmissible infections, was extended for a further period of follow up by the award of a grant from the NHMRC.

Several large national trials of hepatitis C treatment continued to recruit strongly through the newly created Viral Hepatitis Clinical Research Program, and there was an increasing focus on research into the treatment of chronic hepatitis B infection.

With new funding, NCHECR was able to extend its activities in the area of mathematical modelling to cover a number of new areas of application, including human papilloma virus transmission and the projection of HIV epidemics in countries of the Asia-Pacific region.

A wide range of other research, teaching and service activities is presented in the remainder of this report. NCHECR’s Programs are conducted by highly committed staff working in collaboration with sponsors, researchers and health care providers from a wide range of institutions both nationally and internationally. Finally, and most importantly, we acknowledge the people who participate in our studies. They provide us with the only pathway for achieving our motivating goal, which is to acquire information that could be used to improve human health.
The following sections describe NCHECR achievements and activities within Programs during 2005. Each project report lists any sources of funding beyond the NCHECR core grant that were used to fund the activity, as well as NCHECR personnel and external collaborators involved with the project.

The Director, David Cooper directly supervises the Heads of the Programs in Therapeutic and Vaccine Research, Immunovirology and Pathogenesis and Viral Hepatitis Clinical Research. He takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: ESPRIT, SILCAAT, INITIO (see Annual Report 2004), the Vaccine Design and Development Project, AIEDRP, SMART, STACCATO and the NHMRC Program Grant entitled “HIV infection, immunology and vaccine design”. He is also a Co-Director of HIV-NAT, the clinical research collaboration in Bangkok, Thailand, and a member of the Steering Committee of the Cambodian Treatment Access Program.

The Deputy Director, John Kaldor, supports the Director, and directly supervises the Surveillance Program, and the Heads of the Programs in HIV Epidemiology and Prevention, Viral Hepatitis Epidemiology and Prevention and Biostatistics and Databases. He takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: AIEDRP, the Cambodian research program to support the optimal use of antiretroviral therapy, ATAHC, the project on the role of resiliency in responding to blood-borne viral and sexually transmitted infections in Indigenous communities, the VivaGel™ Microbicide Development Consortium (VMDC) program, as well as NCHECR’s contribution to the HIV/AIDS Prevention and Care Project Phase II in Indonesia, the HIV Epidemiological Modelling and Impact (HEMI) Study for Papua New Guinea, Indonesia and East Timor, and the evaluation of the Sydney Medically Supervised Injecting Centre. He is also a member of the Steering Committee of the Cambodian Treatment Access Program.
Surveillance Program

Overview

The Surveillance Program continued to monitor the pattern of transmission of HIV, hepatitis B and C, and specific sexually transmissible infections in Australia in 2005, in collaboration with the Australian Government Department of Health and Ageing, State and Territory health authorities and collaborating networks. Detailed analyses and interpretation of recent trends in new diagnoses of HIV/AIDS, viral hepatitis and sexually transmissible infections, and estimates of HIV and hepatitis C prevalence and incidence in higher and lower risk population subgroups, were published in HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2005. This was the ninth successive issue of the Annual Surveillance Report, and it was formally released by Professor Frank Bowden, Chair of the HIV/AIDS and Sexually Transmissible Infections Sub-Committee of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis, at the 17th Annual Conference of the Australasian Society for HIV Medicine in Hobart in August 2005.

The Annual Surveillance Report 2005 indicated that the number of AIDS cases, adjusted for reporting delay, remained relatively stable over the past three years at around 240 cases per year in 2002-2004. However, the age standardised rate of AIDS diagnosis in the Indigenous population increased from 1.5 per 100,000 population to 3.6 per 100,000 population in 2004, whereas the rate of AIDS diagnosis in the non-Indigenous population continued to decline, from 1.4 per 100,000 population in 2000 to 0.8 per 100,000 population in 2004. Recent trends in the rates of HIV/AIDS diagnosis in the Indigenous population are based on relatively small numbers and may reflect localised occurrences rather than national patterns.

Following a steady decline until 1998, the annual number of new diagnoses of HIV infection increased to 818 by 2004. The number of diagnoses of newly acquired HIV infection also increased from 151 in 1998, to 281 and 253 in 2003 and 2004 respectively, the highest numbers of reported diagnoses since commencement of surveillance for newly acquired HIV infection in 1991. HIV transmission occurred primarily through sexual contact between men. There was no evidence of an increase in HIV transmission through injecting drug use or heterosexual contact. One case of mother-to-child HIV transmission was diagnosed in 2003-2004.

An estimated 14,840 people were living with HIV/AIDS in Australia at the end of 2004, and around 53% were receiving antiretroviral treatment for HIV infection. Median survival following AIDS had increased from 17 months among cases diagnosed by the end of 1995, to 45 months among cases diagnosed in 2001.

The number of new diagnoses of hepatitis C infection reported through the National Notifiable Diseases Surveillance System declined from 20,188 in 2000, to 13,028 in 2004. Hepatitis C transmission continued to occur predominantly among people with a recent history of injecting drug use. Results available through the Collaboration of Australian Needle and Syringe Programs showed that hepatitis C prevalence among men and women who had been injecting drugs for less than three years was 25% in 2004. Hepatitis C prevalence among people who had injected drugs and were aged less than 20 years remained high at 28% in 2004.

An estimated 194,260 people were living with hepatitis C infection in Australia in 2004, including 153,300 people with chronic hepatitis C infection and stage 0/1 liver disease, 32,800 with stage 2/3 liver disease and 8,160 living with hepatitis C related cirrhosis. In 2004, an estimated 2,069 people were treated with ribavirin and interferon combination treatment for hepatitis C infection. The Australia and New Zealand Liver Transplant Register indicated that infection with hepatitis B and hepatitis C was the primary cause of liver disease in 5.6% and 30.7% of liver transplants in 2004, respectively.

Chlamydia was the most frequently reported notifiable communicable infection in Australia in 2004. The number of new diagnoses increased from 16,953 in 2000, to 35,189 in 2004. The population rate of diagnosis of gonorrhoea increased from 31.4 per 100,000 population in 2000, to 37.0 per 100,000 population in 2004, whereas the rate of diagnosis of syphilis remained stable at around 8.7 per 100,000 population in 2000-2004. However, the population rate of syphilis diagnoses almost doubled in New South Wales in 2000-2004, and increased nine fold in Victoria. These increases were almost completely confined to homosexually active men. Among homosexually active men enrolled in the Health in Men cohort study in Sydney, seven, four and three cases of newly acquired syphilis were diagnosed in 2002, 2003 and 2004, respectively, giving an incidence rate of 1.09, 0.43 and 0.5 per 100 person years, respectively.
The **Australian HIV Surveillance Report** continued to be published in 2005, providing quarterly updates on the number of new diagnoses of HIV/AIDS and HIV prevalence and incidence among people seen through a network of metropolitan sexual health clinics. Brief reports on topics of special interest in HIV/AIDS epidemiology were also published in the *Australian HIV Surveillance Report*. The January 2005 issue included a report on hepatitis A and hepatitis B infection among homosexually active men in Sydney who were enrolled in the Health in Men cohort study. The April 2005 issue included a summary of the reported prevalence of HIV infection among homosexually active men participating in Gay Community Periodic Surveys in 1996-2004. Risk factors for late HIV diagnosis among AIDS cases diagnosed in Australia in 2000-2004 was reported in the July 2005 issue. HIV subtypes and transmission of the primary mutation K103N among cases of HIV infection newly diagnosed in South Australia was described in the October 2005 issue.

**Projects**

**National surveillance coordination and information dissemination**

**Support for national surveillance committees**

The National HIV Surveillance Committee, the National Viral Hepatitis Surveillance Committee and the Sexually Transmissible Infections Surveillance Committee each co-ordinate ongoing national surveillance activities within their terms of reference including the development of new initiatives in case surveillance, new analyses of surveillance data, development of standardised surveillance procedures, and communication with and feedback of surveillance outputs to organisations directly involved in surveillance activities.

**Status:** Ongoing

**Personnel:** Ann McDonald, Melanie Middleton, Jiong Li

**Collaborators:** State and Territory health authorities; Australian Paediatric Surveillance Unit; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

**HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report**

Detailed analyses and interpretations of national surveillance data on HIV/AIDS, viral hepatitis and sexually transmissible infections are published in *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report*.

**Status:** Ongoing. The *Annual Surveillance Report 2005* was published for the ninth successive year.

**Personnel:** Ann McDonald, Melanie Middleton, Handan Wand

**Collaborators:** State and Territory health authorities; Australian Paediatric Surveillance Unit; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

**Australian HIV Surveillance Report**

The *Australian HIV Surveillance Report* provides quarterly updates on the number of new diagnoses of HIV infection and AIDS and estimates of HIV incidence and prevalence through a network of sexual health clinics. Articles on topics of special interest in HIV epidemiology are also published in the *Australian HIV Surveillance Report*.

**Status:** Ongoing. The *Australian HIV Surveillance Report*, in its current format, has been published each quarter from July 1990.

**Personnel:** Ann McDonald, Melanie Middleton, Handan Wand

**Collaborators:** State and Territory health authorities; Australian Paediatric Surveillance Unit; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

**Surveillance for HIV/AIDS**

**Monitoring cases of AIDS**

The past pattern of HIV transmission, the pattern of illness associated with advanced HIV immunodeficiency and the impact of antiretroviral treatment on the pattern of illness is monitored through national AIDS surveillance.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald, Melanie Middleton, Handan Wand

**Collaborators:** State and Territory health authorities; Australian Paediatric Surveillance Unit; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

**Monitoring cases of newly diagnosed HIV infection**

The pattern of HIV transmission is monitored through national surveillance for newly diagnosed HIV infection, potentially providing information on more recent patterns of HIV transmission than does AIDS surveillance.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald, Handan Wand

**Collaborators:** State and Territory health authorities; Australian Paediatric Surveillance Unit; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections
Monitoring diagnoses of newly acquired HIV infection

Diagnoses of newly acquired HIV infection are monitored to provide an indication of the current pattern of HIV transmission in Australia.

**Status:** Ongoing during 2004, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

Monitoring perinatal exposure to HIV

The extent and outcome of perinatal exposure to HIV in Australia, including risk factors for perinatal HIV transmission, is monitored to indicate the rate of mother-to-child HIV transmission, the impact of interventions for reducing the risk of perinatal HIV transmission and HIV prevalence among childbearing women.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

Monitoring long-term outcome of newly acquired HIV infection

The long-term outcome of HIV infection is monitored among cases with a known date of HIV acquisition that have progressed to AIDS.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald, Handan Wand

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

Monitoring HIV transmission through specialised tests for incident HIV infection

Specialised tests for diagnosing incident HIV infection are evaluated by comparison with the results of national surveillance for newly acquired HIV infection.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald

**Collaborators:** NSW State Reference Laboratory for HIV; State and Territory health authorities; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

Monitoring HIV subtypes among new HIV diagnoses

HIV subtypes are monitored among cases of HIV infection for which antiretroviral drug resistance testing has been carried out, and then linked to demographic and exposure information held on the National HIV Database.

**Status:** Ethics committee applications to State and Territory health jurisdictions seeking approval to monitor HIV subtypes were in progress.

**Personnel:** Mary Poynten, Ann McDonald, Melanie Middleton

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare; networks involved in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

**Funding:** Australian Centre for Hepatitis and HIV Virology Research

Monitoring survival following HIV/AIDS diagnosis in Australia

The date and cause of death among people with diagnosed HIV infection and AIDS is obtained through linkage to deaths registered with the National Death Index, and the pattern of survival following HIV/AIDS diagnosis analysed and modelled.

**Status:** The sensitivity and specificity of the linkage of deaths registered with the National Death Index to diagnosed cases of HIV infection and AIDS was estimated, and the information used in the analysis of causes of death and survival following HIV/AIDS.

**Personnel:** Ann McDonald, Matthew Law, Fatemeh Nakhaee (PhD student)

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare

**Assessment of self-report of HIV exposure history**

Documentation of self-report of exposure to HIV is obtained through structured sexual history taking among cases of newly diagnosed HIV infection whose exposure was attributed to sources other than male homosexual contact.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Ann McDonald

**Collaborators:** State and Territory health authorities; Australian Institute of Health and Welfare
Surveillance for viral hepatitis

Monitoring cases of newly diagnosed viral hepatitis

The pattern of transmission of viral hepatitis is monitored through national surveillance for newly diagnosed hepatitis B and hepatitis C infection, and newly acquired infections notified to the National Notifiable Diseases Surveillance System. Information on risk factors for newly acquired hepatitis B and C notifications is obtained directly from State and Territory health authorities.


Personnel: Melanie Middleton, Swati Shourie, Jiong Li, Lisa Maher

Collaborators: State and Territory health authorities; Australian Government Department of Health and Ageing

Monitoring perinatally acquired hepatitis C infection and outcome in children

Clinicians on the Australian Paediatric Surveillance (APSU) mailing list are asked to notify newly diagnosed hepatitis C positive children as per case definition and complete a written de-identified questionnaire. The questionnaire asks clinicians to report hepatitis C risk factors, maternal hepatitis C risk factors, clinical assessment and management of positive cases. A follow up questionnaire is completed annually.

Status: Ongoing, with an annual surveillance report included in the APSU report to the National Centre for Disease Control, Australian Department of Health and Ageing Financial Markets Foundation.

Personnel: Suzanne Polis (to February)

Collaborators: Suzanne Polis (from February); Australian Paediatric Surveillance Unit; The Children's Hospital at Westmead; Royal Children's Hospital; Princess Margaret Hospital

Monitoring long-term outcomes of chronic hepatitis B and C

Data is obtained from the Australian and New Zealand Liver Transplant Register on number and underlying cause (hepatitis B and C, other) for liver transplants performed.

Status: Ongoing during 2005, with publication in NCHECR's surveillance reports.

Personnel: Melanie Middleton, Greg Dore

Collaborators: Australia and New Zealand Liver Transplant Register

Surveillance for sexually transmissible infections

A national framework for sexually transmissible infection (STI) control is being developed through the Sexually Transmissible Infections Surveillance Committee.

Status: In 2005, the Sexually Transmissible Infections Surveillance Committee further refined the case definitions for infectious syphilis and syphilis of unknown duration, drafted the case definition for congenital syphilis, finalised its review of the prevalence of review of the prevalence of gonorrhoea in Australia, surveyed jurisdictions about their current and future capacity to collect data on the number of tests conducted for chlamydia, gonorrhoea and syphilis to provide denominator data for STI notifications, and investigated alternate sources of denominator data for chlamydia.

Personnel: Basil Donovan, Claire Vajdic, Melanie Middleton

Collaborators: State and Territory health authorities; Australian Government Department of Health and Ageing; networks involved in surveillance for sexually transmissible infections

Surveillance in selected populations

Needle and syringe program surveys

Annual cross-sectional surveys are conducted during a designated week in October at selected needle and syringe program (NSP) sites throughout Australia. All clients attending participating sites during the survey week are asked to complete a self-administered questionnaire, and to provide a finger-prick blood sample for HIV and hepatitis C antibody testing. NCHECR maintains the national database on behalf of the Collaboration of Australian Needle and Syringe Programs, and develops and carries out analyses of NSP data and prepares surveillance reports and papers for publication.

Status: Ongoing during 2005, with publication in NCHECR's surveillance reports.

Personnel: Swati Shourie, Bethany White, Kathleen Glenday, Jiong Li, Lisa Maher

Collaborators: State and Territory health authorities; NSPs involved in HIV/hepatitis C surveillance; St Vincent's Hospital, Sydney; Association for Prevention and Harm Reduction Programs (ANEX); Australian Injecting and Illicit Drug Users League (AIVL); Justice Health

Handan Wand, Melanie Middleton, John Kaldor, Andrew Grulich, Ann McDonald
Saliva validation study

Validation of saliva testing as an alternative to capillary blood for hepatitis C antibody testing using venous blood, dried blood spots and saliva samples collected from injecting drug users. Also includes the collection of survey data exploring the acceptability of different testing methods.

Status: Data collection entry complete, and analysis in progress.
Collaborators: Philip Cunningham, St Vincent’s Hospital, Sydney; Ingrid van Beek, Sydney Medically Supervised Injecting Centre; Alex Wodak, National Drug and Alcohol Research Centre, St Vincent’s Hospital, Sydney
Funding: NSW Department of Health

Monitoring hepatitis C antibody prevalence through sexual health clinics

Hepatitis C prevalence is monitored among people seen through a network of sexual health clinics who are voluntarily tested for hepatitis C.

Status: Ongoing during 2005, with publication in NCHECR’s surveillance reports.
Personnel: Ann McDonald
Collaborators: Collaborative group on sentinel surveillance in sexual health clinics

Monitoring HIV and viral hepatitis among blood donors

Newly emerging patterns of transmission of HIV and viral hepatitis are monitored among blood donors, a subgroup of the population at low risk of infection who are compulsorily tested for blood-borne viruses.

Status: Ongoing during 2005, with publication in NCHECR’s surveillance reports.
Personnel: Melanie Middleton, Ann McDonald, Lisa Maher
Collaborator: Australian Red Cross Blood Service

Behavioural surveillance for HIV risk factors among homosexual men

Repeated community-based cross sectional surveys of the risk behaviour of homosexual men.

Status: In 2005, surveys were conducted in Sydney (3,413 completed questionnaires), Melbourne (1,804 completed questionnaires), Queensland (1,382 completed questionnaires) and Adelaide (about 630 completed questionnaires).
Personnel: Garrett Prestage, Andrew Grulich
Collaborators: National Centre in HIV Social Research; State AIDS Councils; State PLWHA organisations
Funding: NSW Health Department; Department of Human Services, Melbourne; Queensland Health; Department of Health, Adelaide

Behavioural surveillance for HIV risk factors among Aboriginal and Torres Strait Islander homosexual men

Community-based cross sectional survey of the risk behaviour of Aboriginal and Torres Strait Islander homosexual men.

Status: In 2005, surveys were conducted (233 completed questionnaires, including 160 from homosexually active men) among men recruited from both gay community and Aboriginal or Torres Strait Islander community sites in Queensland. A report of the findings was prepared.
Personnel: Garrett Prestage, Chris Lawrence, Andrew Grulich
Collaborators: Office of Aboriginal and Torres Strait Islander Health; Queensland Aboriginal and Islander Health Council; Queensland AIDS Council; National Centre in HIV Social Research; Australian Federation of AIDS Organisations; Queensland Health
Funding: Office of Aboriginal and Torres Strait Islander Health
Behavioural surveillance for sexual health risk factors among homosexual and bisexual women

Repeated community-based cross sectional surveys of the risk behaviour of homosexual women.

**Status:** Data analysis took place during 2005, as well as publication of the project report for 2004, *Sydney Women and Sexual Health 2004.*

**Personnel:** Garrett Prestage

**Collaborators:** AIDS Council of New South Wales; National Centre in HIV Social Research

**Funding:** AIDS Council of New South Wales

Surveillance Program sentinel surveillance network of sexual health clinics

**Brisbane Sexual Health Clinic**
Site principal: John Patten
Site coordinator: Henry Magon

**Clinic 275**
Site principal: Russell Waddell

**Gold Coast Sexual Health Clinic**
Site principal: John Chuah
Site coordinator: Wendy Fankhauser

**Livingstone Road Sexual Health Centre**
Site principal: Catherine O’Connor
Site coordinator: Ben Allam

**Melbourne Sexual Health Centre**
Site principals: Christopher Fairley, Ian Denham

**Sydney Sexual Health Centre**
Site principal: Basil Donovan
Site coordinator: Ben Judd
Therapeutic and Vaccine Research Program

Overview

Two features of HIV medicine have significant implications for the work of the Therapeutic and Vaccine Research Program (TVRP) and our national and international collaborators. Firstly, HIV medicine is subject to substantial fluxes, some of which are driven by good quality data and sound reasoning, and some of which are driven by fashion and trend. Secondly, as therapies have improved (and one must anticipate will continue to improve), the design and implementation of research becomes considerably more complex. It is therefore an enormous credit to all involved that we continue to make significant research contributions to the management of HIV infection through well designed and conducted research projects. It is equally gratifying that the merits of TVRP are recognised outside of the field of HIV medicine as reflected by a successful application to NHMRC for clinical research in influenza.

Projects that concluded during 2005 included INITIO (see Annual Report 2004), phase I testing of the Virax therapeutic vaccine, phase I testing in Australia of the Australian-Thai HIV Vaccine Consortium prime boost vaccine, and the elegant laboratory and clinical characterisation of metabolic and anthropometric changes that occur following initiation of defined regimens of combination antiretroviral therapy. Each of these has generated at least one peer-reviewed publication in addition to conference presentations nationally and internationally.

Projects that continued included the ESPRIT, SILCAAT and SMART studies with their attendant substudies. It is of note that these three studies require TVRP to coordinate the activities of some 63 clinical sites in nine countries. These sites have recruited and followed over 1,800 patients.

Two new multicentre trials commenced in Australia during 2005 in the form of the STEAL and FLASH projects. The former compares the newly available fixed dose combinations of reverse transcriptase inhibitors for safety and efficacy in patients who are treatment experienced and switching to these new formulations. The latter compares the short and long term safety and efficacy of a cosmetic intervention for management of facial lipoatrophy. STEAL is all the more remarkable since it marks the first occasion that NCHECR has been able to entirely fund an interventional study without requiring external support. Upon completion of enrolment it will be the largest randomised comparison of a therapeutic intervention we have undertaken solely in Australia. Of equal note we are very grateful to the Australian Federation of AIDS Organisations, NSW Health Department and a number of local pharmaceutical companies for their spirited financial support of FLASH.

Preparations continued on two new clinical trials of candidate vaccines for prevention of HIV infection. The first is a follow-up study of the Australian prime-boost technology that will be conducted at HIV-NAT in low-risk volunteers. The study will employ higher doses of clade A/E vaccine constructs in an effort to improve upon the disappointing immunogenicity observed at conclusion of the Australian trial. The second study in collaboration with Merck Sharp and Dohme Australia will recruit volunteers who are at high risk of HIV infection and determine if a candidate vaccine using an adenovirus vector that expresses three HIV genes affects either or both rates of HIV transmission or the natural history of HIV disease in individuals who do become infected. This critically important trial for the field of vaccine research has acquired the name, the STEP study.

During 2005, TVRP also played a leadership role in preparing two substantial applications for review by the Division of AIDS at the US National Institutes of Health. We were asked to join a leadership application (subsequently named INSIGHT) to create a new international network for clinical research in HIV/AIDS. Our second application under this round described the national and international network of clinical research sites with whom we collaborate on defined projects. These considerable and substantial applications underwent review toward the end of 2005 and we are confident that they will be well received with notifications being made in response during 2006.

We have continued to develop ideas for a randomised clinical trial to compare innovative regimens of antiretroviral therapy in treatment naïve subjects. We are optimistic that this trial is likely to commence during 2006.

At an operational level TVRP has commenced further real world evaluation of electronic data collection methods in collaboration with Phase Forward. This exciting opportunity has significant implications for the network that we felt was best addressed by a proper field test through the STEAL study. Preliminary results of this evaluation will be available in 2006. We also implemented the MedDRA system for coding and analyses of adverse events. Both these initiatives maintain the operational systems and capacities of TVRP at a level of sophistication that compares very favourably with other groups in the public and private sector.
In part empirical, and in part the subject of careful planning and management, our model for collaborative research and the highly productive outputs are now increasingly being recognised in other disease areas. Immediate opportunities for us to contribute of course are in the newer areas of research within the NCHECR terms of reference. Importantly however, the model is clearly attractive to other funding agencies given the successful award under an NHMRC Urgent Research mechanism for the preparation of protocols and supporting materials to allow multicentre evaluations of the safety and efficacy of neuraminidase inhibitors for the treatment and prophylaxis of influenza (pandemic).

In summary, another extraordinarily busy but productive year.

Robyn Munro, Wendy Lee, Alison Macdonald, Kymme Courtney-Vega, Kirsten Bailey, Jennifer Tapp

Projects

As well as having a supervisory role as Program Head for all projects that fall within the Therapeutic and Vaccine Research Program, Sean Emery and takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: ESPRIT, SILCAAT, the Vaccine Design and Development Project, STEP, Australian-Thai HIV Vaccine Consortium AE trial, the ITV extension study (see Annual Report 2003), SMART, PHIDISA, FLASH, STEAL, ASK-500 and the Truvadaplus project, and provides project related support to HIV-NAT. He is a Chief Investigator on the NHMRC Urgent Research project relating to pandemic influenza.

Antiretroviral therapy

Studies closed to recruitment or completed during 2005

ML16992 (ALLIANCE)

An open-label study to determine the efficacy and safety of enfuvirtide (T20, Fuzeon) in patients changing therapy to an NRTI-sparing regimen.

Sites: 19
Enrolled/target: 59/60
Personnel: Susan Phipps, Robyn Munro
Funding: Roche Products Pty Ltd

STACCATO

The Swiss-Thai-Australian Treatment Interruption Study. This study compares continuous therapy with intermittent therapy based on CD4 cell count.

Sites: 17 (2 Australia, 7 Thailand, 8 Switzerland)
Enrolled/target: 8/30 Australia, 530/600 internationally
Personnel: Fraser Drummond, Claudette Satchell

ASK-500

A 48-week, randomised study to describe the pharmacokinetic profile and durability of atazanavir-saquinavir-ritonavir once daily, and describe the pharmacokinetic profile of saquinavir-ritonavir using saquinavir 500mg formulation.

Sites: 1 Australia
Enrolled/target: 26/40
Personnel: Alan Winston, Claudette Satchell, Robyn Munro
Funding: F Hoffman-La Roche Ltd
Studies recruiting during 2005

**SMART**
A large, simple, trial comparing two strategies for management of antiretroviral therapy: this study is examining the impact of long-term HIV control by randomising patients to receive antiretrovirals to either maintain an undetectable viral load or maintain an acceptable CD4 count.

**Status:** Recruitment opened May 2002
**Sites:** 22 Australia, 3 New Zealand, 1 Japan, 13 Argentina, 1 Chile, 1 Uruguay, 5 Thailand
**Enrolled/target:** 150/200 Australia, 5,200/6,000 internationally
**Personnel:** Fraser Drummond, Sue Phipps, Claudette Satchell, Sophie Gunn, Robyn Munro
**Funding:** US National Institutes of Health

**PHIDISA I**

**Status:** Recruitment opened January 2004
**Sites:** 6 military medical sites in Republic of South Africa
**Enrolled/target:** 2,000/unlimited
**Personnel:** Allison Humphries
**Funding:** US National Institutes of Health; US Department of Defense; South African National Defence Force

**PHIDISA II**
A randomised, open-label 2x2 factorial study to compare the safety and efficacy of different combination antiretroviral therapy regimens in treatment naïve patients with advanced HIV disease and/or CD4+ cell counts < 200 cells/µL.

**Status:** Recruitment opened January 2004
**Sites:** 6 military medical sites in Republic of South Africa
**Enrolled/target:** 1,391/2,800
**Personnel:** Allison Humphries
**Funding:** US National Institutes of Health; US Department of Defense; South African National Defence Force

Studies in preparation 2005

**STEAL**
A randomised, open-label trial to assess the safety and efficacy of switching to fixed-dose tenofovir-emtricitabine or abacavir-lamivudine: the STEAL Study.

**Status:** In development
**Sites:** 31 sites in Australia
**Target:** 350 patients
**Personnel:** Allison Humphries, Wilma Goodyear, Kymme Courtney-Vega, Lina Safro
**Funding:** Undetermined

**Truvadaplus**
A comparison of once-daily antiretroviral therapy (ART) in HIV infected treatment-naïve subjects.

**Status:** In development
**Sites:** To be decided
**Target:** To be finalised
**Personnel:** Rebekah Puls, Fraser Drummond, Kymme Courtney-Vega
**Funding:** Undetermined

Toxicology/Pharmacology studies

Studies closed to recruitment or completed during 2005

**Pravastatin Study**
A randomised study of pravastatin for the treatment of HIV protease inhibitor-induced hyperlipidaemia.

**Status:** Recruitment closed July 2004. Follow-up completed December 2004.
**Sites:** 1
**Enrolled/target:** 33/40
**Personnel:** Paddy Mallon
**Funding:** US National Institutes of Health; Bristol-Myers Squibb

**Studies recruiting during 2005**

**HAMA 001**
**HIV Infection and Metabolic Abnormalities**
A prospective study of the effect of treatment with antiretroviral medications in HIV-infected individuals on the development of lipodystrophy, cardiovascular risk and bone metabolism.

**Status:** Recruitment opened March 2003
**Sites:** 1
**Enrolled/target:** 49/80
**Personnel:** Paddy Mallon
**Funding:** US National Institutes of Health
**Seronegatives, Antiretrovirals and Metabolic Abnormalities Protocol 2**

A three arm, prospective study to compare the effect of six weeks exposure to the combination of Kaletra® (lopinavir/ritonavir) and Combivir® (AZT/3TC) versus Kaletra® alone or Combivir® alone in HIV-negative healthy subjects on the development of abnormalities of lipid and glucose metabolism.

**Status:** Recruitment opened December 2004  
**Sites:** 1  
**Enrolled/target:** 22/50  
**Personnel:** Paddy Mallon  
**Funding:** US National Institutes of Health

**Study in preparation during 2005**

**Facial Lipoatrophy Trial (FLASH)**

A randomised, open-label study to assess the safety, efficacy and durability of immediate versus deferred subcutaneous injections of polyactic acid in individuals with antiretroviral-associated facial lipoatrophy.

**Status:** In development  
**Sites:** To be decided  
**Target:** 100  
**Personnel:** Dianne Carey, Wendy Lee  
**Funding:** NSW Health Department; Australian Federation of AIDS Organisations; GlaxoSmithKline; Bristol-Myers Squibb (Australia); Abbott Australasia; Roche Australia Pty Ltd; Gilead Sciences; Merck Sharp and Dohme Australia

**Immune-based therapies and vaccines**

**Studies closed to recruitment or completed during 2005**

**SILCAAT**

A phase III, multicentre, randomised study of the biological and clinical efficacy of subcutaneous recombinant, human interleukin-2 in HIV-infected patients with low CD4+ counts receiving active antiretroviral therapy.

**Status:** Recruitment closed October 2002. Follow-up to be completed 2010.  
**Sites:** 17 (12 Australia, 5 Argentina)  
**Enrolled/target:** 293 (126 Australia, 167 Argentina)/125 Australia  
**Personnel:** Sarah Pett, Cate Carey, David Courtney-Rodgers, Simone Jacoby  
**Funding:** US National Institutes of Health

**ESPRIT**

A randomised, open-label, phase III, international study of subcutaneous recombinant interleukin-2 in patients with HIV infection and CD4 lymphocyte count greater than or equal to 300 cells/mm3.

**Status:** Recruitment closed May 2003. Follow-up to be completed 2010.  
**Sites:** 48 (23 Australia, 3 Japan, 1 Singapore, 5 Thailand, 13 Argentina, 3 Israel)  
**Enrolled/target:** 1,233 = 106% of enrolment target (205/247 Australia, 64/65 Israel, 365/300 Thailand, 20/20 Singapore, 554/494 Argentina, 25/35 Japan)  
**Personnel:** Sarah Pett, Cate Carey, David Courtney-Rodgers, Simone Jacoby, Chris Duncombe  
**Funding:** US National Institutes of Health

**HVDDT vaccine**

A randomised, placebo-controlled, double blind, phase I/IIa clinical trial to evaluate the safety and immunogenicity of a candidate clade B prophylactic DNA prime-rFPV boost HIV vaccination strategy.

**Status:** Recruitment closed February 2004. Follow-up completed February 2005.  
**Sites:** 1  
**Enrolled/target:** 24/24  
**Personnel:** Rebekah Puls, Wendy Lee  
**Funding:** US National Institutes of Health

**Studies in preparation during 2005**

**HVDDT vaccine (AE#1)**

A randomised, placebo-controlled, double blind, phase I clinical trial to evaluate the safety and immunogenicity of a candidate prophylactic pHIS-HIV-AE DNA prime-rFPV-HIV-AE boost HIV vaccination strategy.

**Status:** In development  
**Sites:** 1  
**Target:** 10  
**Personnel:** Rebekah Puls, Wendy Lee

The STEP Study

A study to compare a 3-dose immunisation with the Merck HIV vaccine (MRKAd5 HIV-1 gag/pol/nef) to placebo in adults at high risk of HIV infection.

**Status:** In development  
**Sites:** 1  
**Target:** 100  
**Personnel:** Rebekah Puls  
**Funding:** Merck Sharp and Dohme Australia
STALWART
A randomised, open-label, phase II, international study of sc IL-2 with and without concomitant antiretroviral therapy in patients with HIV-1 infection and CD4+ cell counts >300 cells/µL: study of aldesleukin with and without antiretroviral therapy.

Status: In development
Sites: 20
Target: 200 (Australia, Argentina, Thailand)
Personnel: Cate Carey, David Courtney-Rodgers
Funding: US National Institutes of Health

Therapeutic and Vaccine Research Program (TVRP) clinical trials network (Australian/New Zealand sites)

Each site listed below has recruited and followed at least one subject in a TVRP research protocol during 2005.

Australian sites

Australian Capital Territory
Canberra Sexual Health Clinic, Canberra Hospital
Site principal: Ashley Watson
Site coordinator: Ruth Primrose

New South Wales
407 Doctors
Site principal: David Baker
Site coordinator: Robyn Vale
AIDS Research Initiative
Site principal: Cassy Workman
Site coordinator: Vanessa Rees
Albion Street Centre
Site principal: Don Smith
Site coordinator: Jega Sarangapany
Bigge Park Centre, Liverpool Hospital
Site principal: John Quin
Site coordinator: Gary Keogh
Burwood Road General Practice
Site principal: Nicholas Doong
Site coordinator: Jeff Hudson
Clinic 16, Royal North Shore Hospital
Site principal: George Kotsiou
Site coordinator: Joanne Holahan
Holdsworth House General Practice
Site principal: Mark Bloch
Site coordinator: Ruth Hutchison
Immunology and Infectious Diseases Clinic, John Hunter Hospital
Site principal: Michael Boyle
Site coordinator: Pauline Dobson
Immunology B Ambulatory Care Clinic, St Vincent’s Hospital
Site principal: David Cooper
Site coordinator: Richard Norris
Prince of Wales Hospital
Site principal: Kate Clezy
Site coordinator: Suzanne Ryan
Royal Prince Alfred Hospital
Site principal: Roger Garsia
Site coordinator: Marry Moussa
Taylor Square Private Clinic
Site principal: Robert Finlayson
Site coordinator: Robyn Richardson
Waratah Clinic, St George Hospital
Site principal: Pam Konecny
Site coordinator: Robyn Dever
Westmead Hospital
Site principal: Dominic Dwyer
Site coordinator: Margaret Piper

Queensland
AIDS Medical Unit, Queensland Health
Site principal: Mark Kelly
Site coordinator: Jo Murray
Clinic 87, Nambour General Hospital
Site principal: David Sowden
Site coordinator: Alan Walker
The Dolls House, Cairns Base Hospital Sexual Health Services
Site principal: Kay Haig
Site coordinator: Joanne Leamy
Gladstone Road Medical Centre
Site principal: David Orth
Site coordinator: David Youds
Gold Coast Sexual Health Clinic
Site principal: John Chuah
Site coordinator: Denise Lester
Royal Brisbane and Women’s Hospital
Site principal: Anthony Allworth
Site coordinator: Natalie Gerns

South Australia
Flinders Medical Centre
Site principal: Mark Boyd
Site coordinator: Robyn Gilligan
O’Brien Street Practice/The Care and Prevention Programme, Adelaide University
Site principal: Gary Rogers
Site coordinator: Michael Curry
Royal Adelaide Hospital
Site principal: David Shaw
Site coordinator: Wendy Ferguson
Victoria

Carlton Clinic
Site principal: Richard Moore
Site coordinator: Kaye Lowe

Clinical Research Section, Infectious Diseases Unit, The Alfred Hospital
Site principal: Jennifer Hoy
Site coordinator: Janine Roney

Melbourne Sexual Health Centre
Site principal: Tim Read
Site coordinator: Julie Silvers

Middle Park Clinic
Site principal: Ian Chenoweth
Site coordinator: Helen Wood

Northcote Clinic
Site principal: Nicholas Medland
Site coordinator: Helen Wood

Prahran Market Clinic
Site principal: Norman Roth
Site coordinator: Helen Wood

Royal Melbourne Hospital
Site principal: Alan Street
Site coordinator: Janine Roney

The Centre Clinic
Site principal: Nicholas Medland
Site coordinator: Helen Wood

Western Australia

Fremantle Hospital
Site principal: John Dyer
Site coordinator: Jacqueline Kerth

Royal Perth Hospital
Site principal: Martyn French
Site coordinator: Esther Edward

New Zealand sites

Christchurch Hospital
Site principal: Alan Pithie

Waikato Hospital
Site principal: Graham Mills
Site coordinator: Christine Tuffery

Wellington Hospital
Site principal: Tim Blackmore
Site coordinator: Jennifer Masters

Sarah Pett, Dianne Carey, Fraser Drummond, Rebekah Puls
HIV Epidemiology and Prevention Program

Overview

2005 was a very successful year for the HIV Epidemiology and Prevention Program in terms of obtaining research funding, and conducting high quality research on the epidemiology and natural history of HIV infection.

The vaccine preparedness cohort study, known as the Health in Men (HIM) Study, reached its fifth year. This study is conducted in collaboration with the National Centre in HIV Social Research and community partners. The study is now one of the largest ongoing studies of HIV risk in homosexual men in the world, and is probably the most comprehensive in terms of the study of interactions between HIV and sexually transmissible infections (STIs). After five years, the study is maturing and many separate analyses of HIV risk and associated factors are ongoing. In 2005, funding from the US National Institutes of Health ceased, but successful applications to the NSW Health Department and private industry enabled continuation of the study to the end of the year. In November, a NHMRC project grant was awarded which will enable the continuation of the study until 2007, and give the study sufficient power to examine whether specific STIs independently increase the risk of HIV infection. David Templeton, who was awarded a NHMRC Public Health Postgraduate Scholarship in 2004, began a study to examine the role of oral sex in transmission of sexually transmissible infections, the role of circumcision in HIV transmission, and the interrelationship between STI symptoms and diagnosis in the HIM Study as part of his PhD. In 2005, several important findings were published from the Study. First, a comparison of the last protected and unprotected acts of anal intercourse found that disclosure of HIV negative serostatus was a strong predictor of unprotected sex occurring on that occasion. This suggests that HIV negative men are using serosorting as an HIV risk reduction strategy. Second, an analysis of predictors of unprotected anal intercourse in serodiscordant relationships found that an undetectable viral load in the positive partner was predictive of unprotected anal intercourse. Third, data from HIM and other studies was used to describe the emerging syphilis epidemic in Australia. The notification rate of infectious syphilis in New South Wales increased dramatically between 1999 and 2003, and was confined to men. A case series study of men with syphilis found that HIV positive men were greatly over represented among syphilis cases.

The companion cohort study to HIM is of HIV positive homosexual men and is called the Positive Health (pH) Study. In 2005, a UNSW Faculty of Medicine research grant funded the testing of cohort participants for STIs. Initial results presented at the 17th Annual Conference of the Australasian Society for HIV Medicine in Hobart showed that the prevalence of STIs was higher than in HIV negative men.

The study of risk factors for HIV seroconversion continued to recruit well. An analysis, also presented at the 17th Annual Conference of the Australasian Society for HIV Medicine in Hobart, showed that injecting drug use was reported by over 20% of seroconverters.

In October 2005, the VivaGel™ Microbicide Development Consortium, of which NCHECR is one of four members, was awarded a four-year grant from the US National Institutes of Health. The grant will fund a comprehensive development program to evaluate the candidate microbicide SPL7013 ("VivaGel™") in non-clinical studies and clinical trials in Australia and Thailand. This research on an important potential HIV prevention method will build on the internationally recognised strengths of Australian and Thai organisations that have worked together for a number of years.

During 2005, the study of anal intra-epithelial neoplasia in HIV positive and HIV negative men was fully recruited. Also in the field of HIV-related cancer, a protocol was developed to allow linkage of the national HIV and AIDS registers with data from the Australian Institute of Health and Welfare. Such linkage projects involve complex processes for ethics approval. In 2005, ethics permission was granted by UNSW. This project will build upon previous work from the Program, and allow the description of cancer rates in those with chronic HIV infection and on long-term antiretroviral therapy.

Researchers at NCHECR conduct a variety of studies on the relationship between various forms of immune dysfunction and cancer. This extends the work that the HIV Epidemiology and Prevention Program undertakes in HIV-associated cancer. In 2005, we reported that a history of atopic disease, and being an only child or being a first born child in a larger family, were associated with a substantially decreased risk of non-Hodgkin’s lymphoma (NHL). These results are consistent with a hypothesis that early birth order and its immunologic consequence, a Th2-dominated immune response as reflected by a history of atopic disease, are associated with a reduced risk of NHL. We received funding to coordinate an international collaborative analysis of more than ten case-control studies which aim to replicate this finding in studies in Europe and North America. In addition, the study will examine auto-immune disease as a risk factor for NHL. Analyses on the NSW cancer-council funded project on cancer in transplant recipients nearing completion.
Projects

As well as having a supervisory role as Program Head for all projects that fall within the HIV Epidemiology and Prevention Program, Andrew Grulich takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: the international pooled analysis of immune risk factors for lymphoma, the study of the interaction between sexually transmissible infections and HIV infection in homosexual men, cancer in kidney dialysis patients and kidney transplant recipients, the Positive Health Study and the study of risk factors for AIDS in the HAART era.

HIV transmission and prevention research

HIV vaccine preparedness cohort study (Health in Men (HIM) Study)

A vaccine preparedness cohort study of HIV-negative homosexual men.

**Status:** Of 1,427 men enrolled in the study, 895 men were interviewed to end October 2005. In addition to testing for HIV, 98% were tested for hepatitis A and B and syphilis, and 90% were tested for gonorrhoea and chlamydia in the urine, throat and anus.

**Personnel:** Garrett Prestage, Jeff Jin

**Collaborators:** National Centre in HIV Social Research; Australian Federation of AIDS Organisations; AIDS Council of NSW

**Funding:** US National Institutes of Health; NSW Health Department; Becton Dickinson Pty Ltd; GlaxoSmithKline Australia

Interaction between sexually transmissible infections and HIV infection in the HIM study

A cohort study to examine the interaction between sexually transmissible infections and HIV incidence among initially HIV-negative homosexual men.

**Status:** 1,427 men enrolled in the study, of whom more than 90% consented to sexual health screening, including tests for gonorrhoea and chlamydia, as well as herpes simplex virus 1 (HSV1) and herpes simplex virus 2 (HSV2).

**Personnel:** Garrett Prestage, Jeff Jin, Basil Donovan, David Templeton (PhD student)

**Collaborators:** National Centre in HIV Social Research; Cathy Pell, Taylor Square Clinic; Australian Federation of AIDS Organisations; AIDS Council of NSW

**Funding:** US National Institutes of Health; NSW Health Department; Becton Dickinson Pty Ltd; GlaxoSmithKline Australia

Risk factors for HIV seroconversion

A study of risk factors for HIV infection among people with newly acquired HIV infection.

**Status:** By late 2005, 138 men had been enrolled.

**Personnel:** Garrett Prestage, Jeff Jin

**Collaborators:** PHAEDRA investigators (see Immunology and Pathogenesis Program); National Centre in HIV Social Research; Jonathan Volk

**Funding:** US National Institutes of Health

Demographic, behavioural and socio-economic risk factors for AIDS in the era of HAART: a pilot study

A cross sectional analytic study of new AIDS diagnoses in NSW between 1 January 2003 and 31 December 2004, designed to assess demographic, socio-economic and behavioural risk factors for AIDS and how they impact on use and compliance with HAART therapy.

**Status:** Study questionnaires were developed, and institutional ethics committee clearances for specific hospital sites in NSW sought.

**Personnel:** Marianne Jauncey, Ann McDonald

**Collaborator:** Communicable Diseases Branch, NSW Health Department

**Funding:** NSW Health Department

Back row: Patrick McGrath, Brian Acraman, Hedimo Santana, Garrett Prestage
Front row: Leon Botes, Kim Scholey, Jack Bradley
HIV prevention trials

Clinical development program to evaluate the safety and acceptability of the candidate vaginal microbicide, SPL7013

A series of studies under the VivaGel™ Microbicide Development Consortium program designed to comprehensively evaluate the clinical safety of 3% SPL7013 gel (VivaGel™). Topical microbicides such as VivaGel™ are products that are designed to prevent the sexual transmission of HIV and other pathogens.

The first of these studies is a phase 1, double blind placebo controlled study of the safety of 3% SPL7013 gel, when administered to the penis of healthy male volunteers once daily for seven days.

Status: The protocol for the first study was in the final stages of preparation for review by the US National Institutes of Health at the end of 2005.

Site for first study: Melbourne Sexual Health Centre

Enrolled/target for first study: 0/36

Personnel: Mary Poynten, Matthew Law, Lisa Maher

Collaborators: Starpharma Pty Limited; Macfarlane Burnet Institute for Medical Research; Thai Red Cross AIDS Research Centre; Melbourne Sexual Health Centre

Funding: US National Institutes of Health

HIV natural history research

Anal intraepithelial neoplasia (AIN) and anal human papillomavirus (HPV) infection in homosexual men

A prevalence study of AIN and anal HPV infection in a community sample of HIV negative and HIV positive homosexual men.

Status: 128 men in the HIV-positive cohort (pH Study) and 204 men in the HIV-negative cohort (HIM Study) were enrolled. Cytologic analysis of samples was completed and HPV testing was commenced. Men with screen-detected anal abnormalities were referred to St Vincent’s Hospital for follow-up anoscopy and biopsy.

Personnel: Claire Vajdic, Garrett Prestage, Marina van Leeuwen

Collaborators: Dorevitch Pathology - Mayne Health; Sexually Transmitted Infections Research Centre; St Vincent’s Hospital, Sydney; Cytyc Corporation Australia Pty Ltd

Funding: UNSW

Cancer in people with long standing HIV infection

A data linkage study examining rates and risk factors for cancer in people with HIV. A particular focus of the study is to examine rates of cancer in those with long-term mild immune deficiency.

Status: Study protocol developed, ethics approval granted by UNSW.

Personnel: Claire Vajdic, Marina van Leeuwen

Collaborators: Australian Institute of Health and Welfare; Australian HIV Observational Database investigators (see Biostatistics and Databases Program)

NSW lymphoma case-control study

A case control study of risk factors for non-Hodgkin lymphoma in the general population.

Status: Blood samples were analysed for EBV infection and single nucleotide polymorphisms (SNPs). Several manuscripts on the key occupational, environmental and immunological exposures were submitted and accepted for publication. NSW study data was also included in several international pooled analyses, either underway or submitted for publication in the areas of smoking, hepatitis C infection, and sun exposure.

Personnel: Claire Vajdic

Collaborators: The University of Sydney; Viral Epidemiology Section, Division of Cancer Epidemiology and Genetics, National Cancer Institute; St Vincent’s Hospital, Sydney; University of Western Australia; Monash University

Funding: NHMRC

International pooled analysis of immune risk factors for lymphoma

A pooled analysis of case-control studies of immune risk factors for lymphoma.

Status: An international meeting of collaborators was held, and member studies agreed to contribute data in early 2006. Study funding was obtained.

Personnel: Claire Vajdic

Collaborators: University of Southern California; German Cancer Research Centre; Feinberg School of Medicine, Northwest University; Centre for Study and Prevention of Cancer; Aviano Cancer Centre; Catalan Institute of Oncology; University of California, San Francisco; David Geffen School of Medicine, University of California, Los Angeles; University of York; British Columbia Cancer Registry; School of Medicine, Yale University

Funding: Leukaemia Foundation of New South Wales

Cancer in kidney dialysis patients and kidney transplant recipients

A project to link the Australian and New Zealand Dialysis and Transplant Register (ANZDATA) with the national cancer register to allow the identification of cancers that occur at increased rates, and the identifications of risk factors for development of cancer.

Status: Project staff worked with the Australian Institute of Health and Welfare to define the linkage algorithms and rules prior to linkage. An analysis plan was developed and the standardised incidence ratios for all cancer types for the three key exposure periods, prior to dialysis, during dialysis, and after transplantation, were calculated.

Personnel: Claire Vajdic, Matthew Law, Marina van Leeuwen

Collaborators: Australian and New Zealand Dialysis and Transplant Registry (ANZDATA); University of Otago; Westmead Hospital

Funding: NSW Cancer Council
**Australian long-term nonprogressor (LTNP) cohort**

A cohort study, established in 1994, of people with slowly progressive HIV disease.

**Status:** 82 LTNP participants remained under active follow-up to the end of 2005. The median length of infection for these individuals is 19 years.

**Personnel:** Melanie Middleton, Anthony Kelleher

**Collaborators:** Long-term nonprogressor study group, including clinical sites in Sydney, Canberra and Brisbane; NSW HIV Reference Laboratory, St Vincent's Hospital, Sydney

**Positive Health Study**

A cohort study of the health and health-related behaviours of HIV positive people.

**Status:** A total of 566 people living with HIV/AIDS have been enrolled in the study. In 2005, 286 were interviewed, including 46 who were interviewed for the first time. Of these, 177 consented to be tested for hepatitis A and B and syphilis, and for gonorrhoea and chlamydia in the urine, throat and anus.

**Personnel:** Garrett Prestage

**Collaborators:** National Centre in HIV Social Research; Australian Research Centre in Sex, Health and Society; Australian Federation of AIDS Organisations; National Association of People Living with HIV/AIDS

**Funding:** NSW Health Department; Faculty of Medicine, UNSW

Back row: Basil Donovan, Melanie Middleton, Mary Poynten, Ann McDonald
Front row: Claire Vajdic, Andrew Grulich, Marina van Leeuwin
Viral Hepatitis Clinical Research Program

Overview
The first year of the newly created Viral Hepatitis Clinical Research Program (VHCRP), following the division of the previous Viral Hepatitis Program, continued the Centre’s expanding role in viral hepatitis clinical trials and other clinical research.

Enrolment continued in clinical trials examining interferon-based therapy in chronic hepatitis C (CHARIOT) and acute hepatitis C (ATAHC). The CHARIOT trial is a randomised study examining the safety and efficacy of induction dosing pegylated interferon (in combination with ribavirin) in people with hepatitis C genotype 1, and is recruiting from 31 clinic sites around Australia. The Australian Trial in Acute Hepatitis C (ATAHC) is a five year US National Institutes of Health (NIH)-funded study examining the safety and efficacy of pegylated interferon monotherapy in acute and newly acquired hepatitis C. The study also examines the natural history of acute hepatitis C in an untreated prospective cohort. VHCRP also commenced coordination and monitoring of a study of pegylated interferon and ribavirin therapy in people with chronic hepatitis C receiving drug dependency treatment.

Follow-up was completed in HEPCOG, an open-label study examining the impact of chronic hepatitis C treatment on neurocognitive function, mood and quality of life in people with and without HIV coinfection.

By end of 2005, enrolment was close to completion in the TICO trial, a randomised controlled trial examining the safety and efficacy of tenofovir for HIV/hepatitis B coinfection, recruiting through HIV-NAT, Bangkok.

Other clinical research activities included ongoing enrolment into a NIH-funded HIV/hepatitis B coinfection cohort study, a study of lamivudine hepatitis B resistance in HIV/hepatitis B coinfection, and studies of hepatitis C treatment outcomes among injecting drug users.

A further highlight of 2005 was the awarding of a NHMRC project grant to examine the role of hepatitis C neutralising antibodies in acute hepatitis C within the ATAHC study. This grant, led by Dr Heidi Drummer, Macfarlane Burnet Institute for Medical Research and Public Health, is the second ATAHC-associated NHMRC project grant, and further strengthens the collaborations between VHCRP and basic science research groups.

Projects
As well as having a supervisory role as Program Head for all projects that fall within the Viral Hepatitis Clinical Research Program, Greg Dore takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: CHARIOT, ATAHC and TICO.

Australian trial in acute hepatitis C (ATAHC)
A study examining the natural history, safety and efficacy of pegylated interferon therapy for acute and newly acquired hepatitis C among injecting drug users.

Status: Recruitment commenced July 2004, and was ongoing during 2005.
Sites: 18 sites; further sites to be included
Enrolled/target: 60/240
Personnel: Barbara Yeung, Therese Carroll, Pip Marks, Carolyn Day, Anna Doab, Gail Matthews
Collaborators: Macfarlane Burnet Institute for Medical Research and Public Health; School of Pathology, UNSW; South-East Area Laboratory Service, Prince of Wales Hospital; St Vincent’s Hospital, Sydney; Prince Alfred Hospital; The Alfred Hospital; Kirketon Road Centre; Australian Hepatitis Council; Australian Injecting and Illicit Drug Users League (AIVL); Australian network of primary care and hospital-based hepatitis clinics
Funding: US National Institutes of Health; Roche Products Pty Ltd

Australian collaborative study in chronic hepatitis C genotype 1 (CHARIOT)
A randomised active control arm study examining the safety and efficacy of high dose induction pegylated interferon therapy, in combination with ribavirin, for chronic hepatitis C genotype 1 infection.

Status: Recruitment commenced August 2004, and was ongoing during 2005.
Sites: 31
Enrolled/target: 270/816
Personnel: Elizabeth Knight, Suzanne Polis, Wen Cao, Deam Amr, Natalie Espinosa, Pip Marks, Gail Matthews
Collaborators: Stuart Roberts, The Alfred Hospital; Australian network of hospital-based liver and hepatitis clinics
Funding: Roche Products Pty Ltd
**Tenoforv in HIV/hepatitis B coinfection (TICO)**

A randomized controlled trial to compare the safety and efficacy of tenoforv versus lamivudine versus tenoforv plus lamivudine as anti-hepatitis B active agents within the HAART regimen. The trial also compares early hepatitis B viral responses in people with HIV/hepatitis B coinfection, and hepatitis B monoinfection.

**Status:** Recruitment opened February 2004 (Australia), and August 2004 (Thailand).

**Sites:** 5 (4 Australia, 1 Thailand)

**Enrolled/target:** 35/36 for HIV/hepatitis B; 3/15 for hepatitis B

**Personnel:** Elizabeth Knight, Pip Marks, Chris Duncombe, Gail Matthews

**Collaborators:** HIV-NAT; St Vincent’s Hospital, Sydney; Royal Melbourne Hospital; The Alfred Hospital; Monash Medical Centre; Victorian Infectious Diseases Reference Laboratory

**Funding:** Gilead Sciences

**Methadone study: Hepatitis C treatment in drug dependency treatment clients**

Open label study of safety and efficacy of pegylated interferon and ribavirin for chronic hepatitis C in people receiving drug dependency treatment.

**Status:** Recruitment completed November 2005

**Sites:** 4

**Enrolled/target:** 51/50

**Personnel:** Pip Marks, Elizabeth Knight, Deama Amr, Wen Gao, Natalie Espinosa

**Collaborators:** Joe Sasadeusz, Royal Melbourne Hospital; St Vincent’s Hospital, Sydney; Nepean Hospital; Western Hospital

**Funding:** Roche Products Pty Ltd

**Hepatitis C and quality of life: Neuro-psychological involvement (HEPCOG)**

An open label trial of pegylated interferon and ribavirin to examine the impact of hepatitis C, treatment and viral clearance in neurocognitive impairment in people with HIV/hepatitis C coinfection, and hepatitis C monoinfection.

**Status:** Recruitment completed July 2004. Follow-up completed August 2005.

**Enrolled:** 18 HIV/hepatitis C coinfection; 16 hepatitis C monoinfection

**Personnel:** Rosie Thein

**Collaborators:** St Vincent’s Hospital, Sydney; La Trobe University; Royal Prince Alfred Hospital

**Funding:** Roche Products Pty Ltd

**Hepatitis B and C linkage**

This study involves the cross matching of hepatitis B and C notifications to the NSW Health Department over the period 1992-2002 with the NSW Cancer Register and the National Death Index. The information will enable determination of the hepatitis B and C attributable fractions for liver cancer cases, and the liver cancer incidence, liver disease-related and overall mortality rates among people with chronic hepatitis B and hepatitis C.

**Status:** Study completed, including analyses of mortality and cancer incidence for hepatitis C, hepatitis B, and hepatitis C/ hepatitis B coinfection.

**Personnel:** Janaki Amin, Matthew Law

**Collaborators:** NSW Health Department; NSW Cancer Council; Australian Institute of Health and Health Welfare

**Hepatitis C treatment referral in primary care-based methadone clinic**

Rates and predictors of hepatitis C referral and treatment outcomes assessed among a primary care based drug dependency treatment clinic in Redfern.

**Status:** Ongoing

**Collaborator:** The Byrne Surgery

**Natural history of acute hepatitis C**

Studies to examine the natural history of acute and newly acquired hepatitis C, including rates and predictors of viral clearance, risk of reinfection and superinfection, and early virological evolution of hepatitis C. Such studies help define the extent of protective immunity following prior hepatitis C infection, and may provide important insights into hepatitis C vaccine development.

**Status:** A preliminary study of hepatitis C viral diversity in acute hepatitis C monoinfection and acute hepatitis C/HIV coinfection was completed.

**Personnel:** Joanne Micallef (PhD student)

**Collaborators:** School of Medical Sciences, UNSW; South-East Area Laboratory Service, Prince of Wales Hospital; St Vincent’s Hospital, Sydney

**Funding:** US National Institutes of Health
Natural history of HIV/hepatitis B coinfection

A prospective cohort of people with HIV/hepatitis B coinfection to examine the impact of highly active antiretroviral therapy on liver disease progression and provide a means for surveillance of resistance to hepatitis B active agents.

**Status:** A preliminary cross-sectional study of lamivudine resistance among people with HIV/hepatitis B coinfection was completed. Recruitment commenced into a prospective cohort of HIV/hepatitis coinfection.

**Personnel:** Gail Matthews, Wen Cao

**Collaborators:** Johns Hopkins University; Victorian Infectious Diseases Reference Laboratory; The Alfred Hospital; Royal Melbourne Hospital; St Vincent’s Hospital, Sydney

**Funding:** US National Institutes of Health

Hepatitis B epidemiology and disease burden in Vietnam

Studies of seroprevalence and predictors of hepatitis B, and estimates and projections of hepatitis B-related liver disease burden in a rural province of northern Vietnam.

**Status:** Ongoing

**Personnel:** Van Thi Thuy Nguyen (MPH student)

**Collaborator:** School of Public Health and Community Medicine, UNSW

Viral Hepatitis Clinical Research Program (VHCRP) clinical trials network (Australian sites)

Each site listed below has recruited and followed at least one subject in a VHCRP research protocol during 2005.

**Australian Capital Territory**

- Canberra Hospital
  - Site principal: Geoff Farrell
  - Site coordinator: Anne Blunn

**New South Wales**

- 407 Doctors
  - Site principal: David Baker
  - Site coordinator: Robyn Vale

- Albion Street Centre
  - Site principal: George Marinos
  - Site coordinator: Jason Gao

- Bankstown-Lidcombe Hospital
  - Site principal: Chris Meredith
  - Site coordinator: Sandra Bluncoski

- Concord Hospital
  - Site principal: Alice Lee
  - Site coordinator: Vivienne Schiavone

- Concord Hospital
  - Site principal: Alice Lee
  - Site coordinator: Vivienne Schiavone

- Fitton Street Clinic
  - Site principal: Tracey Jones
  - Site coordinator: Nadine Leembruggen

- George Street Clinic
  - Site principal: Jon Watson
  - Site coordinator: Tracey Jones

- Kingston Road Centre
  - Site principal: Ingrid van Beek
  - Site coordinator: Therese Carroll

- Liverpool Hospital
  - Site principal: David Baker
  - Site coordinator: Robyn Vale

- Liverpool Sexual Health Clinic
  - Site principal: John Quin
  - Site coordinator: Pat Walker

- Nepean Hospital
  - Site principal: Martin Weltman, Nghi Phung
  - Site coordinator: Vince Fragogemli

- Royal Prince Alfred Hospital
  - Site principal: Geoff McCaughan, Paul Haber
  - Site coordinator: Sue Mason

- Taylor Square Private Clinic
  - Site principal: Neil Bodsworth
  - Site coordinator: Isabel Prone

- Waratah Clinic, St George Hospital
  - Site principal: John Freiman
  - Site coordinator: Robyn Dever

- Westmead Hospital
  - Site principal: Jacob George
  - Site coordinator: Jasmin Canete, SengKee Teo

- Wollongong Hospital
  - Site principal: Jenny McDonald
  - Site coordinator: Pat Bindley

**Holdsworth House General Practice**
Site principal: Mark Bloch
Site coordinator: Colin Anderson

**Immunology B Ambulatory Care Clinic, St Vincent’s Hospital**
Site principal: Greg Dore
Site coordinators: Rebecca Hickey, Zoe Potgeiter

**John Hunter Hospital**
Site principal: Jon Watson
Site coordinators: Tracey Jones, Nadine Leembruggen

**Kirketon Road Centre**
Site principal: Ingrid van Beek
Site coordinator: Therese Carroll

**Liverpool Hospital**
Site principal: Mark Cornwell
Site coordinator: Wendy Evans

**Liverpool Sexual Health Clinic**
Site principal: John Quin
Site coordinator: Pat Walker

**Nepean Hospital**
Site principals: Martin Weltman, Nghi Phung
Site coordinator: Vince Fragoemli

**Royal Prince Alfred Hospital**
Site principals: Geoff McCaughan, Paul Haber
Site coordinator: Sue Mason

**Taylor Square Private Clinic**
Site principal: Neil Bodsworth
Site coordinator: Isabel Prone

**Waratah Clinic, St George Hospital**
Site principal: John Freiman
Site coordinator: Robyn Dever

**Westmead Hospital**
Site principal: Jacob George
Site coordinators: Jasmin Canete, SengKee Teo

**Wollongong Hospital**
Site principal: Jenny McDonald
Site coordinator: Pat Bindley
Queensland

Nambour Hospital
Site principal: Don Walker
Site coordinator: Bronwyn Rynne

Princess Alexandra Hospital
Site principal: Darrell Crawford
Site coordinators: Fiona Giddens, Julie Roggeveen

Royal Brisbane and Women’s Hospital
Site principal: Barbara Leggett
Site coordinator: Deb D’Arcy

Townsville Hospital
Site principal: John Masson
Site coordinator: Sharon Cooke

South Australia

Flinders Medical Centre
Site principal: John Ring
Site coordinator: Rosalie Altus

Royal Adelaide Hospital
Site principals: Hugh Harley, David Shaw
Site coordinators: Megan Phelps, Catherine Ferguson

The Alfred Hospital
Site principals: Margaret Hellard, Sharon Lewin, Stuart Roberts
Site coordinators: Oanh Nguyen, Craig Scholten, Caroline Day

Western Hospital
Site principal: Ian Kronborg
Site coordinator: Marian Croft

Western Australia

Fremantle Hospital
Site principal: Lindsay Mollison
Site coordinators: Lynette Booth, Gim Andrews

Royal Perth Hospital
Site principal: Wendy Cheng
Site coordinator: Saroj Nazareth

Sir Charles Gairdner Hospital
Site principal: Gary Jefferies
Site coordinator: Joanne Young

Victoria

Austin Hospital
Site principal: Peter Angus
Site coordinators: Lisa Thompson, Brenda Morales

Box Hill Hospital
Site principal: Peter Gibson
Site coordinator: Sarah Chivers

Frankston Hospital
Site principal: David Badov
Site coordinator: Rita Coffey

Geelong Hospital
Site principal: Damian Dowling
Site coordinator: Margaret Wardrop

HealthWorks (referral site)
Site principal: Fran Branwell

Macfarlane Burnet Institute for Medical Research and Public Health
Site principal: Margaret Hellard
Site coordinator: Oanh Nguyen

Monash Medical Centre
Site principal: Bill Sievert
Site coordinator: Sherryne Warner

Royal Melbourne Hospital
Site principal: Joe Sasadeusz
Site coordinators: Maxine Giourouki, Craig Scholten

St Vincent’s Hospital
Site principal: Paul Desmond
Site coordinator: Danielle Croall
Viral Hepatitis Epidemiology and Prevention Program

Overview

The Viral Hepatitis Epidemiology and Prevention Program (VHEPP) was created in 2005. The primary functions of VHEPP are to conduct epidemiological, social and behavioural research examining risk behaviour and blood-borne virus transmission among injecting drug users; monitor trends in blood-borne virus incidence and prevalence among injecting drug users in Australia; undertake support viral hepatitis surveillance activities; and initiate and implement strategic research on effective behavioural and biomedical prevention strategies, vulnerable sub-populations, and epidemiological, cultural and social aspects of viral hepatitis.

Activities in 2005 included studies examining the impact of cultural beliefs and practices on vulnerability to blood-borne viruses among Indo-Chinese injecting drug users, the ethno-epidemiology of psycho-stimulant use and hepatitis C treatment needs of current injecting drug users, and commencement of the evaluation of the Sydney Medically Supervised Injecting Centre.

A highlight of 2005 was the award of a five year NHMRC grant in collaboration with researchers and Indigenous communities in Australia, Canada and New Zealand to examine resilience, blood-borne viruses and sexually transmissible infections in Indigenous communities. The Australian arm consists of a partnership between NCHECR and three of the largest and longest-established urban Aboriginal Community Controlled Health Services: Aboriginal Medical Service, Redfern (Sydney); Derbarl Yerrigan Medical Service (Perth) and the Townsville Aboriginal and Islanders Health Services. This project provides a valuable opportunity to investigate rates of infections in three countries, compare underlying risk and protective factors and increase understanding of the social and cultural factors that protect Indigenous peoples against these infections and their consequences.

Projects

As well as having a supervisory role as Program Head for all projects that fall within the Viral Hepatitis Epidemiology and Prevention Program, Lisa Maher takes specific responsibility as a named Principal Investigator in the following projects:

Clinical development program to evaluate the safety and acceptability of the candidate vaginal microbicide SPL7013 (see HIV Epidemiology and Prevention Program). The role of resiliency in responding to blood-borne viral and sexually transmitted infections in Indigenous communities, Ethno-epidemiology of psycho-stimulant related harms in Australia and the Evaluation of the Medically Supervised Injecting Centre.

Vulnerability to blood-borne viral infections among ethnic Vietnamese injecting drug users

Ethnographic and epidemiological research designed to identify explanatory models of health and illness and risk/protective behaviours, and determine antibody HIV and hepatitis C and associated risk factors in ethnic Vietnamese injecting drug users in South Western Sydney.

Status: Data collection and analysis were completed, and write up was in progress during 2005.
Personnel: Hien Thi Ho (PhD student)
Collaborator: Nick Crofts, Turning Point Alcohol and Drug Centre
Funding: AusAID

Evaluation of the Medically Supervised Injecting Centre (MSIC)

Evaluation of the extension of the MSIC trial (Phase II, 2002-2007) involving primary and secondary data collection including service data, an observational cohort study of injecting drug users, and local resident and business surveys.

Status: All reports were submitted as per contract requirements. The cohort study was in progress.
Personnel: Allison Salmon
Collaborators: Sydney Medically Supervised Injecting Centre; NSW Health Department; Hunter Valley Research Foundation
Funding: NSW Health Department
Participatory action research with young injecting drug users

A participatory needs assessment of young injecting drug users in South Western Sydney who do not access services, designed to inform service planning, build capacity in research practice and increase consumer participation in drug health services.

Personnel: Heidi Coupland
Collaborators: Bankstown Community Health Centre; Campbelltown Drug Health Services
Funding: South Western Sydney Area Health Service

NSW needle and syringe program (NSP) client census

Annual census of clients attending needle and syringe programs in NSW conducted in conjunction with the annual national NSP survey.

Status: The final report of the 2004 census was completed and released. No census was carried out during 2005. The NSW Health Department considered changes to the census model for future data collection.
Personnel: Bethany White
Funding: NSW Health Department

Culture, risk and hepatitis C

Qualitative study examining the relationships between cultural beliefs and practices and hepatitis C-related risk and protective factors, including treatment in Indo-Chinese injecting drug users.

Personnel: Heidi Coupland
Funding: NSW Health Department; Faculty of Medicine, UNSW

Hepatitis C treatment for injecting drug users

Research examining exploring how current injecting drug users perceive hepatitis C treatment and how they feel about participating in clinical trials. The study will assess participants’ level of hepatitis C knowledge, treatment and treatment outcomes and perceived or real barriers to hepatitis C treatment.

Status: Ethical approval obtained and preliminary work commenced in 2005.
Personnel: Carolyn Day, Greg Dore
Collaborators: Australian Hepatitis Council; Australian Injecting and Illicit Drug Users League

Ethno-epidemiology of psychostimulant-related harms in Australia

Multi-disciplinary research which aims to identify factors underlying the rising prevalence of psychostimulant use in Australia and their implications for public health. The study will be conducted in Sydney, Melbourne and Perth and will access a range of psychostimulants using both ethnographic and epidemiological research methods and techniques.

Status: Study commenced in mid 2005, and ethnographic fieldwork progressed.
Personnel: Suzie Hudson (PhD student)
Collaborators: National Drug Research Institute, Curtin University; Monash University; Australian National University
Funding: NHMRC

The role of resiliency in responding to blood-borne viral and sexually transmitted infections in Indigenous communities

A collaborative project in Australia, Canada and New Zealand to examine resilience, blood-borne viruses and sexually transmissible infections in Indigenous communities. With a focus on adolescents and young adults in urban settings, the Australian component of the study will identify factors among Aboriginal and Torres Strait Islander people that protect against acquisition of blood-borne viruses and sexually transmissible infections (BBV/STI), identify factors that promote access to services for prevention and management of BBV/STI, and assess interventions based on these findings. The research will also provide capacity building opportunities for Indigenous researchers and community organisations.

Status: Preliminary work commenced in 2005.
Personnel: Chris Lawrence, Andrew Grulich, Garrett Prestage
Collaborators: Sandra Eades; Aboriginal Medical Service Coop Ltd, Redfern; Derbarl Yerrigan Health Service; Townsville Aboriginal and Islanders Health Services Ltd; Centre for Infectious Disease Prevention and Control, Health Canada; Canadian Aboriginal AIDS Network; University of Ottawa; Ngã Pae o te Mãramatanga, University of Auckland; Auckland University of Technology; University of Otago Medical School
Funding: Tripartite Cooperation Agreement between Canadian Institutes of Health Research (CIHR), the National Health and Medical Research Council of Australia (NHMRC) and the Health Research Council of New Zealand (HRC NZ)
Biostatistics and Databases Program

Overview

The Biostatistics and Databases Program combines both technical support and research functions. The primary functions of the Program are to ensure that across the wide range of NCHECR activities studies are designed appropriately from a statistical perspective, data are housed in properly specified robust databases, and statistical analyses are conducted to high scientific standards. Virtually all NCHECR research activity relies on these technical support functions. As well as supporting the Centre’s other Programs’ research, the Biostatistics and Databases Program has its own research activities, primarily in clinical cohort studies, mathematical modelling and statistical methodology.

The Program develops databases, based on Oracle software, for all NCHECR clinical trials, and also for a number of other studies. During 2005, databases for a number of studies were developed, including FLASH, the Toxicity Substudy of ESPRIT, STEAL, the tenofovir in HIV/hepatitis B coinfection and the therapy for newly acquired hepatitis C study (see Therapeutic and Vaccine Research and Viral Hepatitis Clinical Research Programs). Biostatistical analyses were performed on the Alliance, *ROSEY, *MITOX, *INITIO and *Lipodystrophy Case Definition studies (*see Therapeutic and Vaccine Research Program, Annual Reports 2002 and 2004). A further major activity, with the Therapeutic and Vaccine Research and Viral Hepatitis Clinical Research Programs, was to develop working procedures and databases to implement coding of adverse events across NCHECR clinical trials using the MedDRA database.

During 2005, the Program also continued to undertake clinical cohort studies. The Australian HIV Observational Database (AHOD) followed over 2,000 patients recruited from 27 sites, and continued to provide regular information on antiretroviral use and outcomes among patients with HIV infection in Australia. Data from AHOD also contributed to the Data Collection on Adverse Events of Anti-HIV Drugs Study, a large, international collaborative observational study designed to evaluate the medium-term risk of cardiovascular disease in patients with HIV receiving antiretroviral drugs.

The TREAT Asia HIV Observational Database, an observational study involving several countries in the Asia-Pacific region, continued follow-up during 2005. Data from almost 3,000 patients at 15 sites throughout the region were aggregated. Analyses examined the use of commonly used combination antiretroviral regimens used in the region, and rates of AIDS diagnoses shortly after commencement of antiretroviral treatment.

In mid 2005, Dr David Regan, a post-doctoral mathematical modeller, was recruited to the Program, funded through a NHMRC Capacity Building Grant in mathematical modelling of infectious disease epidemics. This expansion has already allowed significantly greater mathematical modelling work to be undertaken by the Program, including commencing projects modelling chlamydia and human papilloma virus infection in Australia, and an AusAID-funded project, in collaboration with the National HIV Social Research Centre, performing epidemiological and economic modelling of the HIV epidemics in Indonesia, Papua New Guinea and East Timor.

Projects

As well as having a supervisory role as Program Head for all projects that fall within the Biostatistics and Databases Program, Matthew Law takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: The Australian HIV Observational Database, including it’s contribution to the Data Collection on the Adverse Events of Anti-HIV Drugs Study, and the TREAT Asia HIV Observational Database.

The Australian HIV Observational Database (AHOD)

Observational cohort study of patients with HIV. Demographic, clinical and treatment data are aggregated twice each year via electronic data transfer.

Status: 2,329 patients continued to be followed up during 2005.

Personnel: Kathy Petoumenos

Collaborators: Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia
The Data Collection on the Adverse Events of Anti-HIV Drugs Study (DAD)

Large, international, collaborative study aimed at assessing the medium to long-term effects of antiviral treatment of people with HIV in terms of possible increased risk of cardiovascular events.

**Status:** The study combines data from 11 cohorts, including 23,468 patients. Australia contributes 706 patients from the Australian HIV Observational Database. Follow up was confirmed through to at least 2008.

**Personnel:** Kathy Petoumenos

**Collaborators:** Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia; Copenhagen HIV Programme, Hvidovre University Hospital

**Funding:** European Agency for the Evaluation of Medicinal Products (EMEA)

Biostatistics and database support

Writing clinical trial databases, and providing biostatistical input to the design and analysis of all NCHECR projects.

**Status:** During 2005, members of the Program actively contributed to the Toxicity Substudy of ESPRIT and the FLASH, STEAL, Alliance, *ROSEY, *MITOX, *INITIO and *Lipodystrophy Case Definition studies (*see Therapeutic and Vaccine Research Program, Annual Reports 2002 and 2004), as well as the Viral Hepatitis Clinical Research Program’s tenofovir in HIV/hepatitis B coinfection study and the therapy for newly acquired hepatitis C study.

**Personnel:** Noorul Absar, Janaki Amin, Rossitza Chevkenova, Kathy Petoumenos, Handan Wand, Jialun Zhou

**Collaborators:** Other Programs at NCHECR

**Funding:** Project-specific grants

Causes of death among ex-prisoners in NSW

Mortality rates among ex-prisoners in NSW between 1988 and 2002 are assessed by linkage between the Offender Management System at the Department of Corrective Services, and the National Death Index at the Australian Institute of Health and Welfare.

**Status:** Analyses of examining covariate associated with mortality among prisoners were performed.

**Personnel:** Azar Kariminia (PhD student)

**Collaborators:** Corrections Health Service; Tony Butler, Centre for Health Research in Criminal Justice

**Funding:** NHMRC

Data from the highly specialised drugs program

Summary data of patients receiving antiretroviral treatments funded through the Highly Specialised Drugs Program are received from the Australian Government Department of Health and Ageing, and published in annual and biannual surveillance reports.

**Status:** Ongoing during 2005, with publication in NCHECR’s surveillance reports.

**Personnel:** Kathy Petoumenos

**Collaborator:** Highly Specialised Drugs Program, Special Access and Coordination Section, Pharmaceutical Access and Quality Branch, Australian Government Department of Health and Ageing

**Funding:** European Agency for the Evaluation of Medicinal Products (EMEA)

Causes of death among ex-prisoners in NSW

Mortality rates among ex-prisoners in NSW between 1988 and 2002 are assessed by linkage between the Offender Management System at the Department of Corrective Services, and the National Death Index at the Australian Institute of Health and Welfare.

**Status:** Analyses of examining covariate associated with mortality among prisoners were performed.

**Personnel:** Azar Kariminia (PhD student)

**Collaborators:** Corrections Health Service; Tony Butler, Centre for Health Research in Criminal Justice

**Funding:** NHMRC

Mathematical modelling of infectious disease epidemics

Mathematical models are used to assess various aspects of HIV and hepatitis C epidemics in Australia and the Asia-Pacific region.

**Status:** Projects modelling HIV and hepatitis C virus epidemics in Australia were commenced during the second half of 2005.

**Personnel:** Karina Razali (PhD student), David Regan

**Collaborator:** National Centre in HIV Social Research

**Funding:** University of Malaya; NHMRC

TREAT Asia HIV Observational Database (TAHOD)

Observational cohort study of patients with HIV at eleven sites throughout the Asia-Pacific region. Demographic, clinical and treatment data are aggregated twice each year via electronic data transfer.

**Status:** At the data transfer in September 2005, baseline and retrospective data from some 2,957 patients were aggregated. It is expected that follow up will continue for up to a further five years.

**Personnel:** Jialun Zhou, Julian Elliott

**Collaborators:** Network of 15 clinical sites at countries through the Asia-Pacific region

**Funding:** American Foundation for AIDS research (amfAR)
Mathematical modelling for improved planning of infectious disease control policy

This is an NHMRC Capacity Building Grant to develop capacity for mathematical modelling for improved planning of infectious disease control policy in Australia. A number of projects are envisaged over the five-year life of the grant. Initial projects at NCHECR are mathematical models of human papilloma virus and chlamydia transmission in Australia.

Status: Initial training meetings took place in August 2005.

Personnel: David Regan

Collaborators: National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases; National Centre for Epidemiology and Population Health; Centre for International Health; School of Population Health, Melbourne University; Victorian Infectious Diseases Service

Funding: NHMRC

Mathematical modelling of human papilloma virus transmission

This study involves the development of a mathematical model of human papilloma virus (HPV) transmission in Australia to assess the effect of various HPV vaccine schedules on HPV incidence and prevalence. These HPV incidence and prevalence estimates are then used as inputs into separate models of HPV disease natural history to assess the cost-effectiveness of HPV vaccine schedules on preventing cervical cancer.

Status: HPV natural history was reviewed, and preliminary models developed during 2005.

Personnel: David Regan

Collaborators: National Centre in HIV Social Research; CSL Limited

Funding: NHMRC; CSL Limited

HIV Epidemiological Modelling and Impact (HEMI)

This study involves the development of mathematical models to predict the course of the HIV epidemic, based on the best available epidemiological data and three different intervention scenarios in Papua New Guinea, Indonesia and East Timor. The model outputs are applied to forecast the economic, social and security consequences of HIV/AIDS under each of the three intervention scenarios.

Status: Report submitted to AusAID

Personnel: Karina Razali (PhD student)

Collaborator: National Centre in HIV Social Research

Funding: AusAID

Simplified CD4 and HIV viral load monitoring schemes in Thailand

Biostatistical analyses and mathematical models are used to develop and assess simplified CD4 and HIV viral load monitoring schemes in Thai patients with HIV receiving antiretroviral treatment. Analyses are based on the HIV-NAT clinical trial database (see Clinical and epidemiological research in the Asia-Pacific region) and the TREAT Asia HIV Observational Database (TAHOD).

Status: Parametric statistical models to predict immunological or virological failure were developed from the HIV-NAT cohort, and validated in both the HIV-NAT and TAHOD data.

Personnel: Preeyaporn Srasuebkul (PhD student)

Collaborators: HIV-NAT, TAHOD investigators

Funding: American Foundation for AIDS research (amfAR)

Analyses of the National Creutzfeldt-Jakob Disease Registry

Biostatistical and epidemiological advice and support is provided for the analysis and interpretation of Registry data.

Status: Ongoing

Personnel: Handan Wand

Collaborator: The Australia National Creutzfeldt-Jakob Disease Registry

Transmissible spongiform encephalopathies

Biostatistical and epidemiological advice and support regarding assessments of risk of transmission of transmissible spongiform encephalopathies through products derived from blood donations or fetal-calf serum is provided.

Status: Ongoing

Personnel: David Regan

Collaborators: Australian Red Cross Blood Service; Therapeutic Goods Administration; Australian Government Department of Health and Ageing
Australian HIV Observational Database (AHOD) network

New South Wales

407 Doctors
Site principal: David Baker
Site coordinator: Robyn Vale

Bligh Street Clinic
Site principal: Miriam Gotowski
Site coordinators: Sharon Taylor, Lydia Stuart-Hill

Blue Mountains Sexual Health and HIV Clinic
Site principal: Eva Jackson
Site coordinator: Kerrie McCallum

Holden Street Clinic
Site principal: Debbie Allen
Site coordinator: Brooke Strazdinis

Holdsworth House General Practice
Site principal: Mark Bloch
Site coordinators: Colin Anderson, Shikha Agrawal

Illawarra Sexual Health
Site principal: Katherine Brown
Site coordinator: Nina Skobalj

Immunology B Ambulatory Care Clinic,
St Vincent’s Hospital
Site principals: David Cooper, Andrew Carr
Site coordinators: Mark Lacey, Karl Hesse

Lismore Sexual Health and AIDS Services (SHAIDS)
Site principal: David Smith
Site coordinator: Jude Armishaw

Livingstone Road Sexual Health Centre
Site principal: Catherine O’Connor
Site coordinator: Ben Allam

Macquarie Sexual Health Centre
Site principals: David Templeton, Trish Bullen

Medical and Vein Centre
Site principal: David Ellis

Nepean Sexual Health and HIV Clinic
Site principal: Tong Liang

Sydney Sexual Health Centre
Site principal: Basil Donavon
Site coordinator: Ben Judd

Taylor Square Private Clinic
Site principal: Robert Finlayson
Site coordinator: Robyn Richardson

Northern Territory

Communicable Disease Centre, Royal Darwin Hospital
Site principal: Brian Hughes
Site coordinator: Peter Knibbs

Queensland

AIDS Medical Unit, Queensland Health
Site principal: Mark Kelly
Site coordinator: Henry Magon

Blackall Terrace Specialist Centre
Site principal: David Sowden
Site coordinator: Alan Walker

Gladstone Road Medical Centre
Site principal: David Orth
Site coordinator: David Youds

Gold Coast Sexual Health Clinic
Site principal: John Chuah
Site coordinators: Denise Lester, Wendy Fankhauser, Bridget Dickson

The Dolls House, Cairns Base Hospital Sexual Health Services
Site principal: Darren Russell
Site coordinators: Joanne Leamy, Clive D’arcy Evans

South Australia

Care and Prevention Programme, Adelaide University
Site principal: Gary Rogers

Victoria

Carlton Clinic
Site principal: Jonathan Anderson
Site coordinator: Kaye Lowe

Melbourne Sexual Health Centre
Site principal: Tim Read
Site coordinator: Jennifer Laing

Monash Medical Centre
Site principal: Ian Woolley

Prahran Market Clinic
Site principal: Norman Roth
Site coordinator: Helen Wood

The Alfred Hospital
Site principals: Ann Mijch, Jennifer Hoy
Site coordinators: Melissa Bryant, Kerrie Watson

Western Australia

Department of Clinical Immunology, Royal Perth Hospital
Site principal: Simon Mallal
Site coordinators: Jenny Skett, Allison Cain
Immunovirology and Pathogenesis Program

Overview

The Immunovirology and Pathogenesis Program (IVPP) was formed in 2005, resulting from the amalgamation of the Laboratory Support and Primary HIV Infection Research Programs. This resulted from the identification of a number of areas of clear complementarities between these two Programs, and during the year increasing cross fertilisation took place, which was accelerated by the institution of combined weekly meetings, and by steps taken towards the seamless linking of data bases previously held separately by the two groupings. This enhanced the standardisation of common work practices and mechanisms of data analysis.

The work of IVPP during 2005 can be divided into three categories. A substantial proportion of laboratory-based activity was directed towards providing routine or semi-routine laboratory procedures essential for the successful conduct of clinical trials and epidemiological studies, through processing of specimens and conduct of specialised assays. This was in support of studies conducted by IVPP, as well as other NCHECR Programs. Secondly, the conduct of clinical trials and natural history studies commenced by the former Primary HIV Infection Research Program continued. Central to these activities was the continuation of recruitment to the US National Institutes of Health-funded Acute Infection Early Disease Research Program (AIEDRP) in collaboration with Massachusetts General Hospital, a five-year program of research into treatment and pathogenesis of primary HIV infection. And finally, senior scientists and academics within the Program were also responsible for their own research projects on pathogenesis.

During 2005, the laboratory component of IVPP completed the conduct of assays assessing the immunogenicity and mode of action of a fowl pox-based vector co-expressing both HIV proteins and Interferon used as a therapeutic vaccine in patients treated with HAART during primary infection. It continued to act as the Australian coordinating laboratory for the natural history studies conducted through AIEDRP, as well as for the ESPRIT and SMART (see Therapeutic and Vaccine Research Program) studies, and assisted in the successful initiation of the STEAL (see Therapeutic and Vaccine Research Program) and SPARTAC studies.

Other activities in the area of primary HIV infection related support to the HIV-NAT and Thai Red Cross laboratories.

Pathogenesis work relating to CD4 T-cell function in early HIV infection and in natural controllers of the disease expanded during 2005. New methodologies were established in the laboratory resulting in the lodging of one provisional patent, and the preparation of another patent application. Other novel methodologies have been established allowing the molecular characterisation of formalin-fixed cells which will aid our study of HIV-specific T-cell repertoires. This methodology will enhance existing collaborations with Peter Doherty’s and Stephen Kent’s groups (both at The University of Melbourne) and Ian Ramshaw’s group (Australian National University) in T-cell biology aimed at aiding vaccine development.

During 2005, the laboratory was awarded a NHMRC equipment grant which will aid in the establishment of a biologically contained 10 colour 12 parameter high speed cell sorter in the PC3 laboratory, allowing for sorting of lymphocyte sub-populations, and molecular and functional characterisation of these poorly understood sub-populations for the first time. These advances help to keep the laboratory-based research performed within the Program internationally competitive.

Professor Alan Landay completed a year with the Program on sabbatical from Rush Medical School, Chicago. His knowledge of HIV immunology, his high level of enthusiasm and his unparalleled experience with the conduct of immunological assays in the context of clinical trials added a new and invigorating dimension to the IVPP in its inception year.

Projects

As well as having a supervisory role as Program Head for all projects that fall within the Immunovirology and Pathogenesis Program, Anthony Kelleher takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: AINS04, SPARTAC, PHAEDRA, CORE01, the long term non-progressor cohort and the NHMRC Program Grant entitled “HIV infection, immunology and vaccine design”. He provides project-related support to the HIV-NAT and Thai Red Cross HIV Research laboratories.
Clinical trials and cohort studies

The Australian Primary HIV Infection Database

An ongoing prospective cohort of patients with primary HIV infection.

**Status:** During 2005, 66 new cases of newly acquired HIV infection were entered into the primary HIV infection database. Information was routinely updated from laboratory and clinical data bases.

**Personnel:** Tim Ramacciotti, Pat Grey, Kathy Petoumenos, Anthony Kelleher

**Collaborators:** Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert Finlayson, Taylor Square Private Clinic; Robert McFarlane, 407 Doctors; Nick Medland, The Centre Clinic; Philip Cunningham, John Zaunders, Centre for Immunology, St Vincent's Hospital, Sydney

Concerted Action on Seroconversion to AIDS and Death in Europe Study

The Concerted Action on Seroconversion to AIDS and Death in Europe (CASCADE) collaboration is a long term collaborative cohort study on vital status, laboratory markers, antiretroviral treatment changes and disease progression, one aim of which is to discern whether survival or rate of progression to AIDS is altered by earlier treatment.

**Status:** 332 Australian subjects contribute to this cohort, 225 of which were followed during 2005.

**Personnel:** Tim Ramacciotti, Anthony Kelleher

**Collaborator:** Concerted Action on Seroconversion to AIDS and Death in Europe

**Funding:** Medical Research Council

Acute Infection Early Disease Research Program (AIEDRP)

A five-year program for research into the treatment and pathogenesis of primary HIV infection.

**Status:** Collaboration continued with Massachusetts General Hospital under the leadership of Bruce Walker, working in both Sydney and Melbourne with primary care and hospital sites on recruitment, follow up and treatment of people with primary HIV infection.

**Personnel:** Pat Grey, Tim Ramacciotti, Matthew Law, Ansari Shaik, Anthony Kelleher

**Collaborators:** Partners AIDS Research Center (Massachusetts General Hospital), Harvard University; US National Institutes of Health; Don Smith, Albion Street Centre; Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert McFarlane, 407 Doctors; Nick Medland, The Centre Clinic; Philip Cunningham, John Zaunders, Centre for Immunology, St Vincent's Hospital, Sydney

**Funding:** US National Institutes of Health

Core01

The basic protocol of the AIEDRP network, by which acute and early patients are recruited and followed for five years, and within which interventional sub-studies may take place.

**Status:** 49 new participants were enrolled during 2005, making a cumulative total of 200. These patients will continue to be followed up until 2007.

**Personnel:** Tim Ramacciotti, Pat Grey, Anthony Kelleher, Mee-Ling Munier, Ansari Shaik

**Collaborators:** Don Smith, Albion Street Centre; Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert McFarlane, 407 Doctors; Nicholas Medland, The Centre Clinic; Norman Roth, Prahran Market Clinic; Phillip Cunningham, John Zaunders, Centre for Immunology, St Vincent's Hospital, Sydney; Kate McGhie, HIV Immunology Laboratory, Garvan Institute of Medical Research; Partners AIDS Research Center (Massachusetts General Hospital), Harvard University

**Funding:** US National Institutes of Health

Primary HIV and early disease research – Australian cohort (PHAEDRA)

A systematic mechanism to recruit and follow up a cohort of people in Sydney and Melbourne with acute and early HIV-1 infection.

**Status:** 20 new participants were enrolled during 2005, making a cumulative total of 273 (141 of which have been transferred to Core01).

**Personnel:** Pat Grey, Anthony Kelleher, Tim Ramacciotti, Mee-Ling Munier, Jennifer Hoy

**Collaborators:** Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert McFarlane, 407 Doctors; Nicholas Medland, The Centre Clinic; Norman Roth, Prahran Market Clinic; Phillip Cunningham, John Zaunders, Centre for Immunology, St Vincent's Hospital, Sydney; Kate McGhie, HIV Immunology Laboratory, Garvan Institute of Medical Research; Partners AIDS Research Center (Massachusetts General Hospital), Harvard University; The Alfred Hospital; Tim Read, Melbourne Sexual Health; Sydney Sexual Health

**Funding:** US National Institutes of Health
Primary HIV Infection Structured Treatment Interruption Trial (AIN502)

A randomised multicentre trial to determine whether induction therapy followed by treatment interruption is superior to induction therapy alone in the treatment of primary HIV infection.

**Status:** Final US regulatory approval was obtained during 2005, but it was decided not to proceed with the study because it was considered by the study’s steering committee that the scientific question was no longer relevant.

**Personnel:** Pat Grey, Matthew Law, Anthony Kelleher

**Collaborators:** Partners AIDS Research Center (Massachusetts General Hospital), Harvard University; US National Institutes of Health; Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert Finlayson, Taylor Square Private Clinic; Robert McFarlane, 407 Doctors; Nick Medland, The Centre Clinic; Philip Cunningham, John Zaunders, Centre for Immunology, St Vincent’s Hospital, Sydney; Don Smith, Albion Street Centre

**Funding:** US National Institutes of Health

Treatment interruption trial in primary HIV infection (PULSE)

A treatment interruption trial in primary HIV infection to determine whether control of the HIV virus can be achieved by the patient’s own immune system using intermittent therapy initiated in primary infection.

**Status:** During 2005, the last planned analysis of the trial data was completed and a manuscript submitted for publication.

**Personnel:** Pat Grey, Kathy Petoumenos, Mee-Ling Munier, Anthony Kelleher

**Collaborators:** Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House Private Practice; Robert McFarlane, 407 Doctors; Norman Roth, Prahran Market Clinic; John Chuah, Gold Coast Sexual Health Clinic; Kate McGhie, HIV Immunology Laboratory, Garvan Institute of Medical Research; Jonathon Weber, Medical Research Council; Jonathon Weber, Sarah Fidler, Imperial College; Robert Finlayson, Taylor Square Private Clinic; Philip Cunningham, Centre for Immunology, St Vincent’s Hospital, Sydney; Don Smith, Albion Street Centre

**Funding:** Bristol Myers Squibb

Primary HIV infection therapeutic vaccine trial (AIN504)

A randomised phase II study of therapeutic immunisation and treatment interruption among subjects who began potent antiretroviral therapy within 16 days of diagnosis of acute or recent HIV infection.

**Status:** This study passed through regulatory procedures, including obtaining local ethics committee, Gene and Related Therapies Research Advisory Panel and Office of Gene Technology Regulator approvals. The laboratory also successfully completed mandatory training by Merck Research Laboratories for PBMC storage.

**Personnel:** Anthony Kelleher, Pat Grey

**Collaborators:** US National Institutes of Health; Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House Private Practice; Robert McFarlane, 407 Doctors; Cassy Workman, AIDS Research Initiative; Philip Cunningham, Kate Merlin, Centre for Immunology, St Vincent’s Hospital, Sydney

**Funding:** US National Institutes of Health

Randomised trial in primary HIV infection looking at three forms of intervention (SPARTAC)

**Short pulse antiretroviral treatment at seroconversion**

This trial looks at the effect on CD4 T-cells of three interventions at primary HIV infection, either treating with antiretroviral therapy for 12 or 48 weeks or not treating at all until CD4 declines to <350 cells.

**Status:** 11 patients screened, 9 of which were randomised.

**Personnel:** Anthony Kelleher, Pat Grey

**Collaborators:** Medical Research Council; Jonathon Weber, Sarah Fidler, Imperial College; Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House Private Practice; Robert McFarlane, 407 Doctors; Cassy Workman, AIDS Research Initiative; Philip Cunningham, Centre for Immunology, St Vincent’s Hospital, Sydney

**Funding:** Wellcome Trust

Laboratory service and support

**Specimen receipt and processing for clinical trials and natural history studies**

The laboratory provides a service to other NCHECR Programs encompassing the separation of blood components; cryopreservation of serum, plasma and PBMC; and archiving and onshipping of samples. This allows for the smooth running of clinical trials and natural history studies.

**Status:** Ongoing

**Personnel:** Anthony Kelleher, Ciara McGinley, Mee-Ling Munier (PhD student)

**Collaborators:** Kate Merlin, Julie Yeung, Michelle Bailey, St Vincent’s Hospital, Sydney

**Funding:** Project-specific grants

**Immuno-phenotyping of T-cell subsets**

Many NCHECR clinical trial and natural history protocols involve immunological substudies. The laboratory supports these substudies as a semi-routine service.

**Status:** Routine use of 6 colour multiparameter flow cytometry. Validation of up to 10 colour panels completed.

**Personnel:** Anthony Kelleher, Mee-Ling Munier (PhD student), Susanna Ip, David van Bockel (PhD student), Michelle Bailey

**Collaborators:** John Zaunders, St Vincent’s Hospital, Sydney

**Funding:** Project-specific grants
Assays of T-cell function, proliferation, cytotoxicity and identification of antigen specific T-cells, and assays of dendritic cell number and function

A range of assays for assessing CD4+ and CD8+ T-cell function are worked up in the laboratory. These include measures of T-cell proliferation, activation, cytokine secretion, identification of antigen-specific T-cells and enumeration of dendritic cell subpopulations and the cytokines they produce. Such assays are included in the protocols of clinical trials and natural history studies carried out by NCHECR.

Status: A range of T-cell and dendritic cell assays to define mechanisms behind efficacy of Virax’s therapeutic vaccine and the predictors of viral control in PULSE were completed.

Personnel: Anthony Kelleher, Mee-Ling Munier (PhD student), Susanna Ip, David van Bockel (PhD student), Kellie Cheung, Palanee Ammaranond (PhD student)

Collaborators: John Zaunders, ChoeChoe Brereton, St Vincent’s Hospital, Sydney

Funding: Project-specific grants

HIV drug resistance

This project involves the development of expertise in the application of a number of methods of detecting antiretroviral drug resistance through genotypic testing of HIV isolates.

Status: Over 200 HIV-1 resistance genotypes were performed.

Personnel: Anthony Kelleher

Collaborators: Philip Cunningham, Kazuo Suzuki, Leakhena Leas, Leon McNally, Lisa Martin, St Vincent’s Hospital, Sydney

Funding: NSW Health Department

Transmission of resistance in primary HIV infection

This study defines prevalence of resistance mutations in the Sydney population at primary infection, giving insight into the effect of widespread antiretroviral therapy on the prevalence of transmitted resistant virus in the Australian population.

Status: Subtype determination was performed on all sequences. >40 genotypes performed on acute seroconverters.

Personnel: Anthony Kelleher, Palanee Ammaranond (PhD student)

Collaborators: Philip Cunningham, Kazuo Suzuki, Leakhena Leas, Lisa Martin, Leon McNally, St Vincent’s Hospital, Sydney; Damian Purcell, Robert Centre, Department of Microbiology and Immunology, The University of Melbourne

Funding: US National Institutes of Health; NSW Health Department; NHMRC

Laboratory surveillance of incident HIV infection

Laboratory markers are used to determine incident from established HIV infection to monitor the trends in newly acquired infections, forming an important sentinel surveillance tool. The application of the ‘detuned’ ELISA, and analysis of other routine laboratory markers used in the diagnosis of HIV infection, is used in monitoring new infections.

Status: All newly identified cases of HIV infection at the NSW State Reference Laboratory for HIV at St Vincent’s Hospital were analysed.

Personnel: Anthony Kelleher

Collaborator: Philip Cunningham, St Vincent’s Hospital, Sydney; Sara Evans, Lisa Martin, Joanna Sherring, NSW State Reference Laboratory for HIV, St Vincent’s Hospital, Sydney

Funding: NSW Health Department

Pathogenesis research

Evolution of immune responses in primary infection and long-term nonprogressors

This study furthers mechanisms of viral escape from cytotoxic T-lymphocyte responses, and particularly the events leading up to escape from the HLA-B27 mediated T-cell response at the level of T-cell receptor usage. It employs samples and data gathered during the follow-up of the long-term non-progressor cohort (see HIV Epidemiology and Prevention Program), and samples collected from the PHAEDRA cohort.

Status: Novel escape mutations were defined for HLA B27 and A24.

Personnel: Anthony Kelleher, David van Bockel (PhD student), Nabila Seddiki, Palanee Ammaranond (PhD student)

Collaborators: Peter Doherty, Stephen Turner, Department of Microbiology and Immunology, The University of Melbourne; Daniel Douek, David Price, Vaccine Research Centre, US National Institutes of Health; Miles Davenport, Centre for Vascular Research, UNSW

Funding: US National Institutes of Health; NHMRC

iRNA inducing viral latency

This project is established to determine the optimal design of dsRNAs for the induction of transcriptional gene silencing (TGS) of viral genes in HIV-1 infected cells; and to define the pathways by which dsRNAs targeting the promoter regions of HIV-1 induce TGS.

Status: Ongoing

Personnel: Anthony Kelleher

Collaborators: Kazuo Suzuki, St Vincent’s Hospital, Sydney
Characterisation of CD4+ CCR5+ T-cells in primary HIV and other primary viral infections

This project involves investigations of the role CD4+ CCR5+ T-cells in the outcome of disease in the long-term non-progessor (see HIV Epidemiology and Prevention Program) and the PHAEDRA/CORE01 cohorts.

**Status:** Virus-specific CD4+ CCR5+ T-cells were definitively identified and extensively characterised, in a range of primary immune responses to viruses including HIV, CMV, EBV and vaccinia. The time course of the appearance and disappearance of these cells were defined, and differences in the development of memory cells in HIV as against the other viral infections studied were identified.

**Personnel:** Anthony Kelleher, Mee-Ling Munier (PhD student), Susanna Ip

**Collaborators:** John Zaunders, St Vincent’s Hospital, Sydney; Daniel Kaufmann, Partners AIDS Research Center (Massachusetts General Hospital), Harvard University

**Funding:** US National Institutes of Health; NHMRC

IL-7 receptor modulation

The impact of IL-7 and the expression of its receptor on T-cell subsets, T-cell homeostasis, CD4 T-cell recovery post HAART and developing lymphoma are being explored using both *in vitro* and *ex vivo* techniques.

**Status:** Studies of IL-7 receptor on malignant B cells in lymphomas and leukemias commenced.

**Personnel:** Anthony Kelleher, Sarah Sasson (PhD student)

**Collaborators:** John Zaunders, Sandy Smith, Sam Milliken, John Moore, St Vincent’s Hospital, Sydney

**Funding:** US National Institutes of Health; NHMRC

Molecular mechanisms of lipodystrophy

Six research projects examining various aspects of the pathogenesis of HIV-associated lipodystrophy. A range of *ex vivo* molecular analyses, involving measurement of gene expression in both adipose tissue and peripheral blood, are performed in the context of four clinical trials in both HIV-positive patients and HIV-negative healthy controls. This project also includes the development of *in vitro* models to examine the effects of antiretroviral medications in both adipocyte and monocyte cell culture systems.

**Status:** Robust real time PCR analyses to quantify mitochondrial and nuclear gene expression and mitochondrial DNA content are conducted routinely in samples from both clinical trials and cell cultures.

**Personnel:** Paddy Mallon, Rebecca Sedwell, Anthony Kelleher, Heidi Lim (Bachelor of Medical Science (Honours) student)

**Collaborators:** Andrew Carr, Natalie Duarte, St Vincent’s Hospital, Sydney; Jane Li, Garvan Institute of Medical Research

**Funding:** US National Institutes of Health; Bristol-Myers Squibb; Boehringer-Ingelheim

Definition of T regulatory subsets

Studies carried out to define a novel and more rigorous way of defining human T regulatory cells.

**Status:** Assay development was completed, and its use in primary infection, chronic infection and long-term nonprogressors became ongoing. A provisional patent was awarded, and negotiations with biotech companies re licensing of the technology began.

**Personnel:** Nabila Seddiki, Anthony Kelleher, Sarah Sasson (PhD student)

**Collaborators:** John Zaunders, St Vincent’s Hospital, Sydney; Barbara Fasekas, Centenary Institute of Cancer Medicine and Cell Biology, The University of Sydney; Alan Landay, Rush Medical School

**Funding:** NHMRC

Novel assays for assessing T-cell function

Assays designed to amplify small “primed” responses, and also simplified methodologies that may be applicable in the field in developing countries where large scale vaccine trials are likely to be run.

**Status:** Optimal methodology for priming assays was finalised and validated. Using a simplified T-cell assay, optimal methodology for CD4 responses was identified, and validation neared completion. The patent application process proceeded during 2005.

**Personnel:** Mee-Ling Munier (PhD student), Susanna Ip, Anthony Kelleher

**Collaborators:** John Zaunders, St Vincent’s Hospital, Sydney

**Funding:** NHMRC
Immunovirology and Pathogenesis
Program clinical trials network

Each site listed below has recruited or followed at least one subject in a research protocol investigating primary HIV infection during 2005.

New South Wales

407 Doctors
Site principal: David Baker
Site coordinator: Robyn Vale

AIDS Research Initiative
Site principal: Cassy Workman
Site coordinator: Vanessa Rees

Burwood Road General Practice
Site principal: Nicholas Doong
Site coordinator: Jeff Hudson

Holdsworth House General Practice
Site principal: Mark Bloch
Site coordinator: Ruth Hutchison

Immunology B Ambulatory Care Clinic,
St Vincent’s Hospital
Site principal: David Cooper
Site coordinator: Richard Norris

Sydney Sexual Health Centre
Site principal: Anna McNulty
Site coordinator: Bronwyn Bourke

Taylor Square Private Clinic
Site principal: Robert Finlayson
Site coordinator: Robyn Richardson

Victoria

Carlton Clinic
Site principal: Jonathan Anderson
Site coordinator: Kaye Lowe

Clinical Research Section, Infectious Diseases Unit,
The Alfred Hospital
Site principal: Jennifer Hoy
Site coordinator: Janine Roney

Melbourne Sexual Health Centre
Site principal: Tim Read
Site coordinator: Julie Silvers

Prahran Market Clinic
Site principal: Norman Roth
Site coordinator: Helen Wood

The Centre Clinic
Site principal: Nicholas Medland
Site coordinator: Helen Wood
Clinical and epidemiological research in the Asia-Pacific region

Thailand

The Netherlands, Australia, Thailand Research Collaboration (HIV-NAT) is a partnership between NCHECR, the Thai Red Cross AIDS Research Centre in Bangkok and the International Antiviral Therapy Evaluation Centre in Amsterdam.

There are 17 sites in the HIV-NAT clinical trials network; six in Bangkok, nine in regional Thailand and two in Phnom Penh, Cambodia. By December 2005, 17 adult clinical studies and 10 paediatric studies were being conducted at the network sites, with more than 2,200 subjects enrolled. This report lists the projects for which NCHECR personnel play a substantive role.

Research priorities at HIV-NAT in 2005 included antiretroviral (ARV) therapeutic strategies (structured therapy interruption and immediate versus delayed initiation of ARV in children), HIV/tuberculosis co-infection studies, HIV vaccine development, pharmacokinetic studies and new drug development. The research program resulted in 26 publications for the year.

Chris Duncombe is responsible for NCHECR’s contribution to all studies listed below. The local study coordinator is also named within each project where applicable. In addition, Chris Duncombe plays a general supporting role in activities at HIV-NAT.

HIV–NAT 006
A long-term follow-up study of safety and efficacy of antiretroviral therapy for patients who have previously participated in HIV-NAT study protocols.

Status: Recruitment opened June 2003, and is ongoing.
Sites: HIV-NAT
Enrolled: 306
HIV-NAT study coordinator: Anchalee Avihingsanon
Personnel: Chris Duncombe, Stephen Kerr
Funding: HIV-NAT; Ministry of Public Health

HIV–NAT 009
An open label, single arm, non-randomised study to evaluate the efficacy, safety and tolerability of indinavir 800 mg bid plus ritonavir 100 mg bid, in combination with efavirenz 600 mg od, in HIV-1 infected patients who are pre-treated with and have failed combination nucleoside reverse transcriptase therapy. The study includes pharmacokinetic, fat biopsy, and lipodystrophy substudies.

Status: Recruitment opened June 2001, and was completed October 2001. A fourth 48 week extension was completed in July 2005.
Sites: HIV-NAT
Enrolled/target: 60/60
Personnel: Chris Duncombe
Funding: Merck & Co Inc

HIV–NAT 010
A randomised, open label, comparative study to evaluate the efficacy, safety and cost of immediate versus deferred therapy with AZT/3TC/NVP in HIV-infected Thai children with moderate immunodeficiency.

Status: Study completed October 2005.
Sites: 3
Enrolled/target: 43/43
HIV-NAT study coordinator: Jintanat Ananworanich
Personnel: Chris Duncombe
Funding: HIV-NAT; The Government Pharmaceutical Company; Ministry of Public Health

HIV–NAT 011
A single arm study to assess the use of pharmacokinetically guided indinavir dose reductions in patients with chronic renal impairment from indinavir use.

Status: Recruitment opened November 2002, and is ongoing.
Sites: HIV-NAT
Enrolled: 28
HIV-NAT study coordinator: Anchalee Avihingsanon
Personnel: Chris Duncombe
Funding: HIV-NAT
HIV-NAT 012
The effect on HIV-1 elimination rate constant of combination antiretroviral therapy aimed at three independent HIV viral targets (fusion inhibition + reverse transcriptase inhibition + protease inhibition) compared to that aimed at two independent viral targets (reverse transcriptase inhibition + protease inhibition).

Sites: HIV-NAT
Enrolled/target: 36/36
Personnel: Chris Duncombe
Funding: F Hoffman-La Roche Ltd

HIV–NAT 022: Tenofovir in HIV/hepatitis B coinfection (TICO)
This study is described under the Viral Hepatitis Clinical Research Program.

HIV–NAT 027
Efficacy and safety of a saquinavir based regimen in HIV-1 infected Thai patients who have chronic IDV associated nephrotoxicity.

Status: Recruitment opened June 2005, and is ongoing.
Site: HIV-NAT
Enrolled/target: 30/30
HIV-NAT study coordinator: Anchalee Avihingsanon
Personnel: Chris Duncombe
Funding: Roche Laboratories Inc

HIV-NAT 032
Generation of hepatitis B-specific T-cell immunity in individuals with HIV/hepatitis B co-infection receiving hepatitis B-active antiretroviral therapy.

Status: Recruitment opened May 2005, and is ongoing.
Site: HIV-NAT
Enrolled/target: 36/36
HIV-NAT study coordinator: Anchalee Avihingsanon
Personnel: Chris Duncombe

PREDICT 2005
ARV-naive, HIV-infected children between one and twelve years of age with mild or moderate disease severity (CDC clinical category class A or B) and with moderate immune suppression (CD4 lymphocyte percentage between 15% and 24%) will be included in this study. They will be randomised to one of two arms: Immediate antiretroviral (ARV) therapy (ARV initiated on Day 0 of study) or deferred ARV therapy (ARV initiated when CD4% is less than 15%).

Sites: 8 (6 Thailand, 2 Cambodia)
Enrolled/target: 0/300
HIV-NAT study coordinator: Jintanat Ananworanich
Personnel: Chris Duncombe, Robert Delrichs, Stephen Kerr
Collaborators: National Center for HIV/AIDS, Dermatology and STDs; National Institute for Public Health; Thai Red Cross; National Pediatric Hospital
Funding: US National Institutes of Health via a grant to the Thai Red Cross; GlaxoSmithKline; Abbott; F Hoffmann-La Roche Ltd

ESPRIT
This study is described under the Therapeutic and Vaccine Research Program.

STACCATO
The Swiss–Thai–Australian Treatment Interruption Study. An open label, randomised study to evaluate the efficacy, safety, and tolerability of continuous daily boosted saquinavir hard gel capsule/2NRTI versus structured treatment interruption (STI) of the same therapy depending on CD4+ cell counts (CD4-guided treatment).

Status: Study completed December 2005.
Sites: 7
Enrolled/target: 360/360
HIV-NAT study coordinator: Jintanat Ananworanich
Personnel: Chris Duncombe
Funding: The Swiss HIV Cohort Study collaboration; F Hoffmann-La Roche Ltd; Abbott; Gilead Sciences

TREAT Asia HIV Observational Database (TAHOD)
This study is described under the Biostatistics and Databases Program.

Australian-Thai HIV Vaccine Program
A randomised, placebo controlled, double-blind, phase I clinical trial to evaluate the safety and immunogenicity of a candidate prophylactic pHIS-HIV-AE DNA prime and recombinant fowlpox (rFPV)-HIV-AE boost HIV vaccination strategy in healthy Thai volunteers at low risk of HIV infection.

Status: Site, laboratory and community preparation completed.
Site: HIV-NAT
Enrolled/target: 0/24
HIV-NAT study coordinator: Wadchara Pumpradit
Personnel: Chris Duncombe, Stephen Kerr
Funding: US National Institutes of Health
Cambodia

Access to treatment and care for Cambodians living with HIV/AIDS continued to expand during 2005, with the number of people receiving antiretroviral therapy doubling during the year to 12,355. This resulted in Cambodia achieving its contribution towards the WHO/UNAIDS international goal of three million people treated with antiretroviral therapy by the end of 2005. Geographical equity in access also improved with the number of treatment sites increasing from 17 to 32.

NCHECR continued to support expansion of access to HIV treatment through an ongoing partnership with the National Center for HIV/AIDS, Dermatology and STDs (NCHADS) and the National Institute of Public Health (NIPH) of the Cambodian Ministry of Health. Key achievements of the partnership during 2005 were in the areas of program development, clinical care, clinical research and laboratory development.

During 2005, a number of national level programs to support HIV treatment and care were developed. NCHECR staff contributed significantly to improvements in these programs, including revisions to the national HIV care reporting and data systems, further development of centralised antiretroviral (ARV) procurement and logistics, revision of national ARV guidelines, implementation of national CD4 testing quality assurance and development of a national HIV continuing education plan.

During 2005, the Social Health Clinic, an ambulatory clinic in Phnom Penh for Cambodians living with HIV/AIDS, established capacity for treatment and care and a platform for clinical research. The Social Health Clinic currently has a staff of 28, including four doctors, four nurses, a six-member counselling and peer support team, and a six-member research and data management team. Clinic enrolment to December 2005 was 744, of whom 305 commenced ARV therapy.

Clinical research commenced at the Social Health Clinic in June 2005 with support from AusAID for the establishment of a prospective clinical cohort. A major initial focus of the study is ARV adherence, including validation of simple measures, levels of adherence during early ARV therapy and associated factors. Additional work supported by AusAID includes a qualitative study of ARV adherence and a cohort sub-study focussed on improving understanding and diagnosis of immune restoration disease.

NCHECR staff continued to provide technical assistance to the National Laboratory of Public Health, within NIPH, in the development and maintenance of quality managed laboratory diagnostics to support diagnosis, monitoring and treatment of people living with HIV/AIDS.

Cambodia Treatment Access Program (CTAP)

Increasing access to antiretroviral treatment in Cambodia through establishment of treatment clinics and technical assistance to the national HIV treatment program.

**Status:** At the end of 2005, 654 people living with HIV/AIDS were under care, and 305 commenced on antiretroviral therapy.

**Personnel:** Sarah Huffam, Julian Elliott, Jenne Roberts, Robert Oelrichs, Mary Poynten, Iona Millwood

**Collaborators:** National Center for HIV/AIDS, Dermatology and STDs; National Institute for Public Health

**Funding:** F Hoffmann-La Roche Ltd

Cambodian research program to support the optimal use of antiretroviral therapy

Investigation of antiretroviral (ART) efficacy and adherence with a program of qualitative, observational and interventional studies.

**Status:** A cohort study was initiated in June 2005, including prospective collection of treatment and adherence data and storage of biological specimens. This was expanded in December 2005 to include more intensive data collection during early ART in order to investigate the characteristics and methods of diagnosis of immune restoration disease. A qualitative study exploring understandings and use of ART was also conducted in order to better understand the determinants of the high levels of ART adherence currently seen in Cambodia.

**Personnel:** Julian Elliott, Robert Oelrichs, Sarah Huffam, Jenne Roberts, Mary Poynten, Iona Millwood

**Collaborators:** National Center for HIV/AIDS, Dermatology and STDs; National Institute for Public Health

**Funding:** AusAID

PREDICT

This study is described under Thailand.

TREAT Asia HIV Observational Database

This study is described under the Biostatistics and Databases Program.
A study of the prevalence of HIV-related neurological disease in the Asia Pacific Region

A multi-site study to describe the prevalence of HIV related neurocognitive impairment and AIDS dementia complex, peripheral sensory neuropathy and central nervous system opportunistic infections and tumours.

**Status:** National ethics committee approval received in December 2005.

**Personnel:** Sarah Huffam, Julian Elliott

**Collaborators:** Asia Pacific Neuro AIDS Consortium; Macfarlane Burnet Institute for Medical Research and Public Health; National Center for HIV/AIDS, Dermatology and STDs

**Funding:** US National Institutes of Health via a grant to the Macfarlane Burnet Institute for Medical Research and Public Health

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Sarah Huffam, Robert Oelrichs

**Regional**

**Indonesia HIV/AIDS Prevention and Care Project Phase II**

This project supports the development and implementation of HIV care and treatment programs in Indonesia.

**Status:** NCHECR contributed to the project primarily through the Technical Advisory Team chaired by John Kaldor.

**Collaborators:** GRM International Pty Ltd; Macfarlane Burnet Institute for Medical Research and Public Health; Albion Street Centre

**Funding:** AusAID

**HIV Epidemiological Modelling and Impact (HEMI)**

This study is described under the Biostatistics and Databases Program.
NCHECR is involved in a wide range of teaching and training activities (see page 72). During 2005, one doctoral student, one honours student and five Masters students whose research had been supervised or co-supervised by NCHECR staff were awarded their degrees. NCHECR staff also supervised another 38 postgraduate students, including 35 doctoral candidates.

Academic staff at NCHECR continued to be responsible for three courses offered as part of the Master of Public Health degree at the University of New South Wales. Over 100 students passed through the core epidemiology course taught by NCHECR staff in 2005, and a further 32 undertook the specialised electives in epidemiology and HIV/AIDS. Over the years, students who have encountered the work of NCHECR through these courses have gone on to join the research staff at the Centre, and some now act as tutors for current students.

The Therapeutic and Vaccine Research Program Trial Network Site Coordinators Meeting was held again during 2005 in Hobart, and was attended by 48 general site coordinators, plus seven hepatitis C trial coordinators from around Australia and New Zealand. A variety of topics included an update on the current research areas of NCHECR. This annual training day continues to be evaluated extremely well.

The Viral Hepatitis Clinical Research Program (VHCRP) undertook their first training program for hepatitis C nurse coordinators in Sydney. The program’s focus was the Australian Trial in Acute Hepatitis C (ATAHC) Study. Evaluation was extremely positive, and it is hoped that further annual events will continue to strengthen the relationship between VHCRP and the clinical hepatitis/liver clinic network around Australia.

Training provided by NCHECR also included field supervision of students placed from long term programs run by other institutions. Veronica Canale, an overseas exchange student from the University of Padua, Italy, completed a very successful practicum attachment with NCHECR’s laboratory. Jonathan Volk completed his one-year placement with NCHECR under a Fulbright scholarship award.

NCHECR also contributed lectures to a variety of other postgraduate courses during the year.
NCHECR staff continued to participate in a range of advisory bodies, working groups and committees relevant to HIV, hepatitis C and related areas (see page 67). These activities operate at a range of levels from local to international and ensure that NCHECR’s researchers stay closely in touch with the programmatic and policy applications of their work.

During 2005, preparations continued for the 4th International AIDS Society Conference on Pathogenesis and Treatment of HIV infection to be hosted by the Australasian Society for HIV Medicine in Sydney in 2007, with David Cooper as Local Conference Chair and John Kaldor as one of the two Deputy Chairs.

Also of note were David Cooper’s election to Chair of the WHO/UNAIDS HIV Vaccine Advisory Committee; Anthony Kelleher’s membership of the CANVAC Expert Panel Meeting for Networks of Centres of Excellence in Montreal, Canada and the Planning Committee for the NSW Ministry for Science and Medical Research Clinical Research Forum; Andrew Grulich’s membership of the 9th International Conference on Malignancies in AIDS and Other Acquired Immunodeficiencies: Basic, Epidemiologic and Clinical Research Organising Committee and his continuing role in chairing the NSW HIV Health Promotion Committee; and John Kaldor’s membership of the 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment Prevention Science Scientific Committee.

Through John Kaldor’s membership of the Organising Committee led by Alan Landay, and the contribution of a number of other staff members, NCHECR also played a central role in organising an international symposium on vaginal microbicides that was held in Sydney in November. The symposium was largely funded by the US National Institutes of Health, with contributions from the Macfarlane Burnet Institute for Medical Research and Public Health and the Westmead Millennium Institute for Medical Research, as well as NCHECR. It brought together an interdisciplinary program of investigators largely from the United States and the Asia-Pacific region.

NCHECR staff continued to contribute to the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) through Andrew Grulich’s membership of the HIV/AIDS and Sexually Transmissible Infections Subcommittee, Greg Dore’s membership of the Hepatitis C Subcommittee and John Kaldor’s membership of the Indigenous Australians’ Sexual Health Committee.
Research grants

Cooper DA, Emery S, Dwyer D. A prospective study to examine the effectiveness and safety of stockpiled antivirals for pandemic influenza. NHMRC Urgent Research into a Potential Avian Influenza-Induced Pandemic Grant Feb 2006-July 2006, A$142,000.


Kelleher AD, Lloyd A. NHMRC Equipment Grant 2006, A$80,000.


Maher L. Barriers to hepatitis C treatment uptake by Indo-Chinese injecting drug users. Faculty Research Grant, Faculty of Medicine, UNSW 2006-2007, A$20,000.


Zwi A, Kaldor JM, Hodgkinson A. Scoping the development of a Master of Public Health program at the National Institute of Public Health, Cambodia. UNSW Contestable Funding for International Strategic Projects 2006, A$27,300.

Training grants


van Leeuwin M. NHMRC Public Health Postgraduate Scholarship 2006-2008, $63,693.


Other

Amin J. 17th Annual Conference of the Australasian Society for HIV Medicine Epidemiology Poster Prize.
This list includes both full time and part time staff. Activities listed in this report under External boards, committees and advisory groups; Education and training; Publications and Presentations at conferences and meetings relate only to individuals whose primary employment is with NCHECR.

**Director’s office**

**Director and Scientia Professor of Medicine**
David Cooper AO, BSc(Med), MB BS, MD, DSc, FRACP, FRCPA, FRCP

**Executive Assistant**
Janette Button

**Deputy Director’s office**

**Deputy Director and Professor of Epidemiology**
John Kaldor PhD

**Epidemiology Group Coordinator***
Jennifer Kemp

**Administrative Assistants***
Kate Chivers
Carol Harris (part time) (to August)
Amanda Scott BManagement (from March)
Julia Warning BSc(Hons) (part time) (from August)

**Surveillance Program**

The Surveillance Program is headed by the Deputy Director and is made up of staff from the HIV Epidemiology and Prevention Program, the Viral Hepatitis Epidemiology and Prevention Program and the Biostatistics and Databases Program.

**Therapeutic and Vaccine Research Program**

**Head and Associate Professor**
Sean Emery BSc(Hons), PhD

**Associate Professor**
Jennifer Hoy MB BS, Grad Dip Epi Bio, FRACP (part time)

**Lecturers**
Dianne Carey BPPharm, MPH
Kate Clezy MB BS, FRACP (part time)
Fraser Drummond MB ChB, MRCA, DA (UK)
Paddy Mallon BSc(Hons), MB BCh, BAO
Sarah Pett BSc(Hons), MB BS(Hons), DTM&H, MRCP (UK), FRACP
Rebekah Puls BSc(Hons), PhD
Alan Winston MB, ChB, MRCP (UK), DFFP, Dip GUM (to March)

**Senior Clinical Project Coordinators**
Cate Carey RN, BA, MAppSc(Research)
Allison Humphries BSc, MSc(Med), Grad Dip PH (part time)

**Clinical Project Coordinators**
David Courtney-Rodgers
Wilma Goodyear BN, RN (from August)
Sophie Gunn BA(Mod)(Hons) Microbiology, MSc Biotechnology, Dip Bus Studies (from April)
Mary Ellen Harrod BA, Grad Dip Psych (Hons) (from December)
Simone Jacoby BSc, Dip Nutrition, Adv Dip Bot Med
Susan Connor RN, RM, GradCert(Ortho) (to September)
Claudette Satchell BSc(Hons)

**Program Manager**
Kirsten Bailey BA

**Data Managers**
Kymme Courtney-Vega, Dip Sp Th
Wendy Lee
Robyn Munro

**Administrative Assistants**
Margaret Allan BPsych (from October)
Emma Butler BAI(Hons), MA (part time) (from October)
Alison Macdonald MCSP
Jennifer Tapp (to July)
Leeanne Thompson (to January)

* Staff working in the office of the Deputy Director and the Surveillance, HIV Epidemiology and Prevention, Viral Hepatitis Epidemiology and Prevention and Biostatistics and Databases Programs
HIV Epidemiology and Prevention Program

Head and Associate Professor
Andrew Grulich MB BS, MSc, PhD, FAFPHM

Conjoint Professor
Basil Donovan MB BS, MD, Dip Ven (Lond), FChSHM, FAFPHM, FRCPI (part time) (from August)

Lecturers
Marianne Jauncey BMed, Grad Dip App Epi, MPH(Hons), FAFPHM (part time) (from November)
Iona Millwood BA(Hons), PhD (part time)
Mary Poynten MB BS, Dip Child Health, MPH(Hons) (part time)
Garrett Prestage BA(Hons), PhD

Post Doctoral Research Fellow
Claire Vajdic BOptom, PhD (part time)

Senior Research Officer
Ann McDonald BSc, MPH

Research Assistants
Lucette Cysique BSc(Hons), MA (part time) (to February)
Chris Lawrence MAppEpid (March to October)
Melanie Middleton BMedSc, MPH
Marina van Leeuwen BSc(Hons), MPH

Project Manager
Brian Acraman

Study Nurses
Leon Botes RN, MHS(Sexual Health), BCur(Ed & Ad), Dip N, Cert SH&V
Joanne Holden RN (part time) (from March to June)
Kim Scholey RN (part time) (from September)
Harry Smith MA (part time) (to January)

Project Officers
Jack Bradley
Patrick McGrath BA, Dip Ed (part time)
Daniel O’Neill (part time) (to July)
Hédimó Santana BA(Hons)

Interviewers
Eli Braga
Lara Cassar (from September)
Jon de Ruiter
Trevor Dougherty BA Media Communications (Hons)
Paul Kelly (from April to October)
Pól McCann BA(Hons)
Nick Cooper BA(Economics) BSocSci(Hons) (to October)
Grant Mistler (to July)
Greg Reading
John Redmond
Aurelio Vulcaio (from July)

Viral Hepatitis Clinical Research Program

Head and Associate Professor
Greg Dore MB BS, BSc, PhD, FRACP, MPH

Lecturer
Gail Matthews MBChB, MRCP (part time)

Post Doctoral Research Fellow
Carolyn Day BSc (Hons), PhD (part time)

Clinical Trials Manager
Pip Marks BSc

Clinical Project Coordinators
Deama Amr, BSc (Hons), PhD (from September)
Wen Cao BMed, MPH
Natalie Espinosa BAppSc, MHSc (from July)
Elizabeth Knight BSc, MPH
Suzanne Polis RN, BNursing, MPH (to February)
Angeline Premnath, BMedSc (to July)
Barbara Yeung RN, BHSc(Nursing), MPH

Research Assistants
Therese Carroll BSc, MPH (from May)
Anna Doab RN, MPH
Rosie Thein MB BS, MPH (to October)

Administrative Assistants
Victoria Lightfoot BSc (from May)
Virginia Macdonald BSc(Hons), PhD, MPHTM (to January)

Viral Hepatitis Epidemiology and Prevention Program

Head and Associate Professor
Lisa Maher BA, MA, PhD

Surveillance Coordinator
Jiong Li BSc, MPH, MSc, PhD (from August)

Project Coordinator
Heidi Coupland BAppSc, MPH (part time) (from June)
Allison Salmon BPsych, MPH

Research Assistants
Kathleen Glenday BAppSc, MPH (from July)
Swati Shourie BDSc, MDisc (to April)
Bethany White BA(Psych), MPH (to May)

Biostatistics and Databases Program

Head and Senior Lecturer
Matthew Law MA, MSc, PhD

Senior Lecturer
John Murray BSc(Hons), MSc, PhD (part time) (from March)
Lecturers
David Regan BA, BSc(Hons), PhD (from July)
Handan Wand MA, MSc, PhD

Senior Research Assistants
Janaki Amin BSc(Hons), MPH(Hons)
Kathy Petoumenos BSc, MA, MPH(Hons)

Research Assistant
Jialun Zhou MB, MPH

Computer Systems Officers
Noorul Absar BTech, Grad Dip (Inf Sc), MComp (SW Engg)
Rossitza Chevkenova BSc

Immunovirology and Pathogenesis Program
Head and Senior Lecturer
Anthony Kelleher BSc(Hons), MB BS(Hons), PhD, FRACP, FRCPA

Lecturers
Mark Bloch MB BS, MMed (part time)
Robert Finlayson MB BS, Dip Ven, FACVen (part time)
Kersten Koelsch MD (to January)
Robert Macfarlane MB BS, FRACGP (part time)
Nicholas Medland MB BS, BA(Hons), Dip Ven (part time)
Tim Ramacciotti BA(Hons), MD, MPH
Norman Roth MB BS, Dip Av Med, Dip Ven, FACHSHM (part time)
Nabila Seddiki PhD (from March)
Cassy Workman MB BS (part time)

Clinical Project Coordinator
Patricia Grey BA, Post Grad Dip App Sci, CNS, Dip (Counselling)

Research Assistants
Mee-Ling Munier BSc, Grad Dip Epi, MSc (to March)
Kellie Nallaiah BMedSc
Susanna Ip BSc
Ciara McGinley CertAppBio
Rebecca Sedwell BSc (to November)
Michelle Bailey (from November)

Data Administrator
Ansari Shaik BA, MBA

Administrative Assistant
Kylie Butson (to January)
Susan Lewis MA (part time)
Deborah Taylor BA

US National Institutes of Health, HIV Vaccine Design and Development Contract

Chief Operations Officer
Mark Sullivan BSc (to November)

Internationally-based staff

Senior Lecturers
Chris Duncombe MB BS, RAC GP (HIV-NAT, Thailand)
Sarah Huffam MB BS, MPH&TM, FRACP, FACHSHM (NCHADS, Cambodia)
Stephen Kerr BPharm(Hons), MIPH, PhD (HIV-NAT, Thailand)

Lecturer
Julian Elliott MB BS, FRACP (NCHADS, Cambodia)

Research Fellow
Robert Oelrichs BMedSc, MB BS, MD, PhD (NCHADS, Cambodia)

Project Manager
Jennifer Roberts M Intl Mgment (NCHADS, Cambodia) (to March)

Finance and Administration

Manager
Bronwen Turner BA

Business Manager
Annie Tung MPA

Finance Managers
Gina Lam BA(Hons), EMBA (from December)
Janette Murdoch (to October)
Patricia Xu BEc, CPA

Librarian
Coralie Kronenberg BA, Dip IM Lib, AALIA (part time)

Human Resources Advisor
Penelope Lister BA, Grad Dip Jap, MAHRI (to June)
Brigette Sharp BA (Hons) (from September)

Computer Systems Officers
Lisa Howard Dip IT
Charles Tran BCompSc

Finance Administrator
Chloe Lin BSc, BComm, MComm (to October)

Office Administrator
Yvette Toole

* On secondment from the Macfarlane Burnet Institute for Medical Research and Public Health
Administrative Assistants
Courtney Bendall Dip Bus
Ian Brodie BEd, Grad Dip Ed, Ass Dip Hlth Sc

Receptionists
John Redmond (part time)
Sarah Raymond (part time)

Annie Tung, Chloe Lin, Courtney Bendall, Ian Brodie,
Yvette Toole, Janette Button, Penelope Lister, Janette Murdoch,
Sarah Raymond, Bronwen Turner, Patricia Xu
Researchers affiliated to NCHECR

Visiting Professors
Alan Landay BSc, PhD (to June)
Professor of Medicine and Associate Chairman
Department of Immunology/Microbiology
Rush Medical College, Chicago, USA

Peter McDonald AM, MB BS, FRCPA, FRACP, FASM
Emeritus Professor
Flinders University, Adelaide

Senior Visiting Fellow
Philip Cunningham BAppSc(Med)
Chief of Operations
Centre for Immunology
St Vincent’s Hospital, Sydney

Visiting Fellows
Bruce Brew MB BS(Hons), MD, FRACP
Professor of Medicine
St Vincent’s Hospital, Sydney

Nick Crofts MB BS, MPH, FAFPHM
Professor and Director
Turning Point Alcohol and Drug Centre, Melbourne

Cathy Pell MB BS, MM
Specialist General Practitioner
Taylor Square Private Clinic, Sydney

Don Smith MB ChB, MD
Associate Professor
Head of Research Development
Albion Street Centre, Sydney

Alex Wodak MB BS, MRACP, FRACP, MRCP, FAFPHM
Director
Alcohol and Drug Service
St Vincent’s Hospital, Sydney
Bachelor of Medical Science (Honours) student
Heidi Lim (from July to October)

Doctor of Philosophy students
Palanee Ammaranond B Medtech, M Biotech (to October)
Suzie Hudson BSW, PG Cert Addictions, MSW (from July)
Jeff Jin BMed, MPH
Azar Kariminia BMedSc, MSc(RHS&HG) (from May to June)
Joanne Micallef BMedSc(Hons)
Mee-Ling Munier BSc, Grad Dip Epi, MSc (from March)
Fatemeh Nakhaee BSc, MSc
Karina Razali BSc(BioSc), MSc(EpiID)
Sarah Sasson BA, BSc(Hons) (from March)
Preeyaporn Srasuebkal BSc, MSc
David Templeton MBChB Dip Ven
GradCertForensMed FACHSHM (from March)
Rosie Thein MB BS, MPH
David van Bockel BBiotech(Hons)

Fullbright Scholar
Jonathan Volk BA(Psych) (University of California, USA) (to July)

Master of Applied Epidemiology (Indigenous Health) student
Chris Lawrence (to March)

Master of Public Health by research student
Wari Allison BSc(Hons), MB BS (from March)
Juliet Babirye MBChB (to June)

Medical Biotechnology Course student
Veronica Canale (University of Padova, Italy) (from February)

NSW Health Department Trainee Biostatisticians
Aarthi Ayyar BCom (from August)
Katrina Irvine BSc(Psych), MPsych(Org) (to February)
Collaborating organisations

National
Association for Prevention and Harm Reduction Programs Australia (ANEX), Melbourne
Australasian Society for HIV Medicine, Sydney
Australasian Society of Clinical Immunology and Allergy (ASCIA) Primary Immunodeficiency Register, Sydney
Australia and New Zealand Dialysis and Transplant Registry (ANZDATA), Adelaide
Australian Agency for International Development (AusAID), Canberra
Australian Centre for Hepatitis and HIV Virology Research (ACH2), UNSW, Sydney
Australian Federation of AIDS Organisations, Sydney
Australian Government Department of Health and Ageing, Canberra
Australian Hepatitis Council, Canberra
Australian Injecting and Illicit Drug Users League (AIVL), Canberra
Australian Institute of Health and Welfare, Canberra
Australian Liver Association, Sydney
Australian National Creutzfeldt-Jakob Disease Registry, Canberra
Australian National University, Canberra
Australian Paediatric Surveillance Unit and its contributors, Sydney
Australian Red Cross Blood Service, Sydney
Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne
Communicable Diseases Network Australia, Canberra
HIV/AIDS Sexually Transmitted Infections Committee, Canberra
Immunovirology Research Network (IVRN), UNSW, Sydney
National Association of People Living with HIV/AIDS, Sydney
National Centre for Epidemiology and Population Health, Australian National University, Canberra
National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Sydney
National Centre in HIV Social Research, UNSW, Sydney
National Drug and Alcohol Research Centre, UNSW, Sydney
National Serology Reference Laboratory, Australia, Melbourne
Office of Aboriginal and Torres Strait Islander Health (OATSIH), Canberra
Phase Forward Pty Ltd, Sydney
Therapeutic Goods Administration, Canberra

Australian Capital Territory
ACT Corrective Services, Canberra
ACT Health, Canberra
AIDS Action Committee of the ACT, Canberra
Canberra Sexual Health Clinic, Canberra
Communicable Disease Control Program, ACT Health, Canberra
Directions ACT, Canberra
Interchange General Practice, Canberra
John Curtin School of Medical Research, Australian National University, Canberra
The Canberra Hospital, Canberra

New South Wales
407 Doctors, Sydney
Aboriginal Medical Service Coop Ltd, Sydney
AIDS Council of NSW (ACON), Sydney
AIDS Research Initiative, Sydney
Albion Street Centre, Sydney
Albury Base Hospital, Albury, NSW
Albury Community Health Centre, Albury, NSW
Area Public Health Units, NSW Health Department, Sydney
Bankstown Community Health Centre, Sydney
Bankstown Hospital, Sydney
Bigge Park Medical Centre, Sydney
Blacktown Community Health Centre, Sydney
Bligh Street Clinic, Tamworth, NSW
Blue Mountains Sexual Health Clinic, Katoomba, NSW
Burwood Road General Practice, Sydney
Campbelltown Health Services, Sydney
Centre for Health Research in Criminal Justice, Justice Health, NSW Health Department, Sydney
Centre for Immunology, St Vincent’s Hospital, Sydney
Communicable Diseases Branch, NSW Health Department, Sydney
Complex Systems in Biology, Centre for Vascular Research, UNSW, Sydney
Concord Hospital, Sydney
Corrections Health Service, Sydney
Darlington X-Ray, Sydney
First Step Program, Port Kembla, NSW
Garvan Institute of Medical Research, Sydney
General Medical Practice, Burwood, Sydney
Harm Reduction Program, Sydney South West Area Health Service (Western Zone), NSW Health Department, Sydney
Holden Street Clinic, Gosford, NSW
Holdsworth House General Practice, Sydney
Holdsworth House General Practice, Byron Bay, NSW
Hunter Valley Research Foundation, Newcastle, NSW
Illawarra Sexual Health, Port Kembla, NSW
Institute for Health Research, Sydney
John Hunter Hospital, Newcastle, NSW
Justice Health, NSW Health Department, Sydney
K2 Health Service, Sydney
Kirketon Road Centre, Sydney
Lismore Sexual Health Clinic, Lismore, NSW
Liverpool Sexual Health Clinic, Sydney
Livingstone Road Sexual Health Centre, Sydney
Macquarie Sexual Health Centre, Sydney
Multicultural HIV/AIDS and Hepatitis C Service, Sydney
Needle and Syringe Program Services, Royal Newcastle Hospital, Newcastle, NSW
Nepean Hospital, Sydney
Nepean Sexual Health and HIV Clinic, Sydney
NSW Health Department, Sydney
NSW State Reference Laboratory for HIV/AIDS, St Vincent’s Hospital, Sydney
NSW Users and AIDS Association (NUAA), Sydney
People Living with HIV/AIDS (PLWHA), Sydney
Prince of Wales Hospital, Sydney
Resource and Education Program for Injecting Drug Users, Sydney
Responsive User Services in Health (RUSH), Sydney
Royal North Shore Hospital, Sydney
Royal Prince Alfred Hospital, Sydney
School of Medical Sciences, UNSW, Sydney
School of Public Health and Centre for Health Services Research, The University of Sydney, Sydney
School of Public Health and Community Medicine, UNSW, Sydney
Sexual Health and Infectious Diseases Service (SHAIDS), Lismore, NSW
Sexually Transmitted Infections Research Centre, Westmead Hospital, Sydney
South Court Primary Care Needle and Syringe Program, Sydney
St George Hospital, Sydney
St Leonards Medical Centre, Sydney
St Vincent’s Hospital, Sydney
St Vincent’s Medical Imaging, Sydney
Sydney Children’s Hospital, Sydney
Sydney Medically Supervised Injecting Centre, Sydney
Sydney Sexual Health Centre, Sydney
Sydney West Area Health Service HIV/Hepatitis C Prevention Service, NSW Health Department, Sydney
SydPath, Sydney
Taylor Square Private Clinic, Sydney
The Byrne Surgery, Sydney
The Cancer Council NSW, Sydney
The Cancer Institute NSW, Sydney
The Centenary Institute of Cancer Medicine and Cell Biology, The University of Sydney, Sydney
The Children’s Hospital at Westmead, Sydney
The City of Sydney Council, Sydney
The Medical and Vein Centre, Coffs Harbour, NSW
Westmead Hospital, Sydney
Westmead Millennium Institute for Medical Research, Sydney
Wollongong Hospital, Wollongong, NSW

**Northern Territory**

 Clinic 34, Darwin
Communicable Disease Centre, Royal Darwin Hospital, Darwin
Department of Correctional Services, Darwin
Northern Territory AIDS and Hepatitis Council, Alice Springs, NT
Northern Territory AIDS and Hepatitis Council, Darwin
Palmerston Needle and Syringe Program, Palmerston, NT

**Queensland**

 AIDS Medical Unit, Queensland Health, Brisbane
Biala Alcohol and Drug Services, Brisbane
Blackall Terrace Specialist Centre, Nambour, Qld
Brisbane Sexual Health Clinic, Brisbane
Brunswick Street Medical Centre, Brisbane
Cairns Base Hospital, Cairns, Qld
Gladstone Road Medical Centre, Brisbane
Gold Coast Hospital, Southport, Qld
Gold Coast Sexual Health Clinic, Miami, Qld
GRM International Pty Ltd, Brisbane
Kobi House, Toowoomba, Qld
Nambour General Hospital, Nambour, Qld
Princess Alexandra Hospital, Brisbane
Queensland Aboriginal and Islander Health Council, Brisbane
Queensland AIDS Council (QAC), Brisbane
Queensland Corrective Services Commission, Brisbane
Queensland Health, Brisbane
Queensland Injectors Health Network (QuIHN), Brisbane
Queensland Injectors Health Network (QuIHN), Gold Coast, Qld
Queensland Injectors Health Network (QuIHN), Sunshine Coast, Qld
Queensland Medical Laboratory (QML), Brisbane
Queensland Positive People, Brisbane
Royal Brisbane and Women’s Hospital, Brisbane
Sexual Health Service, Cairns Base Hospital, Cairns, Qld
Southcoast Radiology, Pindara Hospital, Benowa, Qld
Townsville Aboriginal and Islanders Health Services Limited, Townsville, Qld
Townsville Hospital, Townsville, Qld
West Moreton Sexual Health Service, Brisbane
South Australia
AIDS Council of South Australia, Adelaide
Clean Needle Program, Drug and Alcohol Services, Adelaide
Clinic 275, Adelaide
Flinders Clinical Trials Pharmacy, Adelaide
Flinders Medical Centre, Adelaide
Hindmarsh Centre, Adelaide
Infectious Diseases Laboratories, Institute of Medical and Veterinary Science, Adelaide
Nunkuwarrin Yunti Community Health Centre, Adelaide
Royal Adelaide Hospital, Adelaide
SAVIVE Noarlunga, Community Health Centre, Adelaide
SAVIVE Norwood, Darling House, Adelaide
SAVIVE Parks, Parks Community Health Centre, Adelaide
SAVIVE Port Adelaide, Port Adelaide Community Health Centre, Adelaide
SAVIVE Shopfront, Adelaide
Shopfront Youth Health and Information Services, Adelaide
South Australian Prison Health Service, Adelaide
The Care and Prevention Program, Adelaide University, Adelaide

Tasmania
Devonport Needle Availability Program, Devonport, Tas
Prison Health Services Tasmania, Hobart
Public and Environmental Health, Launceston, Tas
Tasmanian Council on AIDS, Hepatitis and Related Diseases (TasCAHRD), Hobart
Tasmanian Department of Community and Health Services, Hobart

Victoria
Austin and Repatriation Medical Centre, Melbourne
Austin Hospital, Melbourne
Barwon Health, Geelong, Vic
Box Hill Hospital, Melbourne
CSIRO Animal Health Laboratory, Geelong, Vic
Corrections Victoria, Department of Justice, Melbourne
Department of Human Services, Melbourne
Department of Microbiology and Immunology, The University of Melbourne, Melbourne
Dorevitch Pathology – Mayne Health, Melbourne
Geelong Hospital, Geelong, Vic
Health Information Exchange, Salvation Army, Melbourne
Health Works, Melbourne
La Trobe University, Melbourne
Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne
Melbourne Inner City AIDS Prevention Centre (MINE), Melbourne
Melbourne Sexual Health Centre, Melbourne
Middle Park Clinic, Melbourne
Monash Medical Centre, Melbourne
Monash University, Melbourne
Northcote Clinic, Melbourne
People Living with HIV/AIDS (PLWHA), Melbourne
Positive Living Centre, Melbourne
Prahran Market Clinic, Melbourne
Royal Children’s Hospital, Melbourne
Royal Melbourne Hospital, Melbourne
Royal Women’s Hospital, Melbourne
School of Population Health, The University of Melbourne, Melbourne
South East Alcohol and Drug Services, Outreach and Prevention Program, Melbourne
Southern Hepatitis/HIV/AIDS Resource and Prevention Service (SHARPS), Melbourne
St Vincent’s Hospital, Melbourne
The Alfred Hospital, Melbourne
The Carlton Clinic, Melbourne
The Centre Clinic, Melbourne
Turning Point Alcohol and Drug Centre, Melbourne
Victorian AIDS Council/Gay Men’s Health Centre (GMHC), Melbourne
Victorian Infectious Diseases Reference Laboratory, Melbourne

Western Australia
Centre for Clinical Immunology & Biomedical Statistics, Perth
Communicable Disease Control Directorate, Department of Health, Perth
Department of Health, Perth
Derbarl Yerrigan Health Service, Perth
Fremantle Hospital, Perth
Ministry of Justice, Strategic and Specialist Services Division, Perth
Princess Margaret Hospital for Children, Perth
Royal Perth Hospital, Perth
Sexual Health and Blood Borne Virus Program, Department of Health, Perth
Sir Charles Gairdner Hospital, Perth
The University of Western Australia, Perth
WA AIDS Council Mobile Exchange, Perth
Western Australian AIDS Council, Perth
Western Australian Substance Users Association, Perth and Bunbury, WA
International

Academic Medical Centre, University of Amsterdam, Amsterdam, The Netherlands
Agence Nationale pour la Recherche de SIDA (ANRS), Paris, France
AIDS Clinical Centre, International Medical Centre of Japan, Tokyo, Japan
AIDS Epidemiology Group, University of Otago Medical School, Dunedin, New Zealand
American Foundation for AIDS Research (amFAR), New York, USA
Asia Pacific Neuro AIDS Consortium (APNAC), Coordinating Unit, Sydney
Aviano Cancer Centre, Aviano, Italy
Bamrasnaradura Hospital, Bangkok, Thailand
Beijing Ditan Hospital, Beijing, China
British Columbia Cancer Registry, Vancouver, Canada
Buddhachinnaraj Hospital, Phitsanulok, Thailand
Canadian Aboriginal AIDS Network, Ottawa, Canada
Canadian Trials Network (CTN), Vancouver, Canada
Catalan Institute of Oncology, Barcelona, Spain
Catedra de Enfermedades Infecciosas, Facultad de Medicina, Universidad de la Republica, Montevideo, Uruguay
Center for AIDS Prevention Studies, University of California, San Francisco, USA
Centers for Disease Control and Prevention, Atlanta, USA
Centre for Infectious Disease Prevention and Control, Health Canada, Ottawa, Canada
Centre for Study and Prevention of Cancer, Florence, Italy
Centre Regional D’Essais Clinique VIH, Montreal, Canada
Centro de Asistencia e Investigacion Clinica de Inmunocomprometidos (CAICI), Rosario, Argentina
Chelsea and Westminster Hospital, London, UK
Chiang Rai Regional Hospital, Chiang Rai, Thailand
Chonburi Regional Hospital, Chonburi, Thailand
Christchurch Hospital, Christchurch, New Zealand
Chulalongkorn Hospital, Bangkok, Thailand
Columbia University, New York, USA
Community Information and Epidemiological Technologies Group, Canada Institute of Population Health, University of Ottawa, Ottawa, Canada
Community Research Initiative of New England, Boston, USA
Concerted Action on Seroconversion to AIDS and Death in Europe (CASCADE) and its contributors, Coordinating Unit, London, UK
Copenhagen HIV Programme, Hvidovre University Hospital, Copenhagen, Denmark
David Geffen School of Medicine, University of California, Los Angeles, USA
Denver Infectious Disease Consultants, Denver, USA
Department of HIV/GUM Research, Brighton, UK
Department of Maori and Pacific Health, University of Auckland, Auckland, New Zealand
Department of Preventative and Social Medicine, University of Otago, Dunedin, New Zealand
Division of Public Health and Psychosocial Studies, Auckland University of Technology, Auckland, New Zealand
Division of Statistics, School of Public Health, University of Minnesota, Minneapolis, USA
Faculty of Arts and Education, University of Ottawa, Ottawa, Canada
Feinberg School of Medicine, Northwestern University, Chicago, USA
Fundacion Arriaran, Santiago, Chile
Fundacion Centro de Estudios Infectologicos (FUNCEI), Clinica La Sagrada Familia, Buenos Aires, Argentina
Geneva Hospital, Geneva, Switzerland
German Cancer Research Center, Heidelberg, Germany
Hadassah Medical Centre, Jerusalem, Israel
Harlem Hospital Centre, New York, USA
Harvard University, Boston, USA
HIV Netherlands, Australia, Thailand Research Collaboration (HIV-NAT), Bangkok, Thailand
HIV Project, Ruby Hall Clinic, Pune, India
Hospital Cantonal Universitaire, Geneva, Switzerland
Hospital Central, Mendoza, Argentina
Hospital de Clinicas Jose de San Martin, Buenos Aires, Argentina
Hospital de Enfermedades Infecciosas FJ Muniz, Buenos Aires, Argentina
Hospital General de Agudos JM Ramos Mejia, Buenos Aires, Argentina
Hospital General de Agudos Juan A Fernandez, Buenos Aires, Argentina
Hospital General de Agudos Teodoro Alvarez, Buenos Aires, Argentina
Hospital Interzonal de Agudos San Juan de Dios, La Plata, Argentina
Hospital Interzonal General de Agudos Oscar Alende, Mar del Plata, Argentina
Hospital Italiano de Buenos Aires, Buenos Aires, Argentina
Hospital Kuala Lumpur, Kuala Lumpur, Malaysia
Hospital Rawson, Bajada Pucara, Argentina
Hospital Universitario Clementino, Rio de Janeiro, Brazil
Hvidovre Hospital, Copenhagen, Denmark
Infectologia Hospital Nacional Alejandro Posadas, Haedo, Argentina
INSERM U593, Université Victor Segalen, Bordeaux, France
International AIDS Society, Stockholm, Sweden
International AIDS Therapy Evaluation Centre, Amsterdam, The Netherlands
International Consortium of Investigators Working on Non-Hodgkin’s Lymphoma Epidemiologic Studies, National Cancer Institute, Frederick, USA
Johns Hopkins University, Baltimore, USA
Kaplan Medical Centre, Rehovot, Israel
Massachusetts General Hospital, Boston, USA
Medical Research Council Clinical Trials Unit, London, UK
Medizinische Universitätsklinik, Freiburg, Germany
Ministry of Public Health, Bangkok, Thailand
Montreal General Hospital, Montreal, Canada
Nakornping Hospital, Chiangmai, Thailand
National Center for HIV/AIDS, Dermatology and STD (NCHADS), Phnom Penh, Cambodia
National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, USA
National Institute for Public Health, Phnom Penh, Cambodia
National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, USA
National Institute on Drug Abuse, National Institutes of Health, Bethesda, USA
National Pediatric Hospital, Phnom Penh, Cambodia
Ngā Pae o te Māramatanga, The National Institute of Research Excellence for Māori Development and Advancement, University of Auckland, Auckland, New Zealand
Nuffield Department of Medicine, University of Oxford, Oxford, UK
Osaka National Hospital, Osaka, Japan
Partners AIDS Research Center, Boston, USA
Paediatric European Network for the Treatment of AIDS (PENTA), Coordinating Unit, London, UK
Perinatal HIV Prevention Trial Network, Thailand
Perinatal HIV Prevention Trial Network, Thailand
Queen Elizabeth Hospital, Hong Kong, China
Queen Sawangwattana Memorial Hospital, Sri Racha, Chonburi, Thailand
Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
Rambam Medical Centre, Haifa, Israel
Research Institute for Tropical Medicine, Manila, Philippines
Royal Free Hospital, London, UK
Royal Sussex County Hospital, Brighton, UK
Rush University Medical Center, Chicago, USA
San Francisco General Hospital, San Francisco, USA
Sanpatong Hospital, Chiang Mai, Thailand
School of Medicine, Udayana University and Sanglah Hospital, Denpasar, Bali, Indonesia
Siriraj Hospital, Bangkok, Thailand
Srinagarind Hospital, Khon Kaen, Thailand
Social Health Clinic, Phnom Penh, Cambodia
Swiss HIV Cohort Study Collaboration, Geneva, Switzerland
Taipei Veterans General Hospital and AIDS Prevention and Research Centre, National Yang-Ming University, Taipei, Taiwan
Tan Tock Seng Hospital, Singapore, Singapore
Tel Aviv Sourasky Medical Centre, Tel Aviv, Israel
Terry Beirn Community Programs for Clinical Research in AIDS (CPCRA), Washington, USA
Thai Red Cross Society, Chulalongkorn University Hospital, Bangkok, Thailand
The Government Pharmaceutical Organisation, Bangkok, Thailand
The Peter Medawar Building for Pathogen Research, University of Oxford, Oxford, UK
UNAIDS, Geneva, Switzerland
University Malaya, Kuala Lumpur, Malaysia
University of California, San Francisco, USA
University of Minnesota, Minneapolis, USA
University of Padua, Padua, Italy
University of Southern California, Los Angeles, USA
University of Tokyo Institute of Medical Science, Tokyo, Japan
University of Toronto, Toronto, Canada
University of York, York, UK
Vaccine Research Centre, National Institutes of Health, Bethesda, USA
Vajira Hospital, Bangkok, Thailand
Viral Epidemiology Section, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Frederick, USA
Waikato Hospital, Hamilton, New Zealand
Wellington Hospital, Wellington, New Zealand
Wetherall Institute of Molecular Medicine, Oxford, UK
World Health Organisation, Geneva, Switzerland
World Health Organisation Western Pacific Regional Office, Manila, Philippines
Yale University School of Medicine, New Haven, USA
Yang-Ming University, Taipei, Taiwan
YRG Centre for AIDS Research and Education, Chennai, India

Pharmaceutical and biomedical industry
Abbott Australasia Pty Ltd, Sydney
Becton Dickinson Pty Ltd, Sydney
Boehringer Ingelheim Pty Ltd, Sydney
Chiron Therapeutics, Emeryville, USA
CSL Limited, Melbourne
Cytosc Corporation Australia Pty Ltd, Sydney
F Hoffman-La Roche Ltd, Basel, Switzerland
Gilead Sciences, Melbourne
GlaxoSmithKline Australia, Melbourne
Merck Research Laboratories, West Point, USA
Merck Sharp and Dohme, Sydney
Roche Diagnostics Australia Pty Ltd, Sydney
Roche Molecular Systems, Pleasanton, USA
Roche Products Pty Ltd, Sydney
Starpharma Holdings Ltd, Melbourne
Tibotec, Mechelen, Belgium
Virax Immunotherapeutics, Melbourne
Advisory committees

Scientific Advisory Committee

Peter McDonald AM, MB BS, FRCPA, MRACP, FRACP, FASM (Chair)
Emeritus Professor, Flinders University, Adelaide

Don Baxter BA, Dip Lib
Executive Director, Australian Federation of AIDS Organisations, Sydney

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Richard Hillman BSc(Hons), MD, FRCP, FACHSHM
Senior Lecturer and Senior Staff Specialist, Sexually Transmitted Infections Research Centre, Westmead Hospital, Sydney

Sam Milliken MB BS, FRACP, FRCPA
Senior Lecturer and Senior Staff Specialist, Department of Haematology, St Vincent's Hospital, Sydney

Adrian Mindel MB BCh, MSc(CTM), MD, FRCP, FRACP, FACHSHM
Professor of Sexual Health Medicine, The University of Sydney, Sydney; Director, Sexually Transmitted Infections Research Centre, Westmead Hospital, Sydney

Handan Wand MA, MS, PhD
NCHECR

Kate Clezy MB BS, FRACP (Convenor)
NCHECR

Immune-Based Therapies Working Group

Sharon Lewin MB BS(Hons), FRACP, PhD (Chair)
Director, Infectious Diseases Unit, The Alfred Hospital, Melbourne

Michael Boyle BMedSci, MB BS, MD, FRACP, FRCPA
Staff Specialist, Immunology and Infectious Diseases, John Hunter Hospital, Newcastle, NSW; Conjoint Associate Professor, University of Newcastle, Newcastle, NSW

John Chuah BSc(Med)(Hons), MB BS, FACHSHM
Director, Gold Coast Sexual Health, Miami, Qld

Miles Davenport MB BS(Hons), DPhil
Senior Research Fellow, Centre for Vascular Research, UNSW, Sydney

Roger Garsia MB BS(Hons), PhD, FRACP, FRCPA
Director of Clinical AIDS Services and Staff Specialist in Immunology, Department of Clinical Immunology, Royal Prince Alfred Hospital, Sydney

Anthony Kelleher BSc(Hons), MB BS(Hons), PhD, FRACP, FRCPA
NCHECR

Mark Kelly MB BS(Hons), FRACP
Senior Medical Officer, AIDS Medical Unit, Queensland Health, Brisbane

Stephen Kent MB BS, FRACP, MD (Deputy Chair)
Associate Professor, Department of Microbiology and Immunology, The University of Melbourne, Melbourne

Alan Landay PhD (to July)
Visiting Professor of Immunology, Centre for Immunology, St Vincent's Hospital, Sydney

Matthew Law MA, MSc, PhD
NCHECR
Kirsty Machon BAComm, MA, Grad Dip Arts
HIV Health Policy Officer, National Association of People Living with HIV/AIDS, Sydney

Simon Mallal BMedSci(Hons), MB BS, FRACP, FRCPA
Professor and Executive Director, Centre for Clinical Immunology and Biomedical Statistics, Royal Perth Hospital, Perth

Graeme Stewart AM, BSc(Med), MB BS, PhD, FRACP, FRCPA
Professor and Director of Clinical Immunology, Department of Clinical Immunology and Allergy, Westmead Hospital, Sydney

Alan Strum BSc(Hons) (from May)
Treatments Policy and Education Coordinator, National Association of People Living with HIV/AIDS, Melbourne

John Sullivan PhD, MPH
Principal Scientist, Australian Red Cross Blood Service, Sydney; Associate Professor, Transfusion Medicine and Immunogenetics Research Unit, Central Clinical School, Faculty of Medicine, The University of Sydney, Sydney

Alan Walker RN, BA, Grad Dip App Sci, MPH
Nurse Unit Manager, Nambour General Hospital, Nambour, Qld

Sarah Pett BSc(Hons), MB BS(Hons), DTM&H, MRCP (UK), FRACP (Convenor)
NCHECR

Neurology Working Group
Bruce Brew MB BS(Hons), MD, FRACP (Chair)
Professor and Head, Department of Neurosciences and Neurology, St Vincent's Hospital, Sydney

Margaret Bain BSc(Psych), MClinPsych, MClinNeuropsych
Neuropsychologist, HIV Neuropsychology Service, St Vincent's Hospital, Sydney

Catherine Cherry MB BS, FRACP
Senior Research Fellow, Neurovirology Group, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne; Infectious Diseases Physician, Department of Infectious Diseases and Microbiology, The Alfred Hospital, Melbourne

Steven Ellen MB BS, MMED(Psych), MD, FRANZCP
Head, Department of Consultation–Liaison Psychiatry, The Alfred Hospital, Melbourne

Paul Gorry PhD
Head, HIV Molecular Pathogenesis Laboratory, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne

Barrie Harrison BSc(Hons), PhD
Treatments and HIV Health Promotion Officer, AIDS Council of New South Wales, Lismore, NSW

Matthew Law MA, MSc, PhD
NCHECR

Christopher Lee MB BS (Malaysia), MRCP (UK)
Consultant Physician, Hospital Besar, Kuala Lumpur, Malaysia

Patrick Li MB BS, FHKP, FHKAM (Medicine), FRCP (London), FRCP (Edinburgh)
Chief of Service, Department of Medicine, Queen Elizabeth Hospital, Hong Kong

Catriona McLean BSc, MB BS, FRCPA, MD
Consultant Pathologist, Department of Anatomical Pathology, The Alfred Hospital, Melbourne

Patricia Price PhD
Associate Professor, School of Surgery and Pathology, The University of Western Australia, Perth

Nitin Saksena BSc, MSc, PhD
Head, Retroviral Genetics Division, Centre for Virus Research, Westmead Millennium Institute for Medical Research, Sydney

Jo Watson
Executive Officer, National Association of People Living with HIV/AIDS, Sydney

Steve Wesselingh MB BS, FRACP, PhD
Director, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne

Edwina Wright MB BS, FRACP (Deputy Chair)
Infectious Diseases Specialist, Department of Infectious Diseases and Microbiology, The Alfred Hospital, Melbourne

Cate Carey RN, BA, MAppSc (Convenor)
NCHECR

Viral Hepatitis Working Group
Darrell Crawford MD, FRACP (Chair)
Associate Professor of Medicine, Princess Alexandra Hospital, Brisbane

Janaki Amin BSc(Hons), MPH(Hons)
NCHECR

David Baker MB ChB, DCH, Dip Med (Sexual Health)
General Practitioner, 407 Doctors, Sydney

Robert Batey MSc(Med)(Hons1), MB BS(Hons2), MD, FRACP, FRCP
Clinical Chair, Division of Medicine, John Hunter Hospital, Newcastle, NSW; Area Director, Drug and Alcohol Clinical Services, Hunter Area Health Service, Newcastle, NSW

Ingrid van Beek MB BS, MBA, FAFPHM, FACHAM
Director, Kirketon Road Centre, Sydney; Medical Director, Sydney Medically Supervised Injecting Centre, Sydney
Chris Burrell BSc(Med), MB BS, PhD, FRCPath, FRCPA
Professor of Virology, The University of Adelaide, Adelaide

Greg Dore MB BS, BSc, PhD, FRACP, MPH
NCHECR

Geoff Farrell MD, FRACP
Robert W Storr Professor of Hepatic Medicine, Westmead Millennium Institute for Medical Research, Sydney

Margaret Hellard MB BS, FRACP, PhD, FAFPHM
Head, Centre for Epidemiology and Population Health Research, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne

Susan Kippax BA(Hons), PhD, FASSA
Professor and Director, National Centre in HIV Social Research, UNSW, Sydney

Andrew Lloyd MB BS, MD, FRACP
Professor and Consultant Infectious Diseases Physician, Department of Infectious Diseases, Prince of Wales Hospital, Sydney

Stephen Locarnini MB BS, BSc(Hons), PhD, FRCPath
Divisional Head, Research and Molecular Development, Victorian Infectious Diseases Reference Laboratory, Melbourne; Director, World Health Organisation Collaborating Centre for Virus Reference and Research, Melbourne

Geoff McCaughan MB BS, FRACP, PhD
Professor of Medicine and Director, AW Morrow GE and Liver Centre, The University of Sydney and Royal Prince Alfred Hospital, Sydney; Head, Liver Immunobiology Group, Centenary Institute of Cancer Medicine and Cell Biology, Sydney

Zoe Potgeiter RN, CNS
Clinical Trial Coordinator, Immunology B Ambulatory Care Clinic, St Vincent’s Hospital, Sydney

Stuart Roberts MB BS, FRACP, MD
Deputy Director, Department of Gastroenterology, The Alfred Hospital, Melbourne

Joe Sasadeusz MB BS, FRACP, PhD
Infectious Diseases Physician, Royal Melbourne Hospital and The Alfred Hospital, Melbourne

William Sievert MD, FRACP
Head of Hepatology, Monash Medical Centre, Melbourne

Helen Tyrell BA(Hons), RN, MBA, FACHSE, CHE (from May)
Executive Officer, Australian Hepatitis Council, Canberra

Jack Wallace (to May)
Executive Officer, Australian Hepatitis Council, Canberra

Gail Matthews MB ChB, MRCP (Convenor)
NCHECR

NCHECR Working Groups ex officio

David A Cooper AO, BSc(Med), MB BS, DSc, MD, FRACP, FRCPA, FRCP
NCHECR

Levinia Crooks BA(Hons), Dip Ed (from July)
Chief Executive Officer, Australasian Society for HIV Medicine, Sydney

Anthony Cunningham MB BS, BMedSci(Hons), MD, FRACP, FRCPA, FASM
Director, Westmead Millennium Institute for Medical Research, Sydney; Director, Centre for Virus Research, Westmead Millennium Institute for Medical Research, Sydney

Sean Emery BSc(Hons), PhD
NCHECR

John M Kaldor PhD
NCHECR

Matthew Law MA, MSc, PhD
NCHECR

Peter McDonald AM, MB BS, FRCPA, MRACP, FRACP, FASM
Emeritus Professor, Flinders University, Adelaide
External boards, committees and advisory groups

1st International Workshop on Biomedical Interventions in HIV Therapy in Resource Poor Settings Scientific Committee
(John Kaldor)

1st International Workshop on Targeting HIV Entry Organising Committee
(David Cooper)

3rd International AIDS Society Conference on HIV Pathogenesis and Treatment, Prevention Sciences, Scientific Programme Committee
(John Kaldor)

3rd International AIDS Society Conference on HIV Pathogenesis and Treatment, Clinical Sciences, Scientific Programme Committee
(David Cooper)

4th International AIDS Society Conference on HIV Pathogenesis and Treatment
(David Cooper, Local Conference Chair; John Kaldor, Deputy Local Conference Chair)

4th International Conference on Urban Health Scientific Advisory Committee
(Lisa Maher)

7th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV Organising Committee
(David Cooper)

8th Bangkok Symposium on HIV Medicine Organising Committee
(David Cooper)

9th International Conference on Malignancies in AIDS and Other Acquired Immunodeficiencies, Basic, Epidemiologic and Clinical Research Organising Committee
(Andrew Grulich)

15th International Conference on the Reduction of Drug Related Harm Scientific Program Committee
(Lisa Maher)

Acute Infection and Early Disease Research Program, Pathogenesis Working Group
(Anthony Kelleher)

Acute Infection and Early Disease Research Program, PHAEDRA Steering Committee
(Anthony Kelleher)

Acute Infection and Early Disease Research Program, Structured Treatment Interruptions Trial Steering Committee
(Anthony Kelleher)

AIDS Council of New South Wales Board
(Garrett Prestage)

AIDS Council of New South Wales, HIV and Sexually Transmissible Infections Working Group
(Garrett Prestage)

AIDS Editorial Board
(Andrew Grulich)

amfAR TREAT Asia Steering Committee
(David Cooper, Greg Dore)

AusAID Indonesia HIV/AIDS Prevention and Care Project Phase II, Technical Advisory Team
(John Kaldor)

Australasian Chapter of Addiction Medicine, Chapter Committee
(Adrian Dunlop)

Australasian Health & Research Data Managers Association Education Subcommittee
(Pip Marks)

Australasian Health & Research Data Managers Association Executive Committee
(Elizabeth Knight, Pip Marks)

Australasian Society for HIV Medicine, Antiretroviral Guidelines Panel
(Fraser Drummond)

Australasian Society for HIV Medicine, International Standing Committee
(John Kaldor)

Australasian Society for HIV Medicine, National Clinical Subcommittee
(Fraser Drummond)

Australasian Society for HIV Medicine, National Committee
(Andrew Grulich, immediate past President)

Australasian Society for HIV Medicine, NSW Hepatitis C Prescriber Trial Clinical Subcommittee
(Greg Dore)

Australasian Society for HIV Medicine, Standing Committee on Viral Hepatitis
(Greg Dore, Chair; Lisa Maher)

Australasian Society for HIV Medicine, Treatment Subcommittee
(Fraser Drummond)

Australian Federation of AIDS Organisations, HIV Vaccine Policy Reference Group
(Andrew Grulich)

Australian Federation of AIDS Organisations, Indigenous Injecting Drug User Project Reference Group
(Lisa Maher)
Journal of Drug Issues Editorial Board
(Lisa Maher)

Journal of HIV Medicine Editorial Board
(Andrew Grulich)

Journal of HIV Therapy, Current Trends Advisory Board
(David Cooper)

Law and Sexworker Health (LASH) Core Committee
(John Kaldor)

Lotus House Management Committee
(Lisa Maher, President)

Microbicides for Prevention of HIV Transmission:
Current and Future Perspectives Symposium
Organising Committee
(John Kaldor)

Ministerial Advisory Committee on AIDS, Sexual
Health and Hepatitis, HIV/AIDS and Sexually
Transmissible Infections Subcommittee
(Andrew Grulich)

Hepatitis C Virus Projections Working Group
(John Kaldor, Matthew Law)

Ministerial Advisory Committee on AIDS, Sexual
Health and Hepatitis, Indigenous Australians’ Sexual
Health Committee
(John Kaldor)

Ministerial Advisory Committee on AIDS, Sexual
Health and Hepatitis, Hepatitis C Subcommittee
(Greg Dore)

Monitoring the AIDS Pandemic Steering Committee
(John Kaldor)

National Centre for HIV/AIDS, Dermatology and STD,
Steering Committee for Cambodian Treatment Access
Program (CTAP) and AusAID funded HIV projects
(David Cooper, John Kaldor)

National Centre for Immunisation Research and
Surveillance of Vaccine Preventable Disease Scientific
Advisory Committee
(John Kaldor)

National Centre in HIV Social Research Scientific
Advisory Committee
(John Kaldor)

National Donovanosis Eradication Advisory Committee
(John Kaldor)

National Health and Medical Research Council,
Special Expert Committee on Transmissible
Spongiform Encephalopathies (SECTSE), Working
Group on Biostate
(John Kaldor)

National Health and Medical Research Council,
Special Expert Committee on Transmissible
Spongiform Encephalopathies (SECTSE), Working
Group on Blood Matters
(John Kaldor, Matthew Law)

National Influenza Pandemic Action Committee,
Antivirals and Clinical Trials Working Group
(John Kaldor, Matthew Law)

National Surveillance Committee
(Ann McDonald)

Non-English Speaking Background Needle and
Syringe Program Advocacy Project Reference Group
(Lisa Maher)

NSW Department of Corrective Services Ethics
Committee
(John Kaldor)

NSW Health Department, NSW Multi-Resistant
Organism Expert Group
(John Kaldor)

NSW Health Department, HIV Health Promotion
Committee
(Andrew Grulich, Chair)

NSW Health Department, Medically Supervised
Injecting Centre Evaluation Advisory Committee
(John Kaldor)

NSW Health Department, Sexually Transmissible
Infections Strategy Subcommittee
(David Cooper, John Kaldor)

NSW Ministerial Advisory Committee on Hepatitis
(Greg Dore)

NSW Ministry for Science and Medical Research,
National Clinical Research Forum Planning Committee
(Anthony Kelleher)

People Living with HIV/AIDS NSW Board Advisory
Group
(Garrett Prestage)

PULSE Steering Committee
(Anthony Kelleher)

Repatriation Medical Authority
(John Kaldor)

Review of Sexually Transmitted Infections and Blood
Borne Virus Management and Prevention in the
Northern Territory Steering Committee
(John Kaldor)
Sexual Health Editorial Board
(Andrew Grulich, John Kaldor)

Sexual Health
(David Cooper, Joint Editor)

Sexually Transmitted Infections Editorial Board
(David Cooper)

SILCAAT Executive Committee
(Sean Emery)

SILCAAT Toxicity Committee
(Sarah Pett)

SMART Anal Dysplasia Substudy Team
(Fraser Drummond)

SMART Body Composition Substudy Team
(Fraser Drummond)

SMART Executive Committee
(David Cooper, Fraser Drummond, Sean Emery)

SMART Neurology Substudy Team
(Fraser Drummond)

SMART Protocol Team
(Fraser Drummond)

St Vincent's Hospital Campus Institutional Biosafety Committee
(Anthony Kelleher)

St Vincent's Hospital Human Research Ethics Committee
(Matthew Law)

St Vincent's Hospital Intellectual Property Committee
(Sean Emery)

Steering Committee for NHMRC grant under the International Collaborative Indigenous Health Research Partnership
(John Kaldor)

The 45 and Up Study, Cancer Theme Committee
(Andrew Grulich)

The Cabinet Office NSW, Monitoring Committee of the Medically Supervised Injecting Centre
(John Kaldor)

HIV Netherlands, Australia, Thailand Research Collaboration (HIV-NAT)
(David Cooper, Co-Director)

The University of Sydney, Corrections Health Service and NSW Department of Juvenile Justice Breaking the Juvenile Crime Cycle: Rehabilitating High Risk Young Offenders Reference Group
(John Kaldor)

The University of Sydney, School of Health Information Management External Advisory Committee
(Pip Marks)

TREAT Asia Steering Committee
(David Cooper)

UNAIDS Asia Regional Consultation Ethical Issues and Community Involvement in Prevention Research Trials
(John Kaldor)

UNSW Faculty of Medicine, Faculty Research Grants Committee
(Lisa Maher)

UNSW Human Research Ethics Advisory Panel: Medical/Community
(Greg Dore, Lisa Maher)

UNSW School of Public Health and Community Medicine, Research Degree Committee
(Lisa Maher)

UNSW School of Public Health and Community Medicine, Research Development Committee
(Lisa Maher)

Victorian Government Department of Human Services, Drugs of Dependence Advisory Committee
(Adrian Dunlop)

Vietnamese Australian Buddhist Assistance Trust Management Committee
(Lisa Maher)

Vision Cooperative Research Centre and Institute for Eye Research Human Ethics Committee
(Claire Vajdic)

World Health Organisation-UNAIDS HIV Vaccine Advisory Committee
(David Cooper, Chair)
Cotrimoxazole prophylaxis in HIV infection, World Health Organisation, Geneva, Switzerland
Chris Duncombe

Heptitis B in the Asia-Pacific Region, Janssen-Cilag Pty Ltd, Auckland, New Zealand
John Kaldor

National buprenorphine guidelines, Intergovernmental Committee on Drugs, Canberra
Adrian Dunlop

National clinical guidelines for managing drug use during pregnancy, birth and the early development years of the newborn, Intergovernmental Committee on Drugs, Canberra
Adrian Dunlop

Pacific Regional Training Workshop on HIV Care and Treatment, World Health Organisation, Suva, Fiji
Paddy Mallon

Progress in prevention and care in the context of the 3 by 5 initiative and the perspective of universal access in the Western Pacific Region, UNAIDS and World Health Organisation, Manilla, Philippines
Chris Duncombe

Second generation HIV surveillance in the Pacific, World Health Organisation and The Global Fund to Fight AIDS, Tuberculosis and Malaria, Nadi, Fiji
Lisa Maher
Students supervised or co-supervised by NCHECR personnel

Supervisor(s) in brackets

Activities of students whose primary supervisor is an NCHECR staff member are listed in this report under External boards, committees and advisory groups; Education and training; Publications and Presentations at conferences and meetings.

Bachelor of Medical Science (Honours) awarded

Heidi Lim
Effect of nucleoside reverse transcriptase inhibitors on adipocyte mitochondrial function
(Paddy Mallon, Anthony Kelleher)

Bachelor of Medicine candidates (Year 5 elective term supervision)

Jason Chan
The incidence and predictors of nevirapine association hypersensitivity in a Thai HIV infected population
(Chris Duncombe)

Zewlan Moor
The incidence and predictors of nevirapine association hypersensitivity in a Thai HIV infected population
(Chris Duncombe)

Doctor of Medicine candidate

Gail Matthews
Therapeutic strategies in HIV/viral hepatitis coinfection
(Greg Dore)

Sarah Pett
Aspects of HIV-1 treatment: An exploration of the positive and negative physiological aspects of host-directed treatments for HIV-1 infection
(Sean Emery)

Doctor of Philosophy awarded

Palanee Ammaranond
Evolution of HIV in response to therapeutic and immune mediated pressures
(Anthony Kelleher, David Cooper)

Doctor of Philosophy candidates

Janaki Amin
Hepatitis B and C disease progression
(Matthew Law, Greg Dore)

Mark Boyd
The efficacy, toxicity, pharmacokinetics, pharmacodynamics and pharmacogenomics of indinavir-containing antiretroviral therapy in adult Thai HIV-infected subjects
(David Cooper)

Michael Burke
Factors influencing participation in prevention of mother to child transmission (PMTCT) of HIV programs in Tanzania, East Africa
(John Kaldor)

Dianne Carey
Optimising HIV therapies
(Sean Emery)

Oliver Distler
Molecular and cellular mechanisms for HIV protease inhibitor associated hyperlipidaemia
(David Cooper)

Adrian Dunlop
Treatment for Vietnamese heroin users with new opioid pharmacotherapies
(Lisa Maher)

Katie Edwards
Epidemiological studies of contact lens related infection
(John Kaldor)

Julian Elliott
Expanded use of antiretroviral therapy in resource limited settings
(John Kaldor)

Rachel Green (Curtin University)
Ethnography and epidemiology of drug use
(Lisa Maher)

Peter Higgs (Monash University)
Factors influencing hepatitis C infection among ethnic Vietnamese heroin injectors
(Lisa Maher)

Hien Thi Ho
Cultural influences on risk behaviours and anti-HIV and hepatitis C virus seroprevalence in ethnic Vietnamese injecting drug users in Australia
(Lisa Maher)

Suzie Hudson
Improving understanding of psychostimulant-related harms in Australia: Experiences of street sex workers who inject psychostimulants
(Lisa Maher)
Jeff Jin  
Epidemiology of sexually transmissible infections in gay men in Sydney  
(Andrew Grulich, John Kaldor)

Azar Kariminia  
Mortality among full time prisoners in New South Wales  
(Matthew Law)

Paddy Mallon  
Clinical and molecular aspects of HIV-associated lipodystrophy  
(David Cooper, Anthony Kelleher)

Joanne Micallef  
Natural history of newly acquired hepatitis C infection  
(Greg Dore, John Kaldor)

Ann Mijch (Monash University)  
Measuring and managing HIV virological failure  
(John Kaldor)

John Miller  
Lipodystrophy in patients with HIV disease  
(John Kaldor)

Mee-Ling Munier  
CD4 T-cells in primary HIV infection  
(Anthony Kelleher)

Fatemeh Nakhaee  
Modelling survival following HIV and AIDS in Australia in the era of HAART  
(Matthew Law)

Van Thi Thuy Nguyen  
Hepatitis B natural history and liver disease burden among Vietnamese populations in Thai Binh province and Australia  
(Greg Dore, Matthew Law)

Meredith Nirui  
The health and wellbeing of homeless women and their accompanying children  
(Lisa Maher)

Kathy Petoumenos  
The Australian HIV Observational Database  
(Matthew Law, John Kaldor)

Farhad Pourfazi  
The influence of environmental risk factors on gastric cancer in North West of Iran – Ardabil Province  
(John Kaldor)

Mary Poynten  
Biological and behavioural methods of prevention of HIV/AIDS transmission  
(Andrew Grulich, John Kaldor)

Karina Razali  
Estimates and projections of HIV and hepatitis C virus in Australia and the Asia-Pacific region  
(Matthew Law, John Kaldor)

Allison Salmon  
Establishing the efficacy of health and psycho-social services and drug treatment referrals provided via a medically supervised injecting centre in Kings Cross, Sydney  
(Lisa Maher, John Kaldor)

Sarah Sasson  
Dysregulation of the IL-7/R system in HIV-1 infection and implications for T-cell homeostasis  
(Anthony Kelleher)

Preeyaporn Srasuebkul  
Evaluating CD4 cell count and HIV viral load monitoring strategies in patients commencing antiretroviral treatment  
(Matthew Law)

David Templeton  
Sexually transmitted infections in homosexual men  
(Andrew Grulich)

Rosie Thein  
Measuring the health burden of hepatitis C at an individual and population level in Australia  
(Greg Dore, John Kaldor)

John Zaunders  
Effect of primary HIV-1 infection on subsets of CD4+ and CD8+ T lymphocytes  
(David Cooper, Anthony Kelleher)

Jialun Zhou  
HIV/AIDS natural history and treatment in the Asia-Pacific region; TREAT Asia HIV Observational Database  
(Matthew Law, Greg Dore)

Master of Applied Epidemiology (Indigenous Health) awarded  
Chris Lawrence (Australian National University)  
(John Kaldor, Andrew Grulich)

Master of Biomedical Science by research awarded (practicum supervision)  
Sandra Klijn (Vrije University, The Netherlands)  
The impact of medical care on people living with HIV/AIDS enrolled in clinical trials at HIV-NAT  
(Chris Duncombe)

Julia Teerling (Vrije University, The Netherlands)  
The impact of medical care on people living with HIV/AIDS enrolled in clinical trials at HIV-NAT  
(Chris Duncombe)
Master of Health Science (Sexual Health) awarded
Jeff Hudson (The University of Sydney)
Married men who have sex with men: Exploring a landscape model of fluid sexuality
(Garrett Prestage)

Master of Medicine (Sexually Transmitted Diseases/HIV) awarded (treatise supervision)
Nurlan Silitonga (The University of Sydney)
Trends in the prevalence of gonorrheae and the condom use pattern among female sex workers first attending STD clinic in the mining town, Timika, West Papua, Indonesia 1997-2002
(John Kaldor)

Master of Medicine (Sexually Transmitted Diseases/HIV) candidate (treatise supervision)
Mwadi Kakoma (The University of Sydney)
The clinical correlations of lopinavir trough plasma concentrations with adverse events and concomitant medication use
(Dianne Carey)

Master of Public Health by research awarded
Suzanne Polis
Vertical transmission of hepatitis C virus to infants born to mothers who are infected with hepatitis C virus
(John Kaldor)

Master of Public Health by research candidates
Wari Allison
Establishing an observational database on paediatric antiretroviral therapy in developing countries
(John Kaldor)

Juliet Babirye
The role of infant feeding counselling in prevention of mother-to-child transmission of HIV in Uganda
(Andrew Grulich, John Kaldor)

Adeeba Kamarazulman
Natural history of HIV/AIDS
(Greg Dore, John Kaldor)

Master of Public Health major project awarded
Robert Oelrichs
Implementing a quality management system in a public health laboratory in Cambodia
(John Kaldor)

Bethany White
Prevalence of injecting drug use and associated risk behaviour among regular ecstasy users
(Carolyn Day)

Course coordination
Case Studies in Epidemiology, Master of Public Health, UNSW, Sydney
(Andrew Grulich)

Epidemiology for Public Health, Master of Public Health, UNSW, Sydney
(Andrew Grulich, John Kaldor)

HIV/AIDS: Australian and International Responses, Master of Public Health, UNSW, Sydney
(Greg Dore)

National Institutes of Health Regional Physicians HIV Training Course, 8th Bangkok Symposium on HIV Medicine, Bangkok, Thailand
(Chris Duncombe)

Rational Drug Use, Doctor of Philosophy Program in Social and Administrative Pharmacy, Chulalongkorn University, Bangkok, Thailand
(Stephen Kerr)

Teaching
Advanced Day Course in Hepatitis C (s100 Community Prescribing Pilot), Australasian Society for HIV Medicine, Sydney
(Greg Dore, Gail Matthews)

Advanced HIV Infection, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney, Sydney
(Anthony Kelleher)

Advanced HIV Nursing Course, Albion Street Centre, Sydney
(Dianne Carey)

An epidemiological approach to the critical appraisal of clinical evidence, short courses to the pharmaceutical industry, Sydney/Melbourne
(Andrew Grulich, John Kaldor)

Deviance, Bachelor of Arts, UNSW, Sydney
(Garrett Prestage)

Drug Intervention Training in Australia, Indonesian-Australian Specialised Training Project, The University of New South Wales and Macfarlane Burnet Institute for Medical Research and Public Health, Sydney
(John Kaldor)

Epidemiology for Public Health, Master of Public Health, UNSW, Sydney
(Andrew Grulich, John Kaldor)

ESPRIT and SILCAAT Regulatory Training, ESPRIT and SILCAAT Regional Coordinating Centre, Sydney
(David Courtney-Rodgers)
Global Perspectives on HIV/AIDS, Master of International Public Health, The University of Sydney, Sydney
  (Sean Emery, John Kaldor)
HIV/AIDS: Australian and International Responses, Master of Public Health, UNSW, Sydney
  (Dianne Carey, Greg Dore, Sean Emery, Andrew Grulich, John Kaldor, David van Bockel)
HIV Medicine Interactive Session (St Vincent’s Hospital), Year 6 Medicine, UNSW, Sydney
  (David Cooper)
Immunology 1, Bachelor of Science, UNSW, Sydney
  (Anthony Kelleher)
Immunology 2, Bachelor of Science, UNSW, Sydney
  (Anthony Kelleher)
International Health, Year 4 Medicine, UNSW, Sydney
  (Andrew Grulich)
International Short Course in HIV Medicine, Australasian Society for HIV Medicine, Hobart
  (Sarah Huffam)
Introduction to Clinical Pharmacology, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney, Sydney
  (Dianne Carey)
Introductory Program to HIV and Viral Hepatitis, St Vincent’s Hospital, Sydney
  (Greg Dore)
Population Health and Community Medicine, Year 4 Medicine, UNSW, Sydney
  (Lisa Maher)
Post Registration Nursing Course in Hepatitis C, Sydney Hospital and Sydney Eye Hospital, Sydney
  (Greg Dore)
Post Registration Nursing Course in Infection Control, Sydney Hospital and Sydney Eye Hospital, Sydney
  (Dianne Carey, Greg Dore, John Kaldor)
Post Registration Nursing Course in Ophthalmology, Sydney Hospital and Sydney Eye Hospital, Sydney
  (John Kaldor)
Post Registration Nursing Course in Sexual Health and Venereology, Sydney Hospital and Sydney Eye Hospital, Sydney
  (Janaki Amin, Dianne Carey, Greg Dore, John Kaldor)
Public Health Aspects of HIV/AIDS, Master of Public Health/Master of International Public Health/Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney, Sydney
  (Andrew Grulich)
Public Health Aspects of STDs, Master of Public Health/Master of International Public Health/Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney, Sydney
  (Greg Dore, John Kaldor, Matthew Law)
Short Course in HIV Medicine, Australasian Society for HIV Medicine, Sydney
  (Dianne Carey, Sean Emery, Sarah Pett)
Short Course in HIV Medicine, Australasian Society for HIV Medicine, Hobart
  (Dianne Carey, Paddy Mallon)
Short Course in HIV Medicine for Pharmaceutical Industry, Australasian Society for HIV Medicine and AIDS Treatment Project Australia, Sydney
  (Dianne Carey, Sean Emery, Ann McDonald, Paddy Mallon)
Short Course in HIV Medicine for Pharmaceutical Industry, Australasian Society for HIV Medicine and AIDS Treatment Project Australia, Melbourne
  (Paddy Mallon)
Social Health Clinic Training Program, National Center for HIV/AIDS, Dermatology and STD, Phnom Penh, Cambodia
  (David Cooper, Julian Elliott, Sarah Huffam, John Kaldor, Lisa Maher, Kathy Petoumenos)
The HIV pandemic and global healthcare, Master of International Affairs, Columbia University, New York, USA
  (John Kaldor)
Training in Sexually Transmitted Infections, Family Health International, Phnom Penh, Cambodia
  (Sarah Huffam)
Update on contemporary HIV issues for nurses working in HIV medicine, HIV and Hepatitis C Education Projects, The University of Queensland, Brisbane
  (John Kaldor)
Viruses and Disease, Bachelor of Science, UNSW, Sydney
  (Joanne Micallef)

Tutoring

Clinical and Communications Skills (Prince of Wales Hospital), Phase 1 Medicine, UNSW, Sydney
  (Kate Clezy)
Clinical Medicine (St Vincent’s Hospital), Year 3 Medicine, UNSW, Sydney
  (Fraser Drummond)
Clinical Medicine (St Vincent’s Hospital), Year 4 Medicine, UNSW, Sydney
  (Anthony Kelleher)
Health Maintenance 2, Phase 1 Medicine,
UNSW, Sydney
(Joanne Micallef)

Statistics for Public Health, Master of Public Health,
UNSW, Sydney
(Julian Zhou)

Viruses and Disease, Bachelor of Science,
UNSW, Sydney
(Joanne Micallef)
Funding for 2005

All amounts listed are in Australian dollars. Names of funding organisations are as specified at the time the funding agreement commenced.

**Australian Government Department of Health and Ageing core grant**

The Australian Government Department of Health and Ageing provided an allocation in 2005 to fund the activities and administration of NCHECR.

| Core allocation | 3,624,480 |

**Other Australian Government Department of Health and Ageing grants**

- Hepatitis C surveillance and research activities: 258,183
- Identification of best practice for nucleic acid amplification testing for *Neisseria gonorrhoea*: 7,273
- Survey of Aboriginal and Torres Strait Islander men who have sex with men in Queensland: 6,613

**Other grants and contracts from public sources**

- AIDS Council of New South Wales: 9,091
- American Foundation for AIDS Research: TREAT Asia HIV Observational Database: 408,159
- AusAID: Cambodia HIV/AIDS antiretroviral therapy project: 100,213
- European Medicines Evaluation Agency: Data Collection on Adverse Events of Anti-HIV Drugs Study: 41,648
- Family Health International: Tenofovir prevention study: 262,722
- Institute for Health Research: Career Development Award for Chris Lawrence: 30,000
- Medical Research Council, UK
  - Immune restoration disease in INITIO trial patients: 118,555
  - INITIO Study: 246,526
  - *INITIO Study – Lipodystrophy Substudy*: 50,668
  - SPARTAC Study: 23,492
- NHMRC
  - Causes of mortality following imprisonment in NSW: 68,500
  - Public Health (Australia) Fellowship for Caroline Day: 66,000
  - Public Health (Australia) Fellowship for Claire Vajdic: 23,100
  - The role of resiliency in responding to blood-borne viral and sexually transmitted infections in Indigenous communities: 15,000
- NHMRC Program Grant Subcontract
  - Curtin University: Improving understanding of psycho stimulant-related harms in Australia: 27,310
  - The University of Melbourne: HIV infection – immunology and vaccine design: 295,911
- NSW Health Department
  - Evaluation of the Sydney Medically Supervised Injecting Centre Phase 2: 215,500
  - Expert services in HIV/AIDS, viral hepatitis and sexually transmissible diseases: 225,000
  - Health in Men (HIM) HIV vaccine preparedness cohort study – Extension of the HIM cohort: 122,652
  - Health in Men (HIM) HIV vaccine preparedness cohort study – Project Officer: 104,288
  - New South Wales client census survey: 27,163
  - Research and development infrastructure grant program: 464,845

*(continued next page…)*
Other grants and contracts from public sources  
(…continued from previous page)

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<tr>
<th>Organization</th>
<th>Project Description</th>
<th>Amount</th>
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<td>The Cancer Council of NSW</td>
<td>Cancer in dialysis patients and kidney transplant recipients</td>
<td>27,500</td>
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<tr>
<td>University of Minnesota</td>
<td>SILCAAT Study</td>
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<td>US National Institutes of Health</td>
<td>HIV Vaccine Design and Development Team contract</td>
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<td>Longitudinal cohort of newly acquired hepatitis C infection</td>
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<td>Protease Inhibitor Related Atherosclerosis in HIV</td>
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<td>US National Institutes of Health subcontracts</td>
<td>Massachusetts General Hospital : AIEDRP Study</td>
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<td>Social and Scientific Systems: SMART Study</td>
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<td></td>
<td>University of California San Francisco: Phase 1/11 trial of pharmacological HIV-1 prevention</td>
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<td>University of Minnesota: ESPRIT Study</td>
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<td>University of Minnesota: STALWART Study</td>
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Pharmaceutical industry funding

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<td>Abbott Australia Pty Ltd</td>
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<td>Boehringer-Ingelheim Pty Ltd</td>
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<td>Bristol-Myers Squibb Pharmaceuticals (Australia)</td>
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<td>CSL Research and Development</td>
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<td>Gilead Sciences Inc</td>
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<td>GlaxoSmithKline Research and Development (Australia)</td>
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<td>Janssen-Cilag Pty Ltd</td>
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<td>Merck Sharp &amp; Dohme</td>
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<td>Pfizer Inc</td>
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<td>F Hoffman-La Roche Ltd (Switzerland)</td>
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<td>Roche Products Pty Ltd (Australia)</td>
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<tr>
<td>Virax Immunotherapeutic Pty Ltd</td>
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* Industry funds administered through publicly-funded agencies

Bronwen Turner, Annie Tung
Disclosure of financial and other relationships with industry

As noted under Funding for 2005 (see page 77), NCHECR receives financial support for a number of its projects from pharmaceutical companies. In relation to the companies indicated, staff members listed below either served on advisory boards; received individual travel grants, consultancy payments or honoraria; or were the first degree relative of an employee during 2005.

No staff member owned shares, was a personal recipient of a tied or untied grant or had ownership in intellectual property related to any company that funded NCHECR’s research program during 2005.

Abbreviated forms of the company names have been used for ease of recognition.

<table>
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<tr>
<th>David Cooper</th>
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Presentations at conferences and meetings

Conference oral presentations*


Cooper DA, Yeni P. Virological and immunological outcomes at three years following initiation of antiretroviral therapy with regimens containing a non-nucleoside reverse transcriptase inhibitor or protease inhibitor or both: The INITIO trial. 12th Conference on Retroviruses and Opportunistic Infections. Boston, USA.


Drummond F. When to commence antiretroviral therapy (in established HIV infection). 1st Australasian Consensus Conference on the Use of Antiretroviral Agents in HIV-1 Infected Adults. Hobart.


Dunlop A. Neonatal withdrawal in the antipodes: Management of neonatal abstinence syndrome in Australia. 67th Annual Scientific Meeting of the College of Problems on Drug Dependence. Orlando, USA.

Dwyer DE, Workman C, Amin J, Connor S, Emery SE, Hales G, Miller J, Cooper DA on behalf of the Alliance Study investigators. Final results from the Alliance Study (ML16992) – A 96 week, open-label study to describe the efficacy and safety of enfuvirtide in patients changing therapy to an NRTI-sparing regimen. 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.

* This section includes presentations on which an NCHECR staff member was the presenting author, apart from presentations made at the 17th Annual Conference of the Australasian Society for HIV Medicine and the 12th Conference on Retroviruses and Opportunistic Infections for which all authorships are noted.


Grey P, Smith DE, Bloch M, McFarlane R, Finlayson R, Doong N, Chuah J, Carr A, Cooper DA, Kelleher AD and the PULSE Study Team. Time to commencing long-term antiretroviral therapy, for patients who were treated at primary HIV infection, achieved virological suppression, and then followed a structured interruption strategy. 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.


Kaldor JM. Current global and Australian trends in HIV infection. 5th Australian Update on Paediatric HIV and Hepatitis. Sydney.


Kaldor JM. Update on Repatriation Medical Authority (RMA) activities. 90th National Congress of the Returned and Services League of Australia. Hobart.

Kaldor JM. When is the right time to start an HIV prevention trial? Seventh International Congress on AIDS in Asia and the Pacific. Kobe, Japan.


Kelleher AD. An update on the pathophysiology of primary infection. Australian Centre for HIV and Hepatitis Virology Research Annual Meeting. Terrigal, NSW.

Maher L

Kelleher AD. RX of primary. 1st Australasian Consensus Conference on the Use of Antiretroviral Agents in HIV-1 Infected Adults. Hobart.


Middleton MG, McDonald AM, Kaldor JM. Monitoring the completeness of notifications to the National AIDS Registry via linkage to the National Death Index. 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.


Prestage GP. Queensland Aboriginal and Torres Strait Islander men who have sex with men survey: Findings and implications. Australian Federation of AIDS Organisations Gay Educators Conference. Sydney.


Salmon AM, Kaldor JM, Jauncey M, van Beek I, Maher L. The Sydney Medically Supervised Injecting Centre evaluation: An update after four years of operation. UNSW School of Public Health and Community Medicine Postgraduate Research Student Conference. Sydney.

Sasaduesz J, Dore GJ, Kronberg I, Barton D, Weltman M. An interim analysis from a single-arm, open-label, multicentre pilot study evaluating the efficacy and safety of PEGASYS RBV (peginterferon alfa-2a plus ribavirin) in patients with chronic hepatitis C (CHC) attending a methadone (or drug dependency treatment program) clinic. 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.

Sasson S. Increased plasma IL-7 correlates with decreased CD127 and increased CD132 extracellular expression on T-cell subsets in HIV-1 infection. Australian Centre for HIV and Hepatitis Virology Research Annual Meeting. Terrigal, NSW.


Thein HH, Day C, Dore GJ, Kaldor JM, Maher L. Antibody hepatitis C prevalence and risk behaviours among vulnerable populations attending needle and syringe programs in Australia. 16th International Conference on the Reduction of Drug Related Harm. Belfast, Northern Ireland.

Thein HH, Day C, Kaldor JM, Maher L. Public opinion and community impact of a medically supervised injecting centre in Sydney, Australia. 16th International Conference on the Reduction of Drug Related Harm. Belfast, Northern Ireland.


Zaunders J. Downregulation of antigen-specific CD4+ T-cells during primary HIV-1 infection. Australian Centre for HIV and Hepatitis Virology Research Annual Meeting. Terrigal, NSW.


Zhou J on behalf of the TREAT Asia HIV Observational Database. New AIDS defining illness diagnosed within 90 days after initiation of antiretroviral treatment among patients from the TREAT Asia HIV Observational Database (TAHOD). 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.


Cooper DA. New drugs in development. St Vincent’s Hospital, Centre for Immunology, HIV/Infectious Diseases Immunology Journal Club. Sydney.

Courtney-Rodgers D. ESPRIT and SILCAAT quality assurance update. ESPRIT, SILCAAT, SMART and STALWART Investigator Meeting. Sydney.


Dore GJ. Advances in hepatitis C therapeutics. Viruses in May Workshop. Katoomba, NSW.


Dore GJ. Meeting the challenges in Australian hepatitis C clinical research. CHARIOT Study Investigators Meeting. Sydney.


Dore GJ. Responding to the challenge of hepatitis C. St Vincent’s Hospital Hepatitis C Treatment Awareness Week. Sydney.

Drummond F. Enrolment update, baseline demographics for the SMART study. ESPRIT, SILCAAT, SMART and STALWART Investigator Meeting. Sydney.


Drummond F. NCHECR Therapeutic and Vaccine Research Program study outcomes and ongoing trials. NCHECR Trial Network Site Coordinators Satellite Meeting. Hobart.

Other oral presentations

Ammaranond P. Escape at an immunodominant epitope predicts loss of viral control in HLA-B27 positive individuals. Centre for Immunology Research Seminar. Sydney.

Elliott JH. The Cambodian national HIV care training program. TREAT Asia Network Meeting. Bangkok, Thailand.


Grulich AE. Risk factors for HIV in the Health in Men Study. NSW Health Department Ministerial Committee on AIDS Strategy. Sydney.


Jacoby S. SILCAAT update. ESPRIT, SILCAAT, SMART and STAWART Investigator Meeting. Sydney.


Kaldor JM. Progress at a national level. NSW Health Department Workshop: Aboriginal Sexually Transmitted Infections and Blood-Borne Virus Epidemiology Forum. Sydney.

Kaldor JM. Recent trends in blood-borne viral and sexually transmitted infections among Aboriginal and Torres Strait Islander people in Australia. Australian Federation of AIDS Organisations Bi-Annual Members Meeting. Sydney.

Kaldor JM. Recent trends in HIV/AIDS, hepatitis C and STIs. Townsville Aboriginal and Islanders Health Services Meeting. Townsville.


Kaldor JM. Tenofovir study. St Vincent’s Hospital, HIV/Immunology and Infectious Diseases Unit Journal Club. Sydney.


Kelleher AD. Biomedical prevention. NSW Health Department, AIDS/Infectious Diseases Branch, HIV and Sexually Transmissible Infections Unit. Sydney.


Kelleher AD. Early career training - The transition to clinical researcher. NSW Ministry for Science and Medical Research and the National Health and Medical Research Council National Clinical Research Forum, Clinical Research – Removing the Barriers. Sydney.

Kelleher AD. Utility of T-cell assays. Royal Prince Alfred Hospital, Department of Clinical Immunology. Sydney.


Law MG. Mathematical and statistical modelling at NCHECR. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases Meeting. Sydney.


Law MG. TREAT Asia HIV Observational Database: Methods and processes. TREAT Asia First Paediatric HIV Network Meeting. Bangkok, Thailand.


Lim H. Nucleoside reverse transcriptase inhibitor effects on mouse adipocyte mitochondria. Centre for Immunology Research Seminar. Sydney.

Lim H. Nucleoside reverse transcriptase inhibitor effects on mouse adipocyte mitochondria. Professor William Powderly, School of Medicine and Medical Science, University College Dublin, Dublin, visit to St Vincent’s Hospital, Centre for Immunology. Sydney.


Mallon PWG. Feedback from the 6th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV and the 12th Conference on Retroviruses and Opportunistic Infections - something for everyone. St Vincent’s Hospital, HIV/Immunology and Infectious Diseases Unit Journal Club. Sydney.


Marks P. Trials of treatment for acute or newly acquired hepatitis C. The NCHECR Trial Network Site Coordinators Meeting. Hobart.

Marks P. Viral Hepatitis Clinical Research Program Overview. Australian Trial in Acute Hepatitis C Coordinators’ Meeting. Sydney.


Prestage GP. Queensland Aboriginal and Torres Strait Islander men who have sex with men survey: Findings and implications. Queensland Aboriginal and Torres Strait Islander Sexual Health Congress. Gold Coast, Qld.


Prestage GP. Research on gay men in rural NSW: Findings and implications. NSW Health Rural Forum. Mudgee, NSW.


Prestage GP. Research on gay men in Western Sydney: Findings and implications. Western Sydney Area Health Service Staff Workshop. Sydney.


Prestage GP. Twenty years of ACON and the community response. AIDS Council of New South Wales Staff Workshop. Sydney.


Ritter A, Dunlop A. Buprenorphine and Pregnancy. Buprenorphine and Pregnancy Workshop held during the 67th Annual Scientific Meeting of the College of Problems on Drug Dependence. Orlando, USA.

Sasson S. Linking IL-7/R system with T and B-cell neoplastic events (LINE) study. Centre for Immunology Research Seminar. Sydney.

Satchell CS. SMART monitoring update. ESPRIT, SILCAAT, SMART and STALWART Investigator Meeting. Sydney.


Sedwell R. Nucleoside reverse transcriptase inhibitors and mitochondrial toxicity - Gene expression and functional studies. Professor William Powderly, School of Medicine and Medical Science, University College Dublin, Dublin, visit to St Vincent's Hospital, Centre for Immunology. Sydney.

van Bockel D. HIV-1 virology. Centre for Immunology Research Seminar. Sydney.

van Bockel D. T-cell receptor usage in HLA B27 long-term non-progressors. Characterisation of CD4+ CCR5+ T-cells in primary HIV and other primary viral infections study investigators meeting. Terrigal, NSW.


Yeung B. Screening and enrolment. Australian Trial in Acute Hepatitis C Coordinators’ Meeting. Sydney.

Zaunders J. Early proliferation of CCR5+ CD38+++ antigen-specific CD4+ Th1 effector cells during primary HIV-1 infection. Centre for Immunology Research Seminar. Sydney.

Zaunders J. Informing the generation of primary CD4+ memory responses through studying responses to vaccinia. Acute Infection and Early Disease Research Program Teleconference.

**Conference poster presentations**


* This section includes all posters co-authored by an NCHECR staff member for the 17th Annual Conference of the Australasian Society for HIV Medicine, the 12th Conference on Retroviruses and Opportunistic Infections and the 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment, as well as other selected posters.


Babirye JN, Kaldor JM, Grolich AE. Adherence to Ugandan infant feeding guidelines among HIV-positive and HIV-negative mothers. Uganda Society for Health Scientists Annual General and Scientific Meeting. Kampala, Uganda.

Babirye JN, Kaldor JM, Grolich AE. Adherence to Ugandan infant feeding guidelines among HIV-positive and HIV-negative mothers. UNSW Faculty of Medicine Research Day. Sydney.


Cooper DA on behalf of the Alliance Investigator Group. An analysis of the correlation between the severity of injection site reactions and the amount of subcutaneous fat in the Alliance cohort. 12th Conference on Retroviruses and Opportunistic Infections. Boston, USA.


Ip S. Extracellular and intracellular marker comparison of fresh whole blood, fresh peripheral blood mononuclear cells versus cryopreserved PBMCs. 15th Annual St Vincent’s and Mater Health Research Symposium. Sydney.


Kelleher AD on behalf of the Australian-Thai HIV Vaccine Consortium. Preliminary safety and immunogenicity of a B-subtype DNA prime/recombinant fowlpox boost candidate prophylactic HIV vaccine. 12th Conference on Retroviruses and Opportunistic Infections. Boston, USA.


McGinley C, Munier MLC, Yeung JY, Bailey MR, Merlin KM, Ip S, Brereton C, van Bockel D, Kelleher AD. Importance of ongoing internal quality control program; monitoring the recovery of peripheral blood mononuclear cells (PBMCs) derived from participants of HIV clinical trials. 15th Annual St Vincent’s and Mater Health Research Symposium. Sydney.


Munier MLC, van Bockel D, Zaunders J, Ip S, Merlin K, Satchell CS, McGinley C, Pipersias M, Ammaranond P, Cooper DA, Pett S, Kelleher AD. Ongoing exuberant CD4 T-cell responses in chronic pauci bacillary non-tuberculous mycobacteria immune reconstitution disease are persistent in both peripheral blood and lymphoid tissue. 12th Conference on Retroviruses and Opportunistic Infections. Boston, USA.


Sedwell R, Mallon PWG, Duarte N, Zaunders J, Kelleher AD, Cooper DA, Carr A. Impaired mitochondrial function induced by NRTI is only detectable in the monocyte (CD14+) subset of human PBMC. 7th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV. Dublin, Ireland.


Torriani F, Katlama C, Sulkowski M, Dore GJ, Cooper DA, Dieterich D, Benhamou Y. Sustained virological response (SVR) to peginterferon alfa-2a (40KD) (PEGASYS®) plus ribavirin (COPEGUS®) in HIV-HCV co-infected patients according to antiretroviral therapy (ART) in the AIDS PEGASYS Ribavirin International Co-infection Trial (APRICOT). 10th European AIDS Conference/ EACS. Dublin, Ireland.


Zaunders J, Dyer W, Munier MLC, Ip S, Amyes E, Cooper DA, Kelleher AD. Distinct survival phenotype of CCR5+ antigen-specific CD4+ T lymphocytes in the acute phase of the antiviral responses to HIV-1 and vaccinia. 15th Annual St Vincent’s and Mater Health Research Symposium. Sydney.

Zaunders J, Dyer W, Munier MLC, Ip S, Amyes E, Cooper DA, Kelleher AD. Distinct survival phenotype of CCR5+ antigen-specific CD4+ T lymphocytes in the acute phase of the antiviral responses to HIV-1 and vaccinia. 28th Annual Scientific Meeting of the Australasian Flow Cytometry Group. Gold Coast, Qld.

Zhou J, Paton NL on behalf of the TREAT Asia HIV Observational Database. New AIDS defining illness diagnosed within 90 days after initiation of antiretroviral treatment among patients from the TREAT Asia HIV Observational Database (TAHOD). 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment. Rio de Janeiro, Brazil.

Zhou J, Paton NL, Ditangco R on behalf of the TREAT Asia HIV Observational Database. Experience with the use of a first-line regimen of stavudine, lamivudine and nevirapine among patients from TREAT Asia HIV Observational Database. 17th Annual Conference of the Australasian Society for HIV Medicine. Hobart.

Peer reviewed


Day C, Degenhardt L, Gilmour S, Hall W. The impact of changes to heroin supply on blood-borne virus notifications and injecting related harms in New South Wales, Australia. *BMC Public Health* 2005;5:84.


Degenhardt L, Day C, Hall W, Conroy E, Gilmour S. Was an increase in cocaine use in New South Wales, Australia, accompanied by an increase in violent crime? *BMC Public Health* 2005;5:40.


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**Coralie Kronenberg**


Non-peer reviewed


* invited publication