

NATIONAL CENTRE IN HIV EPIDEMIOLOGY AND CLINICAL RESEARCH

**ANNUAL REPORT 2002** 

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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. The Centre's brief has grown over the years.

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 Commonwealth Department of Health and Ageing. Its work is overseen by a Scientific Advisory Committee, which reports through the Australian National Council on AIDS, Hepatitis C and Related Diseases.



Back Row: Matthew Law, John Kaldor, Sean Emery, Don Smith, Bronwen Turner, Tony Kelleher Front Row: Annie Tung, David Cooper, Andrew Grulich, Greg Dore

NCHECR's primary functions relate to the coordination of national surveillance programs and clinical trials related to HIV/AIDS. The Centre also carries out research on the epidemiological and clinical aspects of HIV/AIDS and other blood-borne viruses and sexually transmissible infections. 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. It also works closely with the two other national HIV research centres, the National Centre in HIV Virology Research and the National Centre in HIV Social Research.

Dissemination of NCHECR's research output is undertaken through publication in scientific journals and a series of surveillance reports.

The Centre conducts its research through seven scientific areas:

- The Surveillance Program
- The Therapeutic and Vaccine Research Program
- The HIV Epidemiology and Prevention Program
- The Viral Hepatitis Program
- The Primary HIV Research Program
- The Biostatistics and Databases Program
- The Laboratory Support Program



The NCHECR is funded by the Commonwealth Department of Health and Ageing, through the Faculty of Medicine at the University of New South Wales, to coordinate national surveillance and carry out clinical and epidemiological research into HIV/AIDS, viral hepatitis and sexually transmissible infections. A five-year renewal of funding for the NCHECR was awarded in 1999. In the middle of 2002, NCHECR underwent scientific review with the outcome being a very favourable report from a panel of international and national experts.

In its surveillance role NCHECR worked with States and Territories to continue to monitor long-term trends in HIV occurrence in Australia. Of concern in several States was the possible resurgence of HIV infection after years of declining levels. Although there is not a clear increasing trend, some indicators are pointing towards the need for a renewed emphasis on prevention.

A range of projects in hepatitis C natural history and treatment were developed within the framework of the newly created Working Group on Viral Hepatitis jointly auspiced by NCHECR and the Australian Liver Association. There was particular emphasis on studies of hepatitis C and HIV coinfection, and studies of newly acquired hepatitis C.

A large grant to study pathogenesis, natural history and treatment of newly acquired HIV infection in collaboration with Massachusetts General Hospital was also awarded. In Australia, recruitment for this project began during the latter part of the year and was progressing successfully through the efforts of collaborating primary care practitioners.

An important undertaking during 2002 was NCHECR's involvement in the evaluation of the Medically Supervised Injecting Centre. This report was due to be finalised in the first half of 2003.

Enrolment continued in one of the largest cohort studies of gay men in the world and reached more than 900 by the end of 2002. This cohort is funded through the development group of the Australian-Thailand HIV Vaccine Consortium. Progress on developing the first clinical trial for the vaccine was also made in 2002 with the goal of recruiting early in 2003.

Monitoring of post exposure prophylaxis for non-occupational exposure to HIV continued with the total in the study reaching 819, making this study population one of the largest of its kind in the world. So far no seroconversions have occurred under treatment.

Under NCHECR coordination, an international study was completed to develop a case definition for lipodystrophy. The algorithm developed from the study will enable clinicians to objectively assess whether or not a patient has developed this metabolic complication. A major advance in treatment options for lipodystrophy resulted from the MITOX study, which showed for the first time an evidence-based strategy for reversing lipoatrophy by switching nucleoside reverse transcriptase inhibitors.

The use of resistance testing in HIV management was investigated through the CREST study that involved clinical sites around Australia comparing two approaches to implementation.

Probably the most important new development for NCHECR during 2002 concerned an expansion of activities in the Asia Pacific Region. Already very active in clinical trials in Thailand through the HIV-NAT program, NCHECR has now established a research relationship with the Ministry of Health in Cambodia. NCHECR has also become involved in developing HIV surveillance through the AusAID-funded HIV/AIDS project in Indonesia.



David Cooper, John Kaldor

Finally, we would like to express our gratitude to the many individuals and organisations that make our work possible, ranging from funding agencies to collaborating clinical sites. We also depend on a range of advisory groups and working groups across the spectrum of our activities and would like to acknowledge their crucial role in the development and implementation of our research program.

David Cooper, Director

Dand Coper

John Kaldor, Deputy Director

# Research activities

The following sections describe NCHECR achievements and activities within Programs during 2002. Staff members, as well as collaborators, from outside organisations are specifically named in association with each area of activity. Three senior staff members are not named because they have a range of supervisory roles, as follows:

The Director, David Cooper, directly supervises the Heads of the Programs in Therapeutic and Vaccine Research and Laboratory Support. He takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: ESPRIT, SILCAAT, INITIO, the National Institutes of Health-funded Vaccine Design and Development Project, AIEDRP, SMART and STACCATO. He is also an active Co-Director of HIV-NAT, the clinical research collaboration in Bangkok, Thailand.

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, Primary HIV Research and Biostatistics and Databases. He takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: AIEDRP, the HIV prevention trial in Cambodia, the HIV/AIDS Prevention and Care Project Phase II in Indonesia, and the US National Institutes of Health-funded project on natural history and treatment for newly acquired hepatitis C.

Sean Emery is Head of the Program in Therapeutic and Vaccine Research. In this capacity he has a particular supervisory role for all projects that fall within the Program, and takes specific responsibility as a named Principal Investigator or externally recognised leading investigator in the following projects: ESPRIT, SILCAAT, the US National Institutes of Health-funded Vaccine Design and Development Project, SMART, CREST, Lipodystrophy Case Definition and ROSEY.

# **Surveillance Program**

NCHECR conducts its surveillance activities in collaboration with the health authorities of all States and Territories and the Commonwealth. It supports specialist subcommittees of the Commonwealth Diseases Network Australia, which develop and implement surveillance procedures. Information is disseminated via the HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report, which provides a comprehensive analysis and interpretation of epidemiological information. The Annual Surveillance Report was published in 2002 for the sixth successive year, and included for the first time, estimates of the number of people living with hepatitis C infection in Australia, hepatitis C prevalence among people seen through a network of sexual health clinics and the numbers of prescriptions of antiviral therapy for the treatment of hepatitis C infection.

Working with the Communicable Diseases Network Australia Case Definitions Working Group, NCHECR assisted in the updating of HIV infection, viral hepatitis and sexually transmissible infections during 2002.



John Kaldor

Work continued on the evaluation of a "detuned" HIV antibody assay for determining whether or not HIV infection had been acquired recently. The Detuned ELISA Working Group was established in 2002 for the purpose of developing an integrated national

policy on detuned testing, incorporating the interests of laboratories, HIV surveillance programs, clinical management and people with, or at risk of, HIV infection.

National case-reporting procedures for hepatitis B, hepatitis C and specific sexually transmissible infections were reviewed during 2002, and an evaluation of the extent to which the Australian Hepatitis C Surveillance Strategy had been implemented was also carried out. A review of newly acquired hepatitis C infection in Australia was undertaken, with characterisation of recent patterns of transmission. A project estimating the number of people living with chronic hepatitis B in Australia was also completed. Published reports on methods of surveillance for sexually transmissible infections in

other countries were reviewed to provide information for further development of sexually transmissible infection surveillance in Australia.

## Surveillance systems

#### Case reporting for HIV and AIDS

The pattern of HIV transmission in Australia continued to be monitored through notification, by State and Territory health authorities, of cases of newly diagnosed HIV infection and AIDS. The national case definitions for newly diagnosed and newly acquired HIV infection were revised in 2002 to include virological as well as immunological evidence of infection, and are awaiting formal adoption by the Communicable Diseases Network Australia.

Results of case reporting for HIV infection and AIDS to the end of 2001 were released in HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2002. AIDS incidence has steadily dropped from its peak of 954 cases in 1994 to 178 cases in 2001. The agestandardised rate of AIDS diagnosis declined over time in both the Indigenous and non-Indigenous populations, but the rate of decline was substantially slower in the Indigenous population. Declining AIDS incidence was attributed to the expanding use, from mid 1996, of antiretroviral treatments for HIV infection. The number of AIDS cases in one subgroup, made up of people whose HIV infection was diagnosed within the preceding three months, did not decline. This group accounted for approximately 40% of the annual number of AIDS diagnoses in 1997-2001.

By the end of 2001, an estimated 12,730 people were living with HIV infection in Australia, a slight increase over the previous year's estimate. This rise was attributed to improved treatments for HIV infection, resulting in better long-term outcomes. Survival following AIDS had more than doubled between 1994 and 1997.

The possibility of a resurgence in HIV transmission has been suggested by results from behavioural surveys indicating a continuing increase in the prevalence of unprotected anal intercourse with casual partners among homosexually active men, and the increasing rates of diagnosis of gonorrhoea. In Victoria, the number of new HIV diagnoses increased quite sharply from 1999 to 2000 with a smaller increase in 2001. However, this trend was not mirrored in other parts of Australia, and there has been little change over time in the rate of diagnosis of newly acquired HIV infection.

Surveillance authorities used nationally agreed procedures to obtain more detailed information on exposure history for all cases of newly diagnosed HIV infection attributed to sources other than male homosexual contact. Of 136 cases of HIV infection newly diagnosed in 2001 for which there was a returned exposure questionnaire, 79% reported a history of heterosexual contact only, 16% reported injecting drug use and exposure history remained undetermined in 5%, usually because the person did not provide a comprehensive history of potential exposure. Among cases attributed to heterosexual contact only, 63% were people from countries of high HIV prevalence or their sexual partners.

Country of birth at HIV diagnosis, for cases whose exposure to HIV was attributed to heterosexual contact, was reported for the first time in the *Annual Surveillance Report*. Of 551 cases of HIV infection newly diagnosed in Australia in 1997-2001 for which there was a returned exposure questionnaire, country of birth was reported as Australia for 35%, and 2% were born in other countries in the Oceania region. One quarter of cases were born in a country in Asia, and 22% were born in a country in sub-Saharan Africa.

Perinatal exposure to HIV was monitored in collaboration with the Australian Paediatric Surveillance Unit. HIV infection remains rare among Australian children. Of 24 cases of perinatal exposure reported in 2001, 22 were in children born to women whose HIV infection was diagnosed antenatally. Almost all women whose HIV infection was diagnosed antenatally had taken antiretroviral therapy in pregnancy and had avoided breastfeeding to reduce the risk of mother-to-child HIV transmission. None of these exposed children acquired HIV infection. Both women whose HIV infection was diagnosed postnatally had breastfed their child.

Investigators: Ann McDonald, Melanie Middleton

Collaborators: State and Territory health authorities; Australian
Paediatric Surveillance Unit; National Serology Reference
Laboratory, Australia

# Case reporting for hepatitis B and hepatitis C infection

During 2002, the National Viral Hepatitis Surveillance Committee of the Communicable Diseases Network Australia, supported by NCHECR, has continued to coordinate activities related to the implementation of hepatitis C surveillance at national level.

Large numbers of cases of newly diagnosed hepatitis C antibody continued to be notified in Australia in 2001. Enhanced surveillance procedures for newly acquired hepatitis C were used by six Australian jurisdictions during 2002, and there was a gradual shift towards the adoption of a consistent case definition for newly acquired hepatitis C infection. NCHECR analysed the information collected during 1997-2000 through enhanced surveillance procedures for newly acquired hepatitis C. The analysis found that the detection and description of incident cases had gradually improved over this time period. While injecting drug use was the most commonly identified risk factor (in 93% of newly acquired cases), sexual contact and tattooing were also identified in small numbers. The study found that less than 3% of cases of hepatitis C infection reported to the National Notifiable Diseases Surveillance System (NNDSS) were identified as newly acquired, highlighting the numerous constraints in the development of diagnostic and surveillance systems for hepatitis C, and the need to strengthen the nation-wide standardised enhanced surveillance system to more effectively monitor newly acquired hepatitis C infections.

The Annual Surveillance Report 2002 presented information provided by the Australia and New Zealand Liver Transplant Register showing that the primary cause of liver disease among the 215 people who had had a transplant in 2000-2001 was hepatitis C infection in 21.4%, and hepatitis B infection in 14% of cases.

As a preliminary step towards developing enhanced surveillance mechanisms for hepatitis B in Australia, NCHECR carried out an analysis in 2002 of the notifications of newly acquired hepatitis B at national level. The analysis found that while all jurisdictions collect basic demographic information, only about half collect the country of birth, racial origin and risk factor information, and the reason for testing and hepatitis B immunisation history are infrequently recorded. Methods of recording risk factor information vary widely across State and Territory jurisdictions.

Investigators: Greg Dore, Monica Robotin

Collaborators: State and Territory health authorities; National Viral
Hepatitis Surveillance Committee

#### Surveillance for sexually transmissible infections

Diagnoses of chlamydia and gonorrhoea increased substantially over the past five years to 105.8 and 33.4 per 100,000 population respectively in 2001. The number of diagnoses of donovanosis increased in 2001 for the first time in the past eight years. Indigenous people continued to be diagnosed with specific sexually transmissible infections (STIs) at much higher rates than non-Indigenous people. Increasing national rates of diagnosis of specific STIs highlight the need for accurate and reliable case reporting and control of these conditions.

Since August 2001, the Sexually Transmissible Infections Surveillance Committee, under the auspices of the Communicable Diseases Network Australia (CDNA), has worked toward the development of a national framework for STI control. The Committee includes representatives from each health jurisdiction, along with key national organisations with an interest in STI control. In July 2002, Russell Waddell replaced John Kaldor as Committee chair.

During 2002, the Committee finalised case definitions for sexually acquired chlamydia, donovanosis, gonorrhoea and syphilis for approval by CDNA, and a draft case definition for congenital syphilis was submitted to CDNA for review. A draft report reviewing current jurisdictional procedures for STI surveillance was produced and work was also begun on a review of STI occurrence in Australia and methods of STI surveillance.

Investigators: Claire Vajdic, Melanie Middleton

**Collaborators:** State and Territory health authorities; Public Health Laboratory Network; Australasian College of Sexual Health Physicians; Commonwealth Department of Health and Ageing

# Monitoring HIV and hepatitis C seroprevalence through sexual health clinics

A network of metropolitan public sexual health clinics in Australia has monitored the pattern of testing for HIV antibody and new HIV diagnoses since 1991. In 2001, the pattern of testing for hepatitis C antibody through the sexual health clinics was reported for the first time in the *Annual Surveillance Report 2002*.

HIV prevalence remained low among people seen through the network of sexual health clinics in 2001. Overall, 32,190 people were seen at the collaborating clinics, 49% were tested for HIV antibody and 58 (0.3%) were newly diagnosed with HIV infection. Of 8,919 people with a history of heterosexual contact in Australia who were tested for HIV antibody, 5 (0.1%) were newly diagnosed with HIV infection. HIV

prevalence was also low among 1,147 female sex workers (0.2%), and among 1,319 people with a history of heterosexual contact overseas (0.2%). HIV prevalence was highest among homosexually active men (1.5%), and among men with an undetermined exposure history (1.7%). Among homosexually active men who were retested within 12 months of their last negative test, HIV incidence was 1.3% among men aged less than 25 years and was 2.4% among men aged 25 years and older.

The extent of testing for hepatitis C antibody varied widely between the collaborating sexual health clinics, from less than 10% to almost 80%. Overall, prevalence of hepatitis C antibody was higher among women than men, and was highest among people with a reported history of injecting drug use.

Investigator: Ann McDonald

Collaborators: Network of sexual health clinics

## Monitoring HIV infection among people entering Australian prisons

The extent and outcome of testing for HIV antibody has been monitored among people received into Australian prisons, in collaboration with jurisdictional corrective services and prison health services, from 1991. Results to the end of 2001 were released in the *Annual Surveillance Report 2002*.

The extent of HIV antibody testing at reception into prison has dropped from over 70% in the early 1990s to less than 60% in 2001. HIV prevalence among tested prison entrants has remained below 0.5% in all States and Territories. A new diagnosis of HIV infection was made for one third of the prison entrants reported to have HIV infection; almost two thirds had been diagnosed at a previous reception.

Investigator: Ann McDonald

**Collaborators:** State and Territory corrective services and prison health services

# Surveillance for HIV, hepatitis C and related risk behaviours among clients at needle and syringe programs

The annual national survey monitoring HIV and hepatitis C infection and related risk behaviours among injecting drug users at sentinel needle and syringe programs (NSPs) was carried out in October 2002. New survey sites were included in Tasmania, and regional New South Wales and Queensland. Almost 2,500 clients at 44 NSPs completed the survey questionnaire and provided blood specimens for HIV and hepatitis C testing.

Results from the 2001 survey were released in the Annual Surveillance Report 2002, and in more detail in a specialised report entitled Prevalence of HIV, HCV and injecting and sexual behaviour among IDU at Needle and Syringe Programs, Australian NSP Survey National Data Report 1995-2001. Overall prevalence of HIV infection was low (0.9%) among 2,342 injecting drug users recruited from 38 sites in 2001. Consistent with previous surveys, HIV prevalence was high among gay, male injectors (16%). Prevalence of hepatitis C virus increased from 53% in 2000, to 58% in 2001. There was a continued increase in hepatitis C virus prevalence among participants reporting less than three years of drug injection from 1998 (17%) to 1999 (20%), 2000 (26%) and 2001 (28%).

Trends in type of drug last injected among survey participants were again reported via the Illicit Drug Reporting System (IDRS) Bulletin, October 2002, in collaboration with the National Drug and Alcohol Research Centre. Data from New South Wales were also included in the Report of the Chief Health Officer for 2002.

Investigators: Margaret MacDonald, Megan Buddle, Julian Zhou Collaborators: Macfarlane Burnet Institute for Medical Research and Public Health; National Drug and Alcohol Research Centre; Alcohol and Drug Service, St Vincent's Hospital, Sydney; Centre for Immunology, St Vincent's Hospital, Sydney; State and Territory health authorities; needle and syringe program sites

# Monitoring HIV, hepatitis B and hepatitis C seroprevalence among blood donors

Cases of newly diagnosed HIV infection in blood donors are routinely notified to NCHECR through the Australian Red Cross Blood Service (ARCBS). The ARCBS also provides summaries of the number of blood donors newly diagnosed with hepatitis B surface antigen or hepatitis C antibody, and the number of blood donors tested for HIV antibody, hepatitis B surface antigen and hepatitis C antibody, broken down by State/Territory and year.

In 2000-2001, 6 cases of HIV infection in blood donors were reported, giving a prevalence of 0.3 per 100,000 donations. In 2001, 123 blood donors were diagnosed with hepatitis B surface antigen, and 159 had hepatitis C antibody, giving prevalences of 13 and 16 per 100,000 donations, respectively.

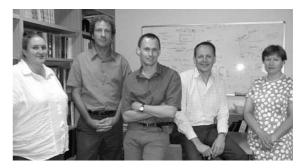
Investigators: Melanie Middleton, Ann McDonald Collaborator: Australian Red Cross Blood Service

# Monitoring HIV and hepatitis C seroprevalence among entrants to the Australian Defence Force

The Australian Defence Force (ADF) provides summaries of the number of new entrants, the number tested for HIV and hepatitis C antibody and the number newly diagnosed with infection, broken down by State/Territory and year of recruitment.

No new cases of HIV infection have been diagnosed among entrants into the ADF since 1996. In the year to 31 March 2001, the prevalence of hepatitis C infection among ADF entrants was 0.91 per 1,000 entrants.

Investigators: Janaki Amin, Ann McDonald Collaborator: Australian Defence Force



Melanie Middleton, John Kaldor, Andrew Grulich, Greg Dore, Ann McDonald

#### Periodic Survey of risk behaviour in gay men

The Periodic Surveys provide behavioural surveillance among gay men at risk of HIV infection. Commencing in Sydney in 1996, the surveys have since been extended to Melbourne, Brisbane, Adelaide, Perth, and Canberra, as well as some regional centres in Queensland.

In 2002, surveys were conducted in Sydney (2,050 completed questionnaires in February; 834 completed questionnaires in August), Melbourne (1,877 completed questionnaires in January), Queensland (1,787 completed questionnaires in June), and Perth (806 completed questionnaires in November).

The previously identified trend of increasing unprotected anal intercourse with casual partners continued to be found in all capital cities. Rates and frequency of HIV testing appear to have changed little over time, but there has been a small decline in the proportion of HIV-positive gay men using antiviral treatments.

Investigators: Garrett Prestage, Andrew Grulich

Collaborators: National Centre in HIV Social Research; Australian
Federation of AIDS Organisations; National Association of People

Living with HIV/AIDS

## Surveillance methods and analyses

## HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2002

Planning of the *Annual Surveillance Report 2002* was guided by an advisory committee which included representatives from affected communities and government agencies, as well as clinicians, and was chaired by Dr Jeremy McAnulty, the nominated representative of the Communicable Diseases Network Australia.

Following suggestions from the Annual Surveillance Report Advisory Committee, the Summary was expanded in the *Annual Surveillance Report 2002* to include key statistics and their interpretation. The presentation of tabulations in the *Annual Surveillance Report 2002* was restructured into sections on diagnosed cases of HIV/AIDS, viral hepatitis and sexually transmissible infections, seroprevalence, risk behaviour and estimates of the number of cases of HIV infection and hepatitis C infection. The data were also presented in figures in the main findings section of the *Annual Surveillance Report 2002*.

Investigators: Ann McDonald, Melanie Middleton

Collaborators: Collaborating networks in surveillance for

HIV/AIDS, viral hepatitis and sexually transmissible infections

#### Australian HIV Surveillance Report

The Australian HIV Surveillance Report continued to be published in 2002, providing quarterly updates on the number of new diagnoses of HIV/AIDS and estimates of 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.

In the January 2002 issue, HIV exposure history was described for cases of HIV infection, newly diagnosed in Australia in 1996-2001, for which exposure was attributed to heterosexual contact only. The first three years of use in Australia of non-occupational post-exposure prophylaxis (PEP) for HIV was summarised in the April 2002 issue. Selected epidemiological, clinical and social research findings reported at the XIV International AIDS Conference, held in Barcelona, Spain, in early July 2002, were summarised in the July issue. In the October issue, changes in the management of HIV surveillance data in New South Wales and trends in new HIV diagnoses were reported.

Investigators: Ann McDonald, Melanie Middleton, Matthew Law Collaborators: State and Territory health authorities; Network of sexual health clinics: Australian Paediatric Surveillance Unit

# Linkage between the National AIDS Registry and the National Death Index

To assess the completeness of AIDS notification in Australia, AIDS cases and deaths following AIDS notified to the National AIDS Registry were matched to AIDS-associated deaths registered with the National Death Index held at the Australian Institute of Health and Welfare. Assessment of the matched deaths suggests that more than 90% of deaths following AIDS had been notified.

Investigator: Ann McDonald

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

# Use of the "detuned" ELISA for monitoring newly acquired HIV infection

Since 1991, national surveillance for newly diagnosed HIV infection in Australia has included the reporting of information on the recency of infection, as defined either by a prior negative antibody test, or the clinical diagnosis of HIV seroconversion illness. Surveillance for newly acquired infection provides a lower bound to the actual extent of HIV transmission because many people with newly acquired HIV infection will not have a documented history of a recent negative test or an HIV seroconversion illness.

The United States Centers for Disease Control and Prevention has developed a serological method for identifying cases of early HIV infection. It makes use of a less sensitive test, which has a high probability of being negative in people whose infection is recently acquired. During 2002, the NSW State Reference Laboratory for HIV/AIDS at St Vincent's Hospital, in collaboration with NCHECR, continued evaluating the performance of the test. Of 571 cases with a detuned result linked to the National HIV Database to retrieve the date of first HIV diagnosis in Australia, 198 (34.1%) were identified as recently infected by the detuned test, whereas 184 (31.6%) had other evidence of recent infection. Of 57 cases with an interval of 180 days or less between the last negative test and the detuned test, 49 (86%) were identified on the detuned test as recent. The detuned test falsely indicated recent infection in 6 of 32 (18.8%) AIDS cases. A Detuned ELISA Working Group was established, for developing an integrated national policy on detuned testing, incorporating the interests of laboratories, HIV surveillance programs, clinical management issues and community responses. The Working Group includes representatives from Australasian Society for HIV Medicine, the National Association of People living with HIV/AIDS, the Public Health Laboratory Network, the National Serology Reference Laboratory, Australia and NCHECR.

Investigators: Ann McDonald, Mark Clements

**Collaborators:** NSW State Reference Laboratory for HIV/AIDS;

**NSW Health Department** 

#### Blood borne viruses in Indigenous people

NCHECR undertook a comprehensive analysis of available surveillance data and reported to national advisory bodies on the issue of injecting and blood borne virus risk among Indigenous people. The report noted that Indigenous people were over represented among attenders at needle and syringe programs (around 8%, compared to around 3% of the Australian population overall), and that there had been some suggestion, based on a small number of cases, of an increase in reported HIV diagnoses among Indigenous people related to injecting drug use.

Investigators: Margaret MacDonald, Ann McDonald, Melanie

Middleton, Greg Dore

**Collaborators:** State and Territory health authorities

# Therapeutic and Vaccine Research Program

During 2002 the Therapeutic and Vaccine Research Program made several important peer-reviewed contributions to HIV medical research, and reached significant milestones in other projects. Furthermore, plans are well advanced for other studies that may be implemented during 2003. Collaborations locally and internationally continue to grow and mature, reflecting the high regard for NCHECR and its clinical resource network.

The MITOX and Lipodystrophy Case Definition projects were completed and accepted for publication in AIDS and The Lancet respectively. MITOX provided the first robust evidence that modification of antiretroviral therapy (switching away from thymidine analogue reverse transcriptase inhibitors) can produce real, albeit modest improvements in peripheral fat among patients with lipodystrophy. The Lipodystrophy Case Definition Study has resulted in an objective case definition for body shape changes in HIV patients based upon a mixture of laboratory and clinical characteristics. This case definition will aid in the assessment of lipodystrophy prevalence, risk factors, pathogenesis, prevention and treatment, and assist in diagnosis. Both studies included a significant contribution from international collaborations. In MITOX, patients were recruited at the Royal Free Hospital in London, and in the Lipodystrophy Case Definition Study, of approximately 800 patients recruited, the majority came from participant sites on four continents other than Australia.

The increasing complexity of HIV medical research coordinated through the Therapeutic and Vaccine Research Program is exemplified by the ROSEY study that completed recruitment during 2002. This randomised, placebo-controlled trial of rosiglitazone with blinded data, multiple substudies and an independent Data and Safety Monitoring Board, is the most sophisticated interventional study undertaken through the NCHECR network in Australia. Results are expected around June 2003. An ongoing collaboration with investigators at the Garvan Institute and the Department of Renal Medicine at Prince of Wales Hospital has given rise to the HAMA and SAMA studies that commenced in 2002. These small studies involve the recruitment and intensive follow up (including serial fat biopsies) of HIV seropositive and negative volunteers to look at the pathogenesis of metabolic complications of antiretroviral therapy. NCHECR personnel also commenced preparation of a clinical trial to examine the safety and efficacy of a polylactic acid preparation (Newfill) as a cosmetic correction for facial lipoatrophy.

The CREST study was completed in mid 2002. Work was begun on a manuscript to describe the primary dataset, and collaborators around the country published three papers arising from the study. NCHECR undertook preparation of an application to the Medical Services Advisory Committee to place HIV drug resistance testing on to the reimbursement schedule in Australia. INITIO completed recruitment with Australian and New Zealand sites contributing 140 patients to a global total of 915. A further 30 patients have been recruited in the Brazilian site participating in this study that is coordinated by NCHECR. Treatment studies focusing on the strategic use of antiretroviral therapy also commenced through the NCHECR network in Australia and New Zealand. The SMART trial completed the opening of 10 preliminary sites (tier 1) in which some 34 patients have been randomised. STACCATO also commenced recruitment, with Australia expected to contribute 30 patients, to a global total of 600.



**Sean Emery** 

During 2002, priority was given to the development of a new randomised study of antiretroviral therapy that would address research questions in people who have never been treated before. A number of proposals were reviewed during the year.

NCHECR is involved

in coordination of the two large international clinical endpoint studies of interleukin-2. The SILCAAT study completed recruitment during 2002 with Australian sites contributing 125 patients. More recently this study has been the subject of some controversy given the decision by Chiron to cease support around the world. NCHECR staff have been involved in negotiations with Chiron to determine if there is any way to continue the study. ESPRIT nearly completed recruitment of the 4000 (197 from Australia) required patients, making it the largest interventional study in HIV disease. NCHECR coordinates this study in Australia, Argentina, Israel, Japan, Singapore and Thailand. NCHECR personnel also play a key role on the ESPRIT Executive Committee.

Therapeutic vaccine research also attained a milestone during 2002 with the completion of recruitment of 35 subjects into the Avipox Therapeutic Vaccine Study at practices in Sydney and Melbourne. Following completion of the protocol mandated 52-week follow-up, patients are offered an extension phase protocol involving

revaccination and then cessation of antiretroviral therapy with follow-up for a further 20 weeks.

During 2002, Therapeutic and Vaccine Research Program personnel were involved in preparation for the conduct of the phase I/II safety and immunogenicity study of the candidate prophylactic HIV vaccine, prepared under the award from the United States National Institutes of Health that was made in 2000. This study is designed to recruit 24 seronegative volunteers at low risk of HIV infection through a single site in Sydney.

NCHECR continued to collaborate with the United States-funded AIDS Malignancy Consortium, and a number of studies are available for examination of new treatment approaches for Kaposi's sarcoma and AIDS related lymphoma. A new opportunity to collaborate with CSL Limited on the development of a therapeutic vaccine for the treatment of anal intraepithelial neoplasia was reviewed.

During 2002, the organisation of the NCHECR working groups underwent significant changes with the rotation of most chairpersons and a large part of each working group's membership. The success and popularity of the twice-yearly working group meetings continued to grow with a participant constituency of approximately 80 collaborators from around Australia.

## **Antiretroviral therapy**

# Studies closed to recruitment or completed during 2002

#### **INITIO**

A randomised trial to evaluate different therapeutic strategies of combination therapy for HIV infection.

**Status:** Recruitment closed April 2002 (Follow-up to be completed March 2004)

**Sites:** 28 (25 Australia / 2 New Zealand / 1 Brazil) **Enrolled/target:** 171(140 Australia and New Zealand / 31 Brazil)/100

**Sponsor:** Medical Research Council, UK / NCHECR

Contact: Dianne Carey, Susan Phipps

#### **CREST I**

A randomised, multi-centre study to assess and compare genotypic and virtual phenotypic resistance testing in HIV-1 infected individuals with an HIV RNA viral load >1500 copies/mL in whom a change in current antiretroviral therapy is indicated.

**Status:** Recruitment closed April 2001 (Follow-up complete August 2002, manuscript in progress)

Sites: 41

Enrolled/target: 338/300

**Sponsor:** Virco Lab Inc / Roche Products Pty Ltd / Boehringer Ingelheim / GlaxoSmithKline / Abbott Australasia Pty Ltd / Bristol-Myers Squibb / Merck Sharpe and Dohme / Perkin-Elmer Biosystems / Australian Technology / Clinical Trials and Research Committee

Contact: Gillian Hales

## Studies recruiting during 2002

#### **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: Open May 2002

Sites: 25 including New Zealand (Tier 1 - 10 sites,

Tier 2 - 15 sites)

Enrolled/target: 34/200 Australia / 797/6,000

internationally

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of

Health, USA

Contact: Fraser Drummond, Sue Phipps

#### ML16992

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

Status: Open November 2002

**Sites:** 19

Enrolled/target: 6/60

**Sponsor:** Roche Products Pty Ltd

Contact: Gillian Hales

#### **STACCATO**

The Swiss-Thai-Australia Treatment Interruption Study. This study compares continuous therapy with intermittent therapy either based on CD4 cell count or on a fixed week on/week off regimen.

Status: Open October 2002

Sites: 6 (Australia / Thailand / Switzerland / Canada /

Argentina)

Enrolled/target: 3/30 Australia, 101/600 internationally

**Sponsor:** NCHECR

**Contact:** Fraser Drummond, Jaimie Cox

## Studies in preparation 2002

#### Once daily antiretroviral therapy for HIV infection

A randomised open-label study in treatment-naïve and experienced HIV infected patients to assess the safety and efficacy of a once-daily regimen of efavirenz, tenofovir and lamivudine with any other antiretroviral combination delivered at least twice daily.

Status: In development
Sites: To be decided
Target: To be finalised
Contact: Fraser Drummond

#### **Pacific**

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

Status: In development Sites: To be decided Target: To be finalised Contact: Fraser Drummond

## Lipodystrophy studies

# Studies closed to recruitment or completed during 2002

#### **MITOX**

A randomised comparative study of continuing therapy versus replacement of thymidine analogue with guanosine analogue in patients with lipoatrophy.

**Status:** Open April 2000, recruitment closed December 2000, study completed August 2002. (Week 24 data published *JAMA* June 2002)

Sites: 16

Enrolled/target: 111/100

**Sponsor:** GlaxoSmithKline / NCHECR **Contact:** Allison Martin, Don Smith

## **ROSEY**

A randomised, double blind, placebo-controlled, multi-centre study of rosiglitazone for the treatment of HIV lipodystrophy.

Status: Recruitment closed June 2002

Sites: 17

Enrolled/target: 108/100

Sponsor: GlaxoSmithKline / Bristol-Myers Squibb /

NCHECR

Contact: Dianne Carey, Allison Martin

#### **Lipodystrophy Case Definition**

An objective case definition of lipodystrophy in HIV-infected adults.

Status: Open September 2000, closed September

2001. Manuscript in press The Lancet

Sites: 32 (Australia / Singapore / Japan / Argentina /

Europe / North America)
Enrolled/target: 790/800

Sponsor: Ingenix Pharmaceutical Services Inc

Contact: Rebekah Puls

## Studies recruiting during 2002

#### MITOX extension

A long-term comparative study of immediate versus deferred replacement of thymidine analogue with guanosine analogue in patients with lipoatrophy.

Status: Open November 2000

**Sites:** 16

Enrolled/target: 82/105

Sponsor: GlaxoSmithKline / NCHECR

Contact: Allison Martin

#### **SAMA 001**

Seronegatives, Antiretrovirals and Metabolic Abnormalities

A randomised study of the effect of treatment with zidovudine (AZT) and lamivudine (3TC) versus stavudine (d4T) and lamivudine (3TC) in HIV negative healthy subjects on the development of abnormalities of lipid and glucose metabolism.

Status: Open June 2002

Sites: 1

Enrolled/target: 12/20

Sponsor: National Heart, Lung and Blood Institute,

National Institutes of Health, USA

Contact: Paddy Mallon



Back Row: Dianne Carey, Fraser Drummond, Gillian Hales

Front Row: Paddy Mallon, Sarah Pett

### Studies in preparation

#### **SAMA 002**

Seronegatives, Antiretrovirals and Metabolic Abnormalities

A randomised study of the effect of treatment with protease inhibitors versus non-nucleoside reverse transcriptase inhibitors in HIV negative healthy subjects on the development of abnormalities of lipid and glucose metabolism.

Status: Pending

Sites: 1 Target: 40

Sponsor: National Heart, Lung and Blood Institute,

National Institutes of Health, USA,

**Contact:** Paddy Mallon

#### **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: Pending

Sites: 1 Target: 80

Sponsor: National Heart, Lung and Blood Institute,

National Institutes of Health, USA

Contact: Paddy Mallon

#### Surgical correction of facial lipoatrophy

A randomised, open-label study to assess the safety, efficacy and durability of immediate or deferred intradermal injections of polylactic acid in patients with facial lipoatrophy associated with HIV antiretroviral therapy.

Status: In development Sites: To be decided Target: To be finalised Sponsor: To be decided Contact: Jaimie Cox

## **Immune-based therapies**

# Studies closed to recruitment or completed during 2002

#### **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: Open April 2000, recruitment closed

October 2002 **Sites:** 12

Enrolled/target: 126/125

**Sponsor:** Chiron Therapeutics / NCHECR **Contact:** Sarah Pett, Cate Carey, Fonnie Chan

#### ITV

Avipox vaccine study

A multicentre, double-blind, placebo-controlled, randomised evaluation of safety and immunogenicity of an avipox vector (rFPV) containing HIV genomic material (*gag*-pol) with or without co-expression of an immuno-enhancing cytokine gene (interferon-gamma) in patients treated with effective antiretroviral therapy commencing during primary HIV infection.

Status: Recruitment closed July 2002

Sites: 6

Enrolled/target: 35/35

**Sponsor:** Virax Immunotherapeutics / ANCAHRD

Clinical Trials and Research Committee

Contact: Rebekah Puls, Alexander Aichelburg

#### HRG 214 (PROBE)

A phase I trial of the pharmacokinetics and safety of the caprine antibody PEHRG214 in persons living with HIV.

Status: Recruitment closed July 2002

Sites: 1

Enrolled/target: 11/15

Sponsor: Probe Pharmaceuticals Pty Ltd

Contact: Sarah Pett

## Studies recruiting during 2002

#### **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/mm<sup>3</sup>.

Status: Open October 2000

Sites: 47 (23 Australia / 3 Japan / 1 Singapore /

5 Thailand / 13 Argentina / 3 Israel)

Enrolled/target: 3553/4000 (197/247 Australia / 1077/1161 Israel, Thailand, Singapore, Argentina, Lenan)

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA

Contact: Sarah Pett, Cate Carey, Fonnie Chan

#### ITV extension

A double-blind placebo-controlled extension study to assess the antiretrovirological properties of a therapeutic HIV vaccine candidate based on recombinant fowlpox virus (rFPV) (ITV extension study).

**Status:** Open **Sites:** 5

Enrolled/target: 16/34

**Sponsor:** Virax Immunotherapeutics

Contact: Rebekah Puls

#### Studies in preparation

#### **HVDDT** vaccine

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

Status: Pending

Sites: 1 Target: 24

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes

of Health, USA / NCHECR

Contact: Rebekah Puls, Tony Kelleher, Alexander

Aichelburg

#### **ASPIRE**

Antiretroviral sparing potential of interleukin-2 as a rational endpoint trial

A randomised open-label phase II international study of subcutaneous recombinant interleukin-2 in patients with HIV-1 infection and CD4+ cell counts of 300-500 cells/mm<sup>3</sup>.

**Status:** Pending **Sites:** To be confirmed **Target:** 680 internationally

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of

Health, USA / NCHECR **Contact:** Sarah Pett, Cate Carey

#### **STALWART**

A randomised open-label phase II international study of subcutaneous recombinant interleukin-2 with and without concomitant antiretroviral therapy in patients with HIV-1 infection and CD4+ cell counts > 300-cells/mm<sup>3</sup>.

**Status:** Pending **Sites:** To be confirmed **Target:** 800 internationally

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of

Health, USA / NCHECR **Contact:** Sarah Pett, Cate Carey



Allison Martin, Susan Phipps, Cate Carey

## Opportunistic infections and AIDSrelated malignancies

Studies closed to recruitment or completed during 2002

#### **IM862**

A phase III, randomised study of IM862 versus placebo in the treatment of AIDS-related Kaposi's sarcoma.

Status: Closed August 2001

Sites: 4

Enrolled/target: 14/40 Sponsor: UNSW / Cytran Contact: Kate Clezy

## Studies recruiting during 2002

#### **AMC 010**

An open study of CHOP (Cyclophosphamide/ Vincristine/ Adriamycin/ Prednisone) chemotherapy with, or without rituximab, for the initial treatment for HIV-related non-Hodgkin's lymphoma.

Status: Recruitment closed March 2002

Sites: 3

Enrolled/target: 1/5 Sponsor: UNSW Contact: Kate Clezy

### **Studies in preparation 2002**

#### **CHAIN**

A double-blind, placebo-controlled, randomised trial to examine the safety and effectiveness of CSL human papilloma virus (HPV) fusion vaccine as treatment for anal intraepithelial neoplasia (AIN) presenting as high grade squamous intraepithelial lesions (HSIL) in HIV positive and seronegative subjects.

**Status:** In development **Sites:** NCHECR network

Enrolled/target: To be determined

**Sponsor:** CSL Limited **Contact:** Jonathan Anderson

#### COL-3

A phase II trial of Col-3 in HIV-related Kaposi's sarcoma.

**Status:** Pending **Sites:** 7 Australia

Enrolled/target: 0/10 Australia / 71/80 USA

**Sponsor:** National Cancer Institute, National Institutes

of Health, USA / NCHECR **Contact:** Kate Clezy

#### EPOCH in non-Hodgkin's lymphoma (AMC034)

A randomised phase II trial of EPOCH given either concurrently or sequentially with rituximab in patients with intermediate or high grade HIV-associated B-cell non-Hodgkin's lymphoma.

**Status:** Pending **Sites:** 1 Australia

Contact: Kate Clezy

Enrolled/target: 0/3 Australia / 1/50 USA

**Sponsor:** National Cancer Institute, National Institutes

of Health, USA / NCHECR

#### **ACTG 5030**

A phase III, prospective, randomised, double-blind, trial of valganciclovir pre-emptive therapy for cytomegalovirus (CMV) viremia as detected by plasma CMV DNA PCR assay.

Status: Pending Australia / recruiting USA

Sites: 2-3 Australia / 30 USA Target: 750 internationally Sponsor: NCHECR Contact: Kate Clezy

### **HIV-NAT Studies**

# Studies closed to recruitment or completed 2002

#### **2NN**

An open-label, comparative study to evaluate the antiviral efficacy of nevirapine and efavirenz in combination with d4T and 3TC.

Status: Open February 2000, second year follow-up

ongoing

Sites: 18 sites internationally

Enrolled/target: 200/200 Thailand / 1200/1200

internationally

**Sponsor:** Boehringer Ingelheim

Contact: Chris Duncombe, Mark Boyd

#### **ACTT 002**

A randomised, open-label, comparative study to evaluate the efficacy of full dose versus half dose of stavudine (d4T) compared to zidovudine (AZT), in combination with didanosine (ddI), in treatmentnaïve HIV-1 infected patients with CD4+ cell count 100-500/ mm<sup>3</sup>.

**Status:** Study terminated by Ministry of Public Health because dual antiretroviral therapy is no longer recommended in Thailand.

Sites: 15 in Thailand Enrolled/target: 293/330

Sponsor: Ministry of Public Health, Thailand / Bristol-

Myers Squibb

Contact: Chris Duncombe

#### HIV-NAT 005

A randomised, open-label, comparative study to evaluate the efficacy and tolerability of indinavir/low dose ritonavir BID versus indinavir TID as part of combination antiretroviral therapy with AZT 300mg/3TC 150mg BID for the treatment of HIV-1 infection in an antiretroviral pre-treated Thai study population.

**Status:** Open June 1999, enrolment completed September 1999. Original 48 week study completed September 2000. 100 week extension completed September 2001.

Sites: HIV-NAT
Enrolled/target: 104/104

**Sponsor:** Merck Sharpe and Dohme / GlaxoSmithKline

/ Ministry of Public Health, Thailand **Contact:** Chris Duncombe, Mark Boyd

#### HIV-NAT 009

An open-label, single-arm, non-randomised study to evaluate the efficacy, safety and tolerability of indinavir 800mg BID plus ritonavir 100mg BID, in combination with efavirenz 600mg OD, in HIV-1 infected patients who are pre-treated with and have failed combination nucleoside reverse transcriptase therapy.

Status: Open June 2002, enrolment completed

October 2002 Sites: HIV-NAT Enrolled/target: 60/60

Sponsor: Merck Sharpe and Dohme

Contact: Mark Boyd

## T-20 series (NP16334, NP16324, NP16325)

Three independent pharmacokinetic studies to investigate the influence of rifampicin, ritonavir, and saquinavir/ritonavir on the pharmacokinetics of T-20 in HIV-infected patients.

Status: Open November 2001, recruitment closed

May 2002 Sites: HIV-NAT Enrolled/target: 37/36

**Sponsor:** F Hoffman-La Roche Ltd

Contact: Mark Boyd



Back Row: Brooke Caldwell, Leeanne McIllvenna Front Row: David Courtney-Rodgers, Robyn Munro, Wendy Lee

#### **ESPRIT**

Phase III comparative study of subcutaneous recombinant IL-2 plus antiretrovirals versus antiretroviral alone. It is a multi-national trial with total volunteers of 4,000

Status: Open October 2001, enrolment closed

November 2002

Sites: 5

Enrolled/target: 300/300

**Sponsor:** Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA / Ministry of Public Health, Thailand / Merck Sharpe and Dohme / Bristol-Myers Squibb (Thailand) / The Government Pharmaceutical

Organization (Thailand) **Contact:** Chris Duncombe

### Studies recruiting during 2002

#### AI-424-008

Evaluation of the safety and antiviral efficacy of a novel HIV-1 protease inhibitor, atazanavir, in combination with d4T and 3TC as compared to a reference combination regimen.

**Status:** Open April 2000 **Sites:** 54 internationally **Enrolled/target:** 31/31

**Sponsor:** Bristol-Myers Squibb **Contact:** Chris Duncombe

#### AI-455-099

Evaluation of the safety and antiviral efficacy of stavudine extended release formulation as compared to stavudine immediate release formulation, each as part of a potent antiretroviral combination therapy.

**Status:** Open October 2000 **Sites:** 54 internationally **Enrolled/target:** 15/35

**Sponsor:** Bristol-Myers Squibb **Contact:** Chris Duncombe

#### **STACCATO**

The Swiss-Thai-Australia Treatment Interruption Study. This study compares continuous therapy with intermittent therapy either based on CD4 cell count or on a fixed week on/week off regimen.

Status: Open January 2002

Sites: 7

Enrolled/target: 100/300

Sponsor: F Hoffman-La Roche Ltd

Contact: Chris Duncombe

#### 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: Open January 2002

Sites: 3

Enrolled/target: 19/40

Sponsor: HIV-NAT / Ministry of Public Health, Thailand

Contact: Chris Duncombe

#### SPD 754.201

Multinational phase II, randomised, double-blind, placebo controlled study to evaluate the antiretroviral activity, pharmacokinetics, genotyping and viral rebound after cessation of four different doses of a new nucleoside reverse transcriptase inhibitor. SPD 754.201.

Status: Open November 2002

Sites: HIV-NAT Enrolled/target: 0/20

Sponsor: Shire Pharmaceutical Development Inc

Contact: Chris Duncombe

#### **HIV-NAT 011**

Down-dosing of indinavir in patients with persistent impaired renal function

Status: Open November 2002

Sites: HIV-NAT Enrolled/target: 0/25 Sponsor: HIV-NAT Contact: Mark Boyd

### Studies in preparation

#### T20-304/NV16390 safety rollover

A simple 'roll-over' safety study to provide continuing T20 for patients who complete the T20 pharmacology studies.

**Status:** Open, awaiting approval of parallel investigator led protocol (HIV-NAT 012)

Sites: HIV-NAT Enrolled/target: 0/36

Sponsor: F Hoffman-La Roche Ltd

Contact: Mark Boyd

# HIV Epidemiology and Prevention Program

Work in the HIV Epidemiology and Prevention Program has focused on two main areas: HIV transmission and its prevention, and the natural history of HIV-related disease.

In the field of transmission research, work in 2002 was dominated by the scaling up of the Health in Men Study, a vaccine preparedness study of HIV risk and transmission in homosexual men. One of the study's key goals is to provide information on the incidence of HIV infection in the target population. By the end of 2002 over 900 men had been enrolled, towards a target at two years of 2000 men. The size and complexity of the study has made it logistically challenging. Men are contacted twice a year, to complete detailed interviews regarding HIV risk behaviours. In addition, once a year, these men are tested for HIV and other sexually transmissible infections. Funding was obtained in 2002 to include testing for gonorrhoea and chlamydia, to evaluate the interaction between these infections and HIV, and to evaluate screening guidelines for sexually transmissible infections in homosexual men.



**Andrew Grulich** 

In the area of prevention, NCHECR's study of non-occupational post-exposure prophylaxis against HIV has grown into one of the largest such investigations in the world. The study has indicated that the national guidelines on use of this therapy are to a large extent being

followed demonstrating that prescription of this therapy is generally appropriate.

In the field of HIV natural history, a new interdisciplinary collaborative group was formed to study the incidence and risk factors for progression of anal intraepithelial neoplasia. This condition is very prevalent in homosexual men with HIV, and in some cases progresses to anal cancer. Although a screening test is available, the high morbidity associated with treatment has resulted in considerable debate about whether or not such screening is indicated.

# HIV transmission and prevention research

# National survey of sexual health and sexual behaviour

Interviewing for this study, the first nationally representative sex survey in Australia, was completed in 2002. Over 19,000 individuals were selected by random digit dialling and underwent a detailed interview regarding sexual behaviour. Response rates in males and females, at around 70%, were in the upper range of those achieved internationally. Initial analysis of this enormous dataset was completed in 2002, with the goal of publication in 2003.

Investigator: Andrew Grulich

**Collaborators:** National Centre in HIV Social Research; Australian Research Centre in Sex, Health and Society; Central Sydney Area Health Service

#### HIV vaccine preparedness cohort study

2002 saw a further 459 men enrolled into the Health in Men vaccine preparedness cohort study, being carried out as a component of the HIV Vaccine Design and Development Team project funded by the United States National Institutes of Health. A total of over 900 men have been enrolled. Participants undergo a socio-behavioural interview and have blood tested for HIV, hepatitis A and B and syphilis at baseline. At annual follow-up, participants are interviewed again and tested for HIV and syphilis, and those negative for hepatitis A and B antibodies at baseline are retested. Between annual interviews participants also complete a brief six-monthly interview by telephone.

The retention rate after one year stood at approximately 85% by the end of 2002. A community report on data collected in 2001 indicated considerable inconsistency between participants' recall of hepatitis vaccine status and the prevalence of seronegativity to hepatitis A and B (32% and 27% respectively). The highly detailed sexual behaviour data collected during the interviews have begun to provide a complex picture of gay men's strategies for risk minimisation during sex with both regular and casual partners. The study will continue enrolling towards a target of 2000 until 2004, and follow up of participants will continue to 2005.

Investigators: Andrew Grulich, Garrett Prestage, Jeff Jin Collaborators: National Centre in HIV Social Research; Australian Federation of AIDS Organisations

## HIV vaccine preparedness cohort study: interaction between sexually transmissible infections and HIV infection

In recent years, increasing rates of gonorrhoea and syphilis have been documented in male homosexual populations in the United States and Europe, and a similar pattern appears to be emerging in Australia. In the Health in Men (HIM) Study, the incidence of syphilis in 2002 was approximately 1%. In 2002, funding was obtained from Becton, Dickinson and Company to allow the addition of urine, throat and anal testing for gonorrhoea and chlamydia in the HIM cohort. Data on the prevalence and incidence of these infections will aid in the evaluation of recently released guidelines on sexual health screening in homosexual men, and will allow an assessment of the interaction with HIV infection.

Investigators: Andrew Grulich, Jeff Jin, Garrett Prestage Collaborators: National Centre in HIV Social Research; Sydney Sexual Health Centre



Back Row: Wayne Bleakley, Hedimo Santana, Garrett Prestage, Brian Acraman

Front Row: Paul Kelly, Harry Smith

#### Non-occupational post-exposure prophylaxis

This study of the use of post-exposure prophylaxis (PEP) after sexual, injecting and other exposures to HIV in the community has grown to become one of the largest in the world, with 850 participants enrolled by the end of 2002, and enrolments continuing at an average of around one each day. During 2002, data from the study showed that prescriptions were beginning to conform to the new national guidelines on the use of non-occupational PEP. There was a trend towards the use of two rather than three antiretrovirals, and little inappropriate prescription. Ninety percent of prescriptions followed male to male sexual exposure, with a total of 65% being receptive and 32% being insertive anal sex. Nine percent of enrolled episodes were in people who had received PEP previously. There have been no cases of HIV seroconversion related to PEP failure. Overall, the use of non-occupational PEP in Australia has been well-targeted, although continued education to reduce the proportion of prescriptions containing three antiretrovirals is needed.

Investigators: Andrew Grulich, Don Smith,Wei Zheng Collaborators: National Centre in HIV Social Research; HIV prescribers in New South Wales, Queensland, Victoria and the Australian Capital Territory

#### Risk factors for HIV seroconversion

In previous years, an ongoing interview-based study of HIV seroconverters was used to examine risk factors for HIV infection among homosexual men. In 2002, recruitment was formally linked to the PHAEDRA Study (see *Primary HIV Research Program*) so that people with newly acquired HIV infection would also complete a socio-behavioural risk factors questionnaire. This mode of recruitment commenced in October, and by year's end 15 participants had been enrolled.

Investigators: Andrew Grulich, Jan Guerin, Garrett

Prestage, Don Smith, Jeff Jin

Collaborators: PHAEDRA investigators

### Risk factors for syphilis in homosexual men

Many large cities in North America and Europe have seen substantial outbreaks of syphilis in homosexual men in recent years. This may reflect increasing sexual risk behaviour for HIV, and syphilis-related genital ulceration may increase the risk of HIV transmission. In 2002, data from some Sydney public health units demonstrated that Sydney was beginning to see an increase in the rate of notification of this disease. A self-administered questionnaire was developed during 2002 and ethics permission for the study obtained. The first few patients were enrolled in the study in the closing days of 2002. This study will provide valuable data to guide the development of interventions to minimise the spread of syphilis among gay men in Australia.

Investigators: Andrew Grulich, Garrett Prestage, Jeff Jin Collaborators: National Centre in HIV Social Research; Taylor Square Private Clinic; Sydney Sexual Health Centre; Marrickville Sexual Health Centre; Holdsworth House General Practice; 407 Doctors

## **HIV** natural history research

#### Cancer in people with HIV infection

For many years, investigators at NCHECR have been at the forefront of linkage-based research into AIDS-related cancer. In 2002, we performed further work on the methodology of HIV and AIDS-cancer registry linkage. NCHECR was in a unique position to perform this research, as very few countries have long-

standing HIV and cancer registries. Our work showed that linkage based on the five years prior to AIDS diagnosis gave results that were very similar to those based on HIV linkage.

Investigators: Andrew Grulich, Matthew Law
Collaborator: Australian Institute of Health and Welfare

#### Time trends in AIDS lymphoma

Investigators at NCHECR have previously published the largest case-control study of AIDS-related lymphoma. The case series of this study was extended to 2002, and now includes 300 cases. The median CD4 count at lymphoma diagnosis increased markedly from around 30 to 180, corresponding with the widespread introduction of effective antiretroviral therapy. Lymphoma became a more frequently occurring first AIDS-defining illness. In a multivariate model, survival from lymphoma improved by 50% in the era of highly active antiretroviral therapy. The improvement in survival occurred regardless of whether or not patients were antiretroviral naïve or experienced at lymphoma diagnosis. It appears lymphoma is no longer a uniformly fatal complication of HIV disease.

**Investigators:** Andrew Grulich, Monica Robotin **Collaborators:** St Vincent's Hospital; Prince of Wales hospital; Royal Prince Alfred Hospital

#### Anal cancer in homosexual men

Linkage studies previously conducted by NCHECR have demonstrated that homosexual men with HIV are at greatly increased risk of anal cancer. In preparation for possible future cohort studies of risk factors for high-grade anal intraepithelial neoplasia, a precursor lesion of anal cancer, a study was undertaken to compare methods for collecting anal smear specimens. Over 70 patients were enrolled and underwent two different techniques of specimen collection (blind and anoscopically guided) in randomised order.

**Investigators:** Andrew Grulich, Claire Vajdic, Jonathan Anderson

**Collaborators:** Albion Street Clinic, Carlton Clinic, Victorian Cytology Service

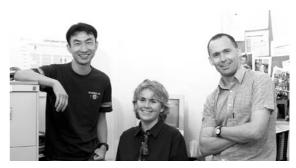
#### Anal intraepithelial neoplasia and anal cancer

While anal cancer is not recognised as being AIDS-related, anal cancer is among the most common cancers in homosexual men with HIV infection. Anal cancer is also much more common in HIV negative homosexual men than in the general population. In 2002 NCHECR established a

collaborative group to examine the incidence, prevalence, and risk factors for anal intraepithelial neoplasia (AIN), anal human papilloma virus (HPV) infection and anal cancer in HIV-positive and HIV-negative Australian homosexual men. Detailed plans for a cohort study of 1,000 men were prepared during 2002. Three collaborating doctors also received training in taking anal smears and anoscopy in San Francisco, under the auspices of the US-AIDS Malignancy Consortium.

**Investigators:** Andrew Grulich, Claire Vajdic, Kate Clezy, Jonathan Anderson

**Collaborators:** Anal intraepithelial neoplasia study group including clinical sites in Sydney and Melbourne; Royal Perth Hospital; Sexually Transmitted Infections Research Centre, Westmead Hospital; Victorian Cytology Service; The University of Sydney



Jeff Jin. Claire Vaidic. Andrew Grulich

#### **Neurological disease in HIV infection**

Despite a reduction in incidence of AIDS dementia complex (ADC) since the introduction of highly active antiretroviral therapy (HAART), neurological disease continues to account for considerable morbidity in people with HIV infection. AIDS case notifications provide one means of monitoring the occurrence and outcomes of ADC.

Analyses undertaken in 2002 showed that there had been a relatively smaller reduction in ADC incidence than for most other AIDS-related illnesses since the introduction of HAART. In other analyses, survival following ADC was found to have increased more than three fold, a gain which exceeds the change in survival observed after all other major AIDS illnesses. Considerable improvements in survival were even seen among people diagnosed with ADC at very advanced levels of immunodeficiency. These findings suggest that the prevalence of ADC in Australia may actually be increasing as a result of relatively smaller reductions in incidence and the increased survival compared to other AIDS-related illnesses.

**Investigators:** Greg Dore, Ann McDonald, Bruce Brew **Collaborators:** State and Territory health authorities

#### Australian long-term nonprogressor cohort

The Australian long-term nonprogressor (LTNP) cohort established in 1994 represents one of the largest in the world. Ninety-four participants have been enrolled in the LTNP Study, and 78 remained under active follow-up to the end of 2002. The majority of LTNP participants have now been infected with HIV for at least 15 years (range 9-18.3 years). To the end of 2002 38 (49%) individuals experienced disease progression, 14 (18%) with a decrease in CD4 T-cell count below 500 cells/µl and 24 (31%) commenced antiretroviral treatment. A lower CD4 T-cell count at study entry was a significant predictor of disease progression, while plasma HIV-1 RNA, age at HIV infection, number of years infected, chemokine receptor (CCR5 and CCR2) mutations, serum 82microglobulin and CD8 T-cell count were not found to predict progression.

Investigators: Jan Guerin, Tony Kelleher

**Collaborators:** Long-term nonprogressor study group, including clinical sites in Sydney, Canberra and Brisbane; Centre for Immunology, St. Vincent's Hospital; HIV Immunovirology Laboratory, Garvan Institute of Medical

Research

#### **Positive Health Study**

The Positive Health (pH) Cohort Study is an interview-based investigation, implemented in 1998 to track the personal impact of HIV infection and associated treatments in New South Wales and Victoria. It documents treatment uptake, as well as other health management strategies and seeks to identify possible reasons for barriers to treatment adherence. A total of 495 people living with HIV/AIDS had been enrolled during the two rounds of interviews prior to 2002. In 2002, a new round of follow-up interviews was commenced. Previous participants were contacted and an additional 50 participants were recruited.

Investigators: Garrett Prestage, Andrew Grulich **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

# **Viral Hepatitis Program**

Activities in hepatitis B and hepatitis C have been undertaken by NCHECR since the early 1990s. Initially, surveillance-based studies were the primary focus. In more recent years NCHECR has expanded viral hepatitis activities into areas such as natural history and clinical research to more closely parallel the HIV research programs. The formation of a designated viral hepatitis program at the start of 2002 acknowledged this expanding role.



**Greg Dore** 

Viral Hepatitis Program activities during 2002 have been predominantly in the areas of hepatitis C transmission among injecting drug users, natural history of hepatitis C and HIV/viral hepatitis coinfection, and therapeutic research in HIV/viral hepatitis

coinfection. The formation in 2001 of the Viral Hepatitis Working Group, as a joint initiative of the Australian Liver Association (ALA) and NCHECR, chaired by the current Chair of the ALA (Dr William Sievert), continued to provide the Centre with guidance in viral hepatitis research, particularly in the area of therapeutic investigations. At the end of 2002 a Clinical Project Leader in Viral Hepatitis was appointed to coordinate clinical trials in viral hepatitis under the direction of the Viral Hepatitis Working Group.

# Hepatitis C epidemiology and prevention among injecting drug users

# A qualitative study of risk behaviour among injecting drug users

Fieldwork was completed in early 2002 on a project funded through the Australian National Council on Drugs and ANCAHRD to identify factors and behaviours that influence transmission of blood-borne viruses among people who inject drugs. In particular, the project focused on factors related to the situation or location of injecting. For example, injection on the street is associated with risk behaviours that differ from those taking place when people inject in the home. Focus group interviews with injectors were also carried out in all States and Territories in 2002. Analysis of ethnographic data was carried out in the in the latter part of 2002.

Investigator: Margaret MacDonald

**Collaborators:** National Drug and Alcohol Research Centre; National Centre in HIV Social Research; Community Service and Research Centre, University of Queensland

#### Hepatitis C transmission among injecting drug users

Monitoring of hepatitis C incidence among injecting drug users at Kirketon Road Centre (KRC) continued, with an annual incidence of 27% recorded for 2001, and a particularly high incidence (42%) among young users. Annual hepatitis C incidence among KRC injecting drug users had been relatively stable over the past five years, but the 2001 incidence is higher than both 1999 (15%) and 2000 (20%).

Initial analyses were undertaken in 2002 to examine hepatitis C incidence among repeat attendees in the needle and syringe program survey (see *Surveillance Program*) over the period 1995-2001. Annual hepatitis C incidence was estimated to be 18%, similar to the figure from KRC. Incidence was particularly high among Indigenous users, and those with a recent history of incarceration.

NCHECR investigators have continued to play an advisory role on two major NHMRC-funded studies of hepatitis C incidence that are being led by other research groups at UNSW. The HITS Study recruited and followed up people at risk within New South Wales prisons, and the CU Study involved the enrolment of a cohort of injecting drug users in three locations around New South Wales.

Investigators: Margaret MacDonald, Jialun Zhou, Greg Dore Collaborators: Kirketon Road Centre; Network of needle and syringe program sites; School of Public Health and Community Medicine, UNSW; School of Pathology, UNSW; South Western Sydney Area Health Service

# Improving needle and syringe program access for marginalised sub-populations in South East Sydney Area Health Service

A collaborative project to support the implementation of the NSW HIV/AIDS Health Promotion Plan, 2001-2003 was established with the South Eastern Sydney Area Health Service. The primary objective of the project was to improve access to needle and syringe program services for injecting drug users in the area. The first phase of the project was established in the St George area, and included different groups involved in needle and syringe program service delivery.

**Investigator:** Margaret MacDonald

**Collaborators:** South East Sydney Area Health Service; St George Alcohol and Other Drug Services; Kirketon Road Centre; National Centre in HIV Social Research

# Evaluation of the Medically Supervised Injecting Centre

In May 1999, the New South Wales parliament passed legislation to establish a medically supervised injecting centre (MSIC) in Kings Cross, Sydney. An evaluation committee was named and an evaluation protocol developed. Baseline data collection commenced in 2000 and the Centre opened in May 2001. NCHECR was given responsibility for coordinating four components of the evaluation under the direction of the Committee:

- During 2002, a repeat phone survey of community opinion of the MSIC and injecting drug use was undertaken, and included interviews with Kings Cross residents and businesses and a State-wide sample of respondents. Participants were selected using randomly generated phone numbers. The survey was conducted in 2002 to allow for a comparison with a similar survey conducted in 2000 prior to the establishment of the MSIC.
- Recording of the number of syringes discarded in the street continued every six months for a onemonth period up until July 2002. Counts were carried out by NCHECR researchers at selected sites in the 2011 postcode area, and South Sydney Council and Langton Centre Clean Up Team reported on counts of syringes collected in Kings Cross.
- Surveys of drug injectors at two needle and syringe programs (NSPs) in Kings Cross, (Kirketon Road Centre and K2) and MSIC were carried out in October 2002 in conjunction with the national NSP survey (see *Surveillance Program*). These surveys have been completed annually since the establishment of the MSIC. Additional items specifically related to the evaluation of the MSIC included history of overdose, treatment uptake, injecting health, and experience of the MSIC.
- NCHECR was also responsible for conducting a focus group of MSIC staff and client attitudes relating to the service.

**Investigators:** Margaret MacDonald, Jialun Zhou, Rosie Thein

Collaborators: AIDS/Infectious Diseases Branch, NSW Health Department; Bureau of Crime Statistics and Research; Kirketon Road Centre; National Drug and Alcohol Research Centre; Medically Supervised Injecting Centre; School of Public Health and Community Medicine, UNSW

# Effectiveness of needle and syringe programs in Australia

Needle and syringe programs (NSPs) were first introduced in Australia in late 1986, with expanded access for injecting drug users from the late 1980s. The Commonwealth Department of Health and Ageing commissioned a study of the economic effectiveness of NSPs in Australia, and NCHECR provided the epidemiological analyses that underpinned the evaluation of economic effectiveness. The report was finalised and released in late 2002.

Published studies of HIV and hepatitis C prevalence and incidence were examined to compare transmission patterns in settings with and without NSPs. These analyses demonstrated a significant effect of NSPs on transmission of both HIV and hepatitis C among injecting drug users. Over the period 1991-2000, it was estimated that NSPs prevented 25,000 HIV infections, and 21,000 hepatitis C infections among injecting drug users in Australia. It was further estimated that by 2010 NSPs would have prevented 4,500 deaths related to HIV/AIDS. The estimated savings through introduction of NSPs in Australia was between \$2.4 and \$7.7 billion depending on the discount rate (5% to 0%) used. The number of quality-adjusted life years gained was estimated to be 715,000 for prevention of HIV infection, and 120,000 for hepatitis C infection.

**Investigators:** Margaret MacDonald, Matthew Law, Greg Dore

**Collaborators:** Health Outcomes International; Michael Drummond, Centre of Health Economics, York University, UK

# Natural history of viral hepatitis

### Natural history of newly acquired hepatitis C

A retrospective study of injecting drug users with newly acquired hepatitis C at Kirketon Road Centre was commenced during 2002. Over the period 1992-2002, 99 cases of newly acquired hepatitis C were retrospectively determined and analysed. Based on hepatitis C RNA testing of stored serum specimens, an estimated 25-40% of cases underwent viral clearance within two years of estimated time of infection. The vast majority of cases of viral clearance occurred within the initial 12 months.

A systematic review of longitudinal studies of acute hepatitis C was undertaken to determine the proportion and predictors of viral clearance. A total of 26 studies over the period 1991-2002 were included. A meta-analysis of these studies estimated that 25% of cases would undergo viral clearance, with post-transfusion acquired hepatitis C having a lower likelihood of viral clearance (17%), than infection acquired through other means (28%).

These studies provided preliminary data that were included in an application to the United States National Institutes of Health to examine both the natural history of newly acquired hepatitis C and therapeutic feasibility and efficacy among injecting drug users.

**Investigators:** Joanne Micallef, Greg Dore **Collaborators:** Kirketon Road Centre; Virology Division, Department of Microbiology, Prince of Wales Hospital

#### Natural history of chronic hepatitis C

In 2002, further studies were conducted that built on systematic reviews of the natural history of chronic hepatitis C undertaken in 2000-2001. A review of longitudinal studies of liver disease progression among people with chronic hepatitis C in treatment settings was performed. These studies used repeat liver biopsies to estimate hepatic fibrosis progression, in contrast to previous cross-sectional studies that relied on estimates of duration of hepatitis C infection to determine disease progression. A meta-analysis of five studies provided a median hepatic fibrosis progression rate of 0.11 Metavir units/year among people with chronic hepatitis C not receiving antiviral therapy. This estimate is similar to the 0.12 Metavir units/year progression estimate from our previous meta-analysis of cross-sectional liver clinic studies, but considerably higher than the 0.06 Metavir units/year estimate from longitudinal communitybased studies. The estimate of liver disease progression in a treatment setting has been incorporated into natural history models to assess the cost-effectiveness of hepatitis C antiviral therapy.

Natural history models based on our previous systematic review of chronic hepatitis C were presented at a World Health Organisation workshop in Geneva as part of a Global Burden of Hepatitis C Disease project. These natural history models will be incorporated into models to estimate and project hepatitis C-related liver disease at a global level.

**Investigators:** Greg Dore, Matthew Law, Anthony Freeman **Collaborators:** None

### Natural history of HIV/viral hepatitis coinfection

Studies were undertaken on aspects of the natural history of HIV and hepatitis B and C coinfection. Within the Australian HIV Observational Database (AHOD), an analysis of prevalence and predictors of hepatitis B and hepatitis C and the impact of viral hepatitis on HIV disease progression was performed. Prevalence estimates for hepatitis B and hepatitis C were 6% and 13% respectively, equating to approximately 2,300 people with HIV in Australia

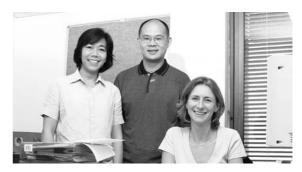
who are coinfected with either hepatitis B or hepatitis C. Although there was a small reduction in CD4 responsiveness following commencement of highly active antiretroviral therapy (HAART) among people with HIV and hepatitis C coinfection, clinical HIV disease progression was not influenced by viral hepatitis coinfection.

Similar findings in regard to the influence of viral hepatitis coinfection on HIV disease progression were found in a study of HIV/viral hepatitis coinfection within the HIV-NAT cohort. The issue of antiretroviral therapy-related hepatotoxicity was also examined in the HIV-NAT cohort, with hepatitis B and hepatitis C found to be strong risk factors for hepatotoxicity. The risk of hepatotoxicity was particularly high among persons with HIV/viral hepatitis coinfection commenced on nevirapine-containing antiretroviral therapy regimens.

The influence of hepatitis C on HIV disease progression was further examined in a retrospective analysis of the CAESAR (Canada, Australia, Europe, South Africa) randomised clinical trial. Within this trial population, hepatitis C coinfection varied considerably among HIV risk groups and between countries, with prevalence above 90% among injecting drug users, and the highest prevalence in Spain and Italy (around 50%). This study also demonstrated that hepatitis C coinfection does not appear to influence HIV disease progression.

**Investigators:** Janaki Amin, Phillip Law, Kathy Petoumenos, Doug Lincoln, Greg Dore

**Collaborators:** Australian HIV Observational Database investigators; HIV Netherlands Australia Thailand Research Collaborative (HIV-NAT), Bangkok, Thailand



Rosie Thein, Jialun Zhou, Gail Matthews

# Viral hepatitis therapeutic research and related areas

#### Viral hepatitis therapeutic research

A retrospective analysis of the efficacy of tenofovir in treatment of HIV/hepatitis B within the 903 Gilead Study was undertaken. The 903 Study is an ongoing randomised controlled trial comparing the safety and efficacy of lamivudine, stavudine, efavirenz to lamivudine, tenofovir, efavirenz among people with HIV and no prior antiretroviral therapy. The anti-hepatitis B activity of lamivudine versus lamivudine and tenofovir was compared in 11 study subjects with HIV/hepatitis B coinfection and high baseline HBV viral load. The study provided preliminary evidence of greater HBV viral suppression and reduced HBV resistance development in the combination therapy arm.

Through the Viral Hepatitis Working Group several projects in therapeutic research in viral hepatitis were under development during 2002. A randomised controlled trial of the safety and efficacy of lamivudine versus tenofovir versus lamivudine and tenofovir within highly active antiretroviral therapy (HAART) regimens for people with HIV/hepatitis B coinfection was approved for funding by Gilead Sciences.

A pilot study of the safety and efficacy of pegylated interferon for treatment of newly acquired hepatitis C was developed. The study protocol allows for recruitment of people with hepatitis C antibody seroconversion within a two-year period or acute clinical hepatitis, with a treatment course of openlabel pegylated interferon for six months.

A protocol for a randomised study comparing 24 and 48 weeks of pegylated interferon and ribavirin combination therapy for South-East Asian genotype hepatitis C was also developed. Recent retrospective data suggest high efficacy for the hepatitis C genotypes 6,7,8,9 typically found in Australians with hepatitis C born in South-East Asia.

Investigators: Gail Matthews, Greg Dore
Collaborators: Australian Liver Association, Gilead
Sciences, Roche Products Pty Ltd

#### Quality of life and hepatitis C

A pilot study of hepatitis C and neuropsychological impairment was developed in 2002 to examine cognitive function and other neuropsychological parameters among people with hepatitis C and HIV/hepatitis C coinfection; and the impact of pegylated interferon and ribavirin combination therapy and viral clearance on neuropsychological function.

A systematic review of hepatitis C quality of life studies was also undertaken. Quality of life adjustments were developed based on this systematic review and will be employed in population level models to estimate and project hepatitis C-related morbidity in the community. Preliminary quality of life adjustments were used within the Hepatitis C Estimates and Projections Working Group report. Based on these estimates, 22,500 life years were lost among people with chronic hepatitis C in 2001, with 72% among people with early or non-progressive liver disease.

**Investigators:** Rosie Thein, Matthew Law, Greg Dore **Collaborators:** Roche Products Pty Ltd

# Primary HIV Research Program

2002 saw a number of developments to NCHECR's special interest area of primary HIV infection. The major event for this research program was the awarding from the National Institutes of Health of a collaborative grant with Massachusetts General Hospital for a five-year program of research into treatment and pathogenesis of primary HIV infection. This grant designates participation in the Acute Infection and Early Disease Research Program (AIEDRP) network of the Division of AIDS, National Institutes of Health, USA and represents a major advancement in this program area.



Don Smith

Our large treatment interruption study (PULSE) completed recruitment during 2002, with 68 patients enrolled. This represents one of the largest randomised trials of treatment during primary HIV infection anywhere in the world.

#### The Australian Primary HIV Infection Database

During 2002 the Primary HIV Research Program continued the consolidation of its long-standing cohort of people with newly acquired HIV infection. Since 1985, 407 individuals have been followed as part of this cohort. Their clinical data have been transferred from earlier database formats to NCHECR's standard Oracle database platform with updated information being collated from a number of sources. To improve long-term follow up, cross-referencing with the Australian HIV Observational Database (see Biostatistics and Databases Program) has been achieved. Progress was also made in the electronic downloading of laboratory data, with new patients now being recruited via the PHAEDRA cohort. This new database has been renamed The Australian Primary HIV Infection Database (APHID) and is now able to standardise long-term follow-up on the PHAEDRA cohort, together with participants in all the ongoing and completed treatment trials. Data from this combined cohort have been used to update the status of patients in collaborative studies.

**Investigators:** Tim Ramacciotti, Jan Guerin, Pat Grey, Kathy Petoumenos, Don Smith

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

For the last five years, NCHECR has participated in the Concerted Action on Seroconversion to AIDS and Death in Europe (CASCADE) collaboration.

Activity during 2002 included follow up of vital status, as well as the collection of data on laboratory markers, antiretroviral treatment changes, and disease progression and type, for the 279 Australian members of the cohort.

Analyses of the full CASCADE dataset were undertaken by NCHECR staff to assess the role that timing of antiretroviral treatment initiation may have, when begun early in primary HIV infection, on CD4+ cell counts and plasma viral RNA, as well as long-term outcomes such as progression to AIDS and survival. Preliminary results have suggested a virologic and immunologic benefit to early treatment. Further analyses are planned to discern whether survival or rate of progression to AIDS is altered by earlier treatment.

Investigators: Tim Ramacciotti, Jan Guerin

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

#### **Acute Infection Early Disease Research Program**

The successful grant submission to the United States National Institutes of Health-sponsored Acute Infection and Early Disease Research Program (AIEDRP) by NCHECR, in collaboration with Bruce Walker's team at Massachusetts General Hospital, has led to a five-year funding program for research into the treatment and pathogenesis of primary infection. The funding from the grant in 2002 was used to establish the PHAEDRA cohort.

**Investigators:** Pat Grey, Jan Guerin, Tim Ramacciotti, Matthew Law, Don Smith, Tony Kelleher

Collaborators: Partners AIDS Research Centre (Massachusetts General Hospital), Harvard University, USA; National Institutes of Health, USA; 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

# Primary HIV, acute and early disease research – Australian cohort

The primary HIV, acute and early disease research -Australian cohort (PHAEDRA) was established to provide a systematic mechanism to recruit and follow up a cohort of people in Sydney and Melbourne with acute and early HIV-1 infection. Individuals diagnosed with acute and early HIV-1 infection have been recruited to this observational cohort either prospectively or retrospectively, provided they have documented evidence of primary HIV infection (PHI) and have stored clinical specimens at the appropriate time points during the first year of HIV seroconversion. This study does not mandate any treatment, and study participants may initiate antiretroviral therapy at any stage during infection in consultation with their treating clinician. Clinical and laboratory data have been collected at regular time points which coincide with routine clinic visits, with additional specimens stored for future immunological and virological investigations.

From the start of recruitment into the PHAEDRA cohort in early September, 70 individuals were enrolled during 2002. Thirty-eight were newly diagnosed seroconverters and the other 37 seroconverters were retrospectively recruited from other clinical studies in PHI. Establishment of this cohort has provided a basis for a broad range of clinical, and pathogenic investigations in primary HIV infection.

**Investigators:** Jan Guerin, Don Smith, Tony Kelleher, Tim Ramacciotti, Mee-Ling Munier

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, Sydney; Partners AIDS Research Center (Massachusetts General Hospital) Harvard University, USA



Susan Lewis, Pat Grey

#### Treatment interruption trial in primary HIV infection

This treatment interruption trial in primary HIV infection (PULSE) was initiated in 2000 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. Patients were randomised to receive 12 months of combined antiretroviral therapy with or without hydroxyurea therapy (six months for those recruited after December 2001), and stop treatment if their viral load was undetectable, and commence if their viral load returned to 5,000 copies/mL. Three such treatment interruptions were allowed before outcomes were measured.

A total of 72 patients have been screened, and 68 commenced medications. During 2002, 20 patients were recruited, and enrolment closed in August 2002.

The primary analyses will compare the randomised treatment groups in terms of strategy success, and immunological and virological markers at two years.

Investigators: Don Smith, Pat Grey, Mee-Ling Munier Collaborators: Robert Finlayson, Taylor Square Private Clinic; Mark Bloch, Holdsworth House Private Practice; Robert Mcfarlane, 407 Doctors; Norman Roth, Prahran Market Clinic; Dr John Chuah, Gold Coast Sexual Health Clinic; Kate McGhie, HIV Immunology Laboratory, Garvan Institute of Medical Research; John Zaunders, Phillip Cunningham, Centre for Immunology, St Vincent's Hospital, Sydney

# Biostatistics and Databases Program

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, study data are housed in properly specified robust databases, and statistical analyses are to high scientific standards. To be successful, virtually all NCHECR research activity relies on professional and efficient delivery of 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 longitudinal observational data, mathematical modelling, and statistical methodology.

The Program provides databases, based on Oracle software, for all NCHECR clinical trials, and also for a number of other studies. Of particular note during 2002 was database support for a trial of rosiglitazone in HIV infection (see Therapeutic and Vaccine Research *Program*). This trial included extensive data collection, involving several substudies, leading to a complex relational study database. The study database also included reporting systems which were a key component in the trial's ongoing management. The rosiglitazone trial was also the first NCHECR trial to adopt a full dynamic minimisation randomisation scheme, requiring the development of specific software and randomisation procedures. The Program also for the first time organised the establishment of, and reported to, a study Data and Safety Monitoring Board.

Another major area of activity during 2002 involved the development of new database systems for national HIV surveillance. This work aimed to integrate several current surveillance databases into a single Oracle database to support national surveillance activities over the next decade and beyond.

During 2002 the Program continued to develop its research activities in the collection and analysis of longitudinal observational data. The Australian HIV Observational Database (AHOD), now into its fourth year of operation with over 2,000 patients recruited from 26 sites, continued to provide surveillance-type data on antiretroviral treatment use among patients with HIV infection in Australia.

Preliminary discussions were undertaken in 2002 to start a new HIV observational study in several countries in the Asia-Pacific region. Protocols were also written to establish an observational study of people with chronic hepatitis C infection, again based on AHOD methodology.

Mathematical models were developed to assess trends in HIV incidence in Australia among homosexual men between 1995 and 2006. The Hepatitis C Virus Projections Working Group also published its final report *Estimates and Projections of the Hepatitis C Virus Epidemic in Australia 2002*.



**Matthew Law** 

Although the Program does not have any formal teaching responsibilities, it does undertake wideranging informal biostatistical training. In the first half of 2002, the program provided placement training to a trainee biostatistician from the NSW Health

Department. Furthermore, virtually all NCHECR doctorate and Master's candidates receive biostatistical mentoring and training from staff within the Program. In October, the Program also organised a workshop at the International Clinical Trials Symposium on methodological issues in the design of phase III HIV-vaccine clinical trials.

#### The Australian HIV Observational Database

The Australian HIV Observational Database (AHOD) was established to systematically collect information relating to demographic factors, markers of disease stage and treatment uptake in people with HIV infection attending clinical sites in Australia.

Recruitment to the AHOD cohort commenced in June 1999, and since then there have been seven data transfers from the collaborating sites to NCHECR, most recently in September 2002. In total, 2,086 patients from 26 sites throughout Australia have now been recruited to the database.

The prevalence and risk factors for hepatitis B and hepatitis C coinfection in AHOD were assessed in 2002. More than 77% of AHOD patients have been tested for hepatitis B and/or hepatitis C infection at some time. Among these tested patients, the prevalence of hepatitis B surface antigen and hepatitis C antibody was 6% and 13%. The risk factors for HIV/hepatitis B coinfection were exposure to HIV by receipt of blood products or unknown routes of transmission, older age and coinfection with hepatitis C. The risk factors for hepatitis C were exposure to HIV by injecting drug use or receipt of blood.

Causes of death, and the risk factors for HIV-related and HIV-unrelated deaths were also examined in AHOD in 2002. It was found that just over half (54%) of the

reported deaths were not directly related to HIV disease, and the most common causes of HIV-unrelated deaths were liver failure and lung cancer. HIV-unrelated deaths were associated with more advanced HIV disease (low CD4 count and receipt of a larger number of antiretroviral treatment combinations) in a similar way to HIV-related deaths.

AHOD also participated in the international collaboration, PLATO, assessing the factors that contribute to the success of antiretroviral treatment in heavily pre-treated patients experiencing virologic failure. Results indicated that treatment changes with one or preferably two new drugs were associated with improved virologic and immunologic outcome.

Summary AHOD biannual reports were published in July and December and data were also presented in the *Annual Surveillance Report 2002*, all of which are now available on the NCHECR website.

**Investigators:** Kathy Petoumenos, Matthew Law **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

The Data Collection on the Adverse Events of Anti-HIV Drugs (DAD) Study is a 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. The study is coordinated through the Copenhagen HIV Programme in Denmark, and involves observational data from approximately 23,000 people with HIV from 11 cohorts in Europe, the United States and Australia followed for two years.

The Australian contribution to the DAD Study is based on eight sites in the Australian HIV Observational Database (AHOD). Anonymised data on 719 patients recruited into AHOD were forwarded to the coordinating office in Copenhagen in 2000. Since then there have been two follow-up transfers, the most recent in July 2002. During 2002, modelling work was used to estimate three-year risk of myocardial infarctions (MIs) among the DAD participants based on baseline covariate data. Models indicated an increasing risk of MI with more aggressive antiretroviral treatment at baseline, but absolute risks of MI were low (<2% over three years) in all treatment groups. Results of two-year follow-up data looking at the primary endpoint of the DAD Study, increased risk of MIs, have been analysed and will be reported in early 2003.

Investigators: Kathy Petoumenos, Matthew Law
Collaborators: Network of clinical sites (GPs, hospitals
and sexual health clinics) throughout Australia

# Mathematical modelling of HIV incidence among homosexual men in Australia 1995-2006

Previous mathematical models have indicated that any decrease in HIV incidence in homosexual men due to decreased infectiousness from antiretroviral treatment (ARV) may be offset by modest increases in unsafe sex. A mathematical model was developed to assess the effects of ARV use and increasing unprotected anal intercourse with casual partners (UAIC) in homosexual men on HIV incidence during 1995-2001, and to project for HIV incidence depending on trends in ARV use and UAIC. HIV incidence during 1995-2001 was estimated assuming that 70% of men diagnosed with HIV received ARVs, and a 10% annual increase in UAIC. For 2001-2006, scenarios included ARV levels remaining at 70% or declining to 50% by 2006, combined with UAIC levels remaining at the 2001 level or continuing to increase annually by 10%.

The number of incident HIV cases per year was predicted to have declined during 1996-1998 due to the introduction of effective ARVs, with a slow increase during 1998-2001 due to increased levels of UAIC when use of therapies was fairly stable. From 2001, a continued increase in UAIC was predicted to lead to a rise in HIV incidence. A rise in UAIC combined with a moderate decline in ARV use could lead to a 50% increase in HIV incidence by 2006. These models suggest widespread ARV use has had some effect in reducing HIV incidence among homosexual men in Australia. However, if current trends in UAIC and ARV use continue, a resurgent HIV epidemic is predicted.

**Investigators:** Mark Clements, Garrett Prestage, Andrew Grulich, Matthew Law

Collaborator: National Centre in HIV Social Research

# Estimates and projections of the hepatitis C epidemic in Australia

Under the auspices of ANCAHRD, the Hepatitis C Virus Projections Working Group was reconstituted in 2001, and published its final report during 2002. Membership of the group included statisticians, epidemiologists, clinicians, representatives of the Commonwealth and State and Territory Health Departments and members of the affected community. Mathematical models were used to combine data on the epidemiology of hepatitis C virus in Australia with data on natural history and quality of life. These models estimated there were 210,000 people living with hepatitis C in Australia in 2001, of whom 53,000 had cleared their infection, 124,000 had chronic hepatitis C infection with early (stage 0/1) liver disease, 27,000 chronic hepatitis C

infection with moderate (stage 2/3) liver disease, and 6,500 were living with cirrhosis. The number of people living with hepatitis C-related cirrhosis, and the numbers of hepatitis C-related liver failure and hepatocellular carcinoma were all projected to treble by 2020. Hepatitis C-related morbidity was estimated to be substantial, corresponding to a total of 22,500 quality adjusted life years (QALYs) lost, with the majority of QALYs lost in people with early (77% lost) or moderate (18% lost) liver disease.

Investigators: Matthew Law, Greg Dore

Collaborators: Hepatitis C Virus Projections Working Group



Janaki Amin, Matthew Law, Noorul Absar

#### Data from the highly specialised drugs program

Antiretroviral treatments for HIV-related disease, and some treatments for HIV/AIDS opportunistic infections, are funded through the Highly Specialised Drugs (HSDs) Program, a joint Commonwealth Government and State/Territory mechanism for the supply of HSDs, coordinated federally by the Commonwealth Department of Health and Ageing. As a condition of Commonwealth funding of antiretroviral treatment for people seen in community or day services, State and Territory Health Departments provide summaries to the HSDs Program of the number of people receiving, and the number of prescriptions for, each antiretroviral drug on a quarterly basis.

Summary data on the number of people prescribed antiretroviral treatment by year and antiretroviral agent were included in the *Australian HIV*Observational Database Biannual Report, and the Annual Surveillance Report 2002.

Between January and July 2002, the total number of people prescribed antiretroviral treatment was approximately 6,900, and just over 2,000 were prescribed prophylaxis for opportunistic infections.

Investigators: Kathy Petoumenos, Matthew Law
Collaborators: Highly Specialised Drugs Program, Special
Access and Coordination Section, Pharmaceutical Access
and Quality Branch, Commonwealth Department of Health
and Ageing

## **TREAT Asia HIV Observational Database**

During 2002, discussions were held with the Therapeutics, Research, Education and Training (TREAT) Asia network, an initiative funded through the American Foundation for AIDS Research (amfAR), about starting an observational database of people living with HIV in countries in the Asia-Pacific region. Core clinical data on people living with HIV, including demographic data, any HIV-treatments received, and HIV disease outcomes including HIV viral load, CD4 counts, AIDS defining illnesses and causes of death, will be collected. Data will be aggregated and analysed at NCHECR using the methods successfully employed in the Australian HIV Observational Database. It is anticipated that a network of sites in India, China, Malaysia, Singapore, Thailand, Cambodia, Hong Kong and other Asian countries can be established early in 2003. Initial objectives of the database will be to assess HIV disease natural history and treatment in Asian countries.

**Investigators:** Matthew Law, Kathy Petoumenos, Greg Dore **Collaborators:** TREAT Asia network; American Foundation for AIDS Research

#### **Biostatistics and database support**

To ensure timely and appropriate statistical advice into all NCHECR projects, the four biostatisticans from the Program are each aligned with two or three of the NCHECR working groups. The two database programmers are aligned so that one programmer supports clinical trial activities and the other programmer supports epidemiological databases.

In fulfilling support roles for NCHECR projects, the Program attempts to reconcile the advantages of continuity of support to particular projects by given individuals, with the disadvantages this can bring in terms of individual work loads and delivering high quality outcomes in a timely fashion. Broadly speaking, the strategy has been a flexible approach, allowing continuity of support where possible, but with individuals contributing to particular projects depending on individual workloads, competing priorities and important deadlines.

**Investigators:** Matthew Law, Noorul Absar, Janaki Amin, Mark Clements, Kathy Petoumenos, Terry Sharkey

Collaborators: None

# Laboratory Support Program

The work of the Laboratory Support Program during 2002 can be divided into two major categories. First of all, much of the laboratory's activity is directed towards providing support of a routine or semi-routine nature to clinical trials and epidemiological studies, through processing of specimens and conduct of specialised assays. Secondly, the laboratory's senior scientists are responsible for their own research programs on pathogenesis.



Tony Kelleher

As the laboratory received minimal funding from NCHECR's core grant in 2002, success in attracting external funding was essential for the laboratory's survival.

The laboratory played a central role in the successful application by NCHECR, in

collaboration with Massachusetts General Hospital, to the United States National Institutes of Health (NIH) for funding through the Acute Infection Early Disease Research Program (AIEDRP) for research studies into primary HIV infection.

The laboratory was also successful in an application with Ackichi Iwamoto , University of Tokyo in an application to the Japanese Science Foundation for immunopathogenic research related to development of immunotherapeutics for HIV infection.

During 2002, the laboratory took delivery of one of only two digital multi-parameter flow cytometers in the country, through funding from the NIH for the HIV Vaccine Design and Development Teams project, the AIEDRP grant and through the initiation of collaborative agreements with both the Victor Chang Research Institute and the Garvan Institute of Medical Research. This agreement, involving the three major research institutes located on the St Vincent's Hospital campus, is the first of its kind. The laboratory also was successful in application to UNSW for equipment funding to purchase a Zeiss ELIspot reader. This equipment helps the laboratory to remain internationally competitive.

The laboratory has also installed a controlled rate freezer for the more efficient cryopreservation of peripheral blood mononuclear cells and other tissue.

## Service and support

Virtually every clinical trial conducted by NCHECR during 2002 involved the collection of specimens that were processed, stored, transported or analysed in various ways by the immunovirology laboratory. The laboratory also conducted the serological testing for HIV and hepatitis C of over 3,000 dried blood spots collected from attendees at needle and syringe programs around the country.

The laboratory operated under the principles of Good Laboratory Practice. It has established its own internal quality control procedures, and participates in collaborative quality assurance programs for specimen storage coordinated by NCHECR Working Groups, and programs for flow cytometry through the international trials, INITIO and SILCAAT (see *Therapeutic and Vaccine Research Program*).

The laboratory also maintains a fully archived repository of cryopreserved serum, plasma and peripheral blood mononuclear cell samples.

An important recent development in evaluation of the effectiveness of therapy and vaccine involves measuring the extent of immune reconstitution of the HIV-specific immune response that can be induced by intervention. In 2002 the laboratory monitored T-cell responses in the context of a number of clinical trials through extended immunophenotyping panels, and assays of T-cell function (including lymphoproliferation, IFN-gamma ELISpots and intracellular cytokine staining). IFN-gamma ELISpot and ICC were extensively assessed and the assays validated, with cut-off levels, sensitivity and specificity of these assays determined formally. The synthesis of class I tetrameric complexes became routine in the laboratory.

Determination of T-cell subsets by surface phenotype and intracellular staining also continued in the context of the primary infection treatment study, PULSE (see *Primary HIV Research Program*).

Investigators: Tony Kelleher, Mee-Ling Munier, David van Bockel

**Collaborators:** Claudette Satchell, Kate McGhie, Ilya Henner, Philip Cunningham, John Zaunders, St Vincent's Hospital, Sydney

## Pathogenesis research

The immunovirology laboratory has been involved in a range of projects investigating basic questions in the pathogenesis of HIV infection.

# Laboratory surveillance for antiretroviral drug resistance

The rates of resistance in transmitted HIV were investigated by studying prevalence of resistance in people with recently acquired infection. This study was performed retrospectively back to 1992, and then prospectively during 2002. The most recent analyses involved comparison of the trends in treatment uptake and the development of resistance. In contrast to results from North America and most of Europe, rates of resistance in transmitted virus are low. Rates of resistance to protease inhibitors have not increased. The rates of resistance to reverse transcriptase inhibitors have fallen since their peak in the mid 1990s prior to the advent of highly active antiretroviral therapy (HAART), and the type of mutations seen has changed.

**Investigators:** Tony Kelleher, Palanee Ammaranond (PhD student)

**Collaborators:** Kazuo Suzuki, Leakanna Leas, Philip Cunningham, St Vincent's Hospital, Sydney

#### The role of gag mutations in antiretroviral resistance

This project is based upon observations made within the laboratory that there are viral mutations outside the regions coding for reverse transcriptase and protease that may impact upon HIV's susceptibility to antiretroviral drugs. A particular region of interest has been the gag gene, which codes for the proteins making up the core of the virus. We have described mutations at protease cleavage sites within Gag that reduce sensitivity of protease inhibitors. Other insertions within the p6 region of Gag have complex effects on viral fitness and appear to require compensatory mutations in accessory proteins. The effects of the interactions of these mutations on viral replicative capacity were explored. In 2002 these observations were extended through the construct of recombinant viruses containing either gag or vpr mutations alone or in combination in a standard genetic background.

Investigators: Toshi Shijuku (Visiting Fellow), Tony Kelleher Collaborators: Kazuo Suzuki, Leakena Leas, Philip Cunningham, Sabine Piller, St Vincent's Hospital, Sydney

# 2LTR (long term repeat) excision circles as a measure of viral turnover in people receiving suppressive therapy

Prior to integration into human cells, viral DNA may form DNA circles through ligation of the LTR regions of the HIV gene. These circles represent a by-product of viral infection of cells, and have a longer half life than viral RNA which often falls to undetectable levels following therapeutic intervention with highly active antiretroviral therapy (HAART). It is possible that 2LTR circles, if they have a half-life longer than RNA but shorter than the turnover of the infected cell. could represent a marker of continuing viral turnover. During 2002, a real time PCR assay was developed for the quantification of 2LTR circles. Contrary to prominent earlier publications, our data and others found that these excision circles were long-lived and their half-life depended entirely on cell turnover and activation. As such they provided no more insight into the rates of viral turnover in individuals with undetectable viral load than other more simple and straightforward measures.

Investigators: Anna Swanson (Bachelor of Science

(Honours) student), Tony Kelleher

Collaborator: Kazuo Suzuki, St Vincent's Hospital, Sydney

## Dendritic cell depletion, T-cell homeostasis, spontaneous T-cell apoptosis, T-cell turnover and modulation of IL-15 and IL-7 in primary HIV infection

Dendritic cells play a critical role in priming of T-cell responses to pathogens such as viruses. There are two subsets of these cells, plasmacytoid and myeloid derived dendritic cells. Depletion or alteration of these cells could explain some of the CD4+ T-cell dysfunction seen in HIV infection. In investigations conducted during 2002, markers of CD4+ T-cell activation and subpopulations of dendritic cells were measured concurrently at various stages of HIV infection, particularly in primary infection, to identify when functional alterations to essential immunological cell types start to occur. We found that there was depletion of plasmacytoid dendritic cells early in primary infection, and that there was evidence for concurrent dysregulation of the secretion of IL-7 and IL-15. IL-7 levels are elevated in primary infection and do not normalise with effective highly active antiretroviral therapy (HAART). IL-7 causes proliferation of naïve cells under very specific circumstances. However, the proliferation induced is unique. Cells remain phenotypically naïve and proliferate with kinetics different from those seen with other cytokines such as IL-2 or IL-15. The regulation of the expression of IL-7 receptor is the subject of ongoing work.

Investigators: Tony Kelleher, Sarah Sasson (Bachelor of Science (Honours) student), Mee-Ling Munier Collaborator: John Zaunders, St Vincent's Hospital, Sydney

## Viral escape from HIV-specific CTL responses in primary infection and long-term non-progression

Although the phenomenon of viral escape from CTL mediated immune response during HIV infection is now accepted, the evolution of the immune response prior to and during the generation of the escape mutant is unstudied. Studies during 2002 have attempted to track the evolution of the CD8+ T-cell response immediately prior to the generation of escape mutants in HLA-B27+ individuals. Studies using sequences derived from entire viral genomes will allow the mapping of the sequential development of escape mutants in individuals from primary infection onwards, and relate these changes to the degree of viral control seen within an individual.

**Investigators:** Tony Kelleher, Palanee Ammarannond (PhD student)

**Collaborators:** Kate McGhie, St Vincent's Hospital; Todd Allen, Partners AIDS Research Center (Massachusetts General Hospital), Harvard University, USA

#### Inhibition of viral replication by iRNA constructs

It is now clear that short dsRNAs, 21-23 nucleotides long, can induce HIV-1 gene silencing in vitro. dsRNAs targeting the transcribed regions of the HIV-1 genome induce gene silencing by a post transcriptional gene silencing (PTGS) mechanism which results in increased rates of viral mRNA degradation. This type of process has been well described in a wide variety of cell types from plants to insects through to mammalian cells.

However, in plants RNA duplexes can also induce gene silencing through a separate and distinct mechanism, transcriptional gene silencing (TGS). TGS induced by dsRNAs targeting the promoter regions of plant genes is associated with RNA-directed DNA methylation (RdDM) of cytosine residues within the targeted promoter region. This process of hypermethylation appears essential for TGS and can be reversed by inhibitors of methylation. Outside the context of dsRNA induced gene silencing, the association between transcriptional silencing, DNA methylation and chromatin remodelling is well known and these processes impact upon gene expression in a range systems. We reasoned that since methylation of DNA and chromatin restructuring is associated with induce HIV-1 latency then dsRNAs targeting the promoter region of the virus may result in gene silencing of HIV-1 and the induction of a state of viral latency.

This work developed during 2002 through the exploration of TGS induction in HIV-1 infected cells employing dsRNA targeting the promoter region of HIV-1. In vitro data reveal reductions in viral replication by up to 1,000 fold of both laboratory strains and clinical isolates of HIV-1. The mechanism of this effect is under investigation as are alternative delivery mechanisms.

Investigators: Tony Kelleher, Toshi Shijuku (Visiting Fellow)
Collaborators: Kazuo Suzuki, Robyn Ward, Catherine
Suter, St Vincent's Hospital, Sydney



David van Bockel, Mee-Ling Munier

# Characterisation of the molecular defects contributing to therapy-related lipodystrophy

The molecular mechanisms underlying the development of antiretroviral therapy-related lipodystrophy and lipoatrophy are not well understood, but appear to be related to different abnormalities in the metabolism of adipose tissue, monocytes and macrophages. During 2002, preliminary data regarding abnormalities in certain enzymic pathways have been gathered using semi-quantitative PCR techniques. These are in the process of being confirmed by real time techniques.

Investigator: Paddy Mallon, Patrick Unemori (Visiting

Fellow), Tony Kelleher

Collaborator: Andrew Carr, St Vincent's Hospital, Sydney

# Research outside Program areas

## Creutzfeldt-Jakob Disease

## Analyses of the National Creutzfeldt-Jakob Disease Registry

During 2002, NCHECR continued its collaboration with the Australia National Creutzfeldt-Jakob Disease Registry, providing statistical and epidemiological advice and support for the analysis and interpretation of Registry data. This year, emphasis was placed on refining the routine reporting of the Creutzfeldt-Jakob Disease (CJD) surveillance data recorded by the Registry. Age-standardised rates were adopted, as well as reporting incident numbers of cases. Graphical and tabular summaries were improved. The age-standardised incidence rate of CJD in Australia in the late 1990s and early 2000s continues to be around 1.0 per million, with similar rates according to State/Territory and country of birth.

**Investigator:** Mark Clements

Collaborator: The Australia National Creutzfeldt-Jakob

Disease Registry

#### Transmissible spongiform encephalopathies

NCHECR continued to provide statistical and epidemiological support to two projects aimed at assessing the risk of transmissible spongiform encephalopathies (TSEs). First, during 2002 the Australian Red Cross Blood Service conducted a large national survey of some 10,000 blood donors, collecting information on travel and residency histories. This survey will provide ongoing information on the likely effect on blood supplies of donor deferral strategies based on travel or residence in specific countries. The possible risks of such strategies, in terms of reduced blood supply, and the benefits in terms of deferring donations from donors carrying the TSE infectious agents are being investigated. Second, in collaboration with the Therapeutic Goods Administration, risk assessments were refined of the potential for transmission of TSEs through blood derived products, vaccines, and ophthalmic and other surgery.

Investigator: Matthew Law

**Collaborators:** Australian Red Cross Blood Service; Therapeutic Goods Administration; Commonwealth

Department of Health and Ageing

## Immune deficiency and cancer

#### Non AIDS lymphoma case-control study

The NCHECR's previous work in studying infective and immunologic causes of AIDS-related lymphoma has now been extended to the HIV-uninfected population. Enrolment on this large case control study, with over 700 cases and controls, was completed in 2002. Initial analyses of ultraviolet radiation as a risk factor for non-Hodgkin's lymphoma were conducted, and a collaborative agreement negotiated with the United States National Cancer Institute to allow the testing of biological specimens for infective risk factors. A meeting was held with the Interlymph international collaborative group on lymphoma epidemiology at which a pooled analysis of hepatitis C infection as a risk factor for lymphoma risk was proposed.

Investigators: Andrew Grulich, Claire Vajdic

Collaborators: NSW Cancer Council; Viral Epidemiology
Laboratory, United States National Cancer Institute

# Cancer in kidney dialysis patients and kidney transplant recipients

People with immune deficiency, whether congenital, iatrogenic or HIV-infection related, are known to be at increased risk of developing a range of cancers. However, there remains uncertainty over which cancers occur at increased rates, and why they occur at increased rates. NCHECR researchers with an interest in immune deficiency and cancer formed a collaborative team to examine the occurrence of cancer in these patients prior to and after treatment by dialysis and kidney transplantation. This study was funded by The Cancer Council New South Wales in 2002, and will link data held by three world-class Australian registries; the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA), the National Death Index and the National Cancer Registry.

Investigators: Andrew Grulich, Claire Vajdic, Matthew Law Collaborators: Australian and New Zealand Dialysis and Transplant Registry (ANZDATA); University of Otago; Westmead Hospital

# International activities

### **Thailand**

NCHECR continued its partnership in HIV clinical research with the Thai Red Cross AIDS Research Centre and the Netherlands International Antiviral Therapy Evaluation Centre under the name of HIV-NAT. By the end of 2002, HIV-NAT had 1,500 participants enrolled in 16 clinical trials at 20 sites in Thailand. The majority of participants attend HIV-NAT research clinics in Bangkok. The two largest studies are the National Institutes of Health-sponsored ESPRIT study of interleukin-2 (see Therapeutic and Vaccine Research Program), which has enrolled 350 patients in Thailand and the STACCATO study of structured therapy interruption (see Therapeutic and Vaccine Research Program), which has enrolled 300 patients at seven Thai sites. A pilot paediatric trial, the first at HIV-NAT, now has 40 children enrolled in a study to assess the optimum time to initiate antiretroviral therapy in a resource-limited setting. A part of this study is assessing the impact of antiretroviral therapy on the neuropsychological functioning of children with vertically transmitted HIV infection.



**Chris Duncombe** 

A pharmacokinetic laboratory was established at HIV-NAT in late 2002 with a grant from PharmAccess International in The Netherlands to purchase a high performance liquid chromatograph. Studies include the pharmacokinetics of

once daily saquinavir plus ritonavir and the optimum does of indinavir in Thai patients. This pharmacokinetic laboratory will also serve as a regional reference centre for bioequivalence studies of generic antiretrovirals produced in Thailand and in the region.

HIV-NAT's partner organisation, Thai Red Cross AIDS Research Centre, is expanding voluntary counselling and testing in three provinces in Thailand through a grant from the American Red Cross. Through the MTCT-Plus initiative, HIV-NAT and the Thai Red Cross AIDS Research Centre are providing access to antiretroviral therapy for HIV-infected women and their families. With a grant from Columbia University, matched with donation funds from the Thai Red Cross Society, an estimated 500 family members will receive antiretroviral treatment from this project in 2003.

An active teaching program continues at HIV-NAT, with students from Australia and The Netherlands spending three to six months studying and working in a clinical trials unit in a developing county. As part of the HIV-NAT regional training program, physicians and nurses from China, Bangladesh and India attended courses in HIV medicine during the past 12 months. The 5th Bangkok Symposium on HIV Medicine, organised by HIV-NAT every January was attended by more than 400 participants from 11 countries in the region.



Mark Boyd

Preparation commenced for the Thai phase of the Australian Thai Vaccine Initiative. The four components include laboratory, social and community programs in addition to the main clinical trial that will recruit up to 200 of HIV-negative volunteers in Thailand commencing in 2004.

### Cambodia



Julian Elliott

NCHECR has provided technical assistance to the National Center for HIV/AIDS, Dermatology and STDs (NCHADS) of the Cambodian Ministry of Health over recent years in the areas of HIV surveillance and the development of

treatment guidelines. In 2002 this relationship was expanded with the secondment of Dr Julian Elliott to the AIDS Care Unit of NCHADS. He has begun to support NCHADS in the development of national HIV care policy, strategies and guidelines. This has included contributions to a new national framework for HIV care including the use of antiretroviral therapy. He will also assist NCHADS to facilitate the development of HIV research that is appropriate to the particular needs of Cambodia. This will include both prevention cohort studies and longitudinal clinical studies including randomised clinical trials. During 2002 preliminary work began on assessing the feasibility of conducting a randomised controlled trial of HIV prevention using tenofovir.

### Indonesia

During 2002 NCHECR joined a consortium bidding for the Indonesia HIV/AIDS Prevention and Care Project Phase II, supported by AusAID. The consortium was led by GRM International Pty Ltd and the Macfarlane Burnet Institute for Medical Research and Public Health, and was ultimately successful in winning the bid. NCHECR's responsibility is primarily in surveillance for HIV/AIDS and sexually transmissible infections. In addition, John Kaldor is chairing the Technical Advisory Team for the project which brings together participating agencies on a regular basis to plan project inputs and ensure quality control. 2002 largely involved project planning with in-country staff initiating the project in September. The first meeting of the Technical Advisory Team was held at NCHECR in November.

# Teaching and training highlights

NCHECR is involved in a wide range of teaching and training activities (see page 62). During 2002, an Honours student and four Masters candidates whose research projects had been supervised by NCHECR staff were awarded their degrees. NCHECR staff also supervised another twenty-seven postgraduate students, including twelve 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. Some 100 students passed through the core epidemiology course taught by NCHECR staff in 2002, and a further 45 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.

NCHECR's contribution to hepatitis C education and training increased during 2002. Greg Dore was involved in the establishment of the Australasian Society for HIV Medicine's prescribers course for training primary care practitioners in the use of \$100 drugs for the management of hepatitis C. He also conducted a series of community forums and workshops in hepatitis C.

Forty NCHECR study coordinators from around Australia and New Zealand attended the Therapeutic and Vaccine Research Program (TVRP) coordinators' training day in Melbourne. Coordinators were provided with an update on the current research areas of the TVRP.

NCHECR also contributed lectures to a variety of other postgraduate courses during the year.

# Service highlights

During 2002 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 58). These activities operate at a range of levels from local to international and ensure that NCHECR's researchers stay closely in touch with the real life applications of their work.



**David Cooper** 

Of particular note were the continuing roles of David Cooper as Co-Chair of the Organising Committee for the annual International Workshop on Adverse Drug Reactions and Lipodystrophy; John Kaldor as a member of the NHMRC Project Grants Committee, and as the Asian regional

representative of the International AIDS Society Governing Council; and Andrew Grulich as President of the Australasian Society for HIV Medicine. Andrew Grulich also co-chaired the Organising Committee for the Australasian Society for HIV Medicine's 14th Annual Conference, and Greg Dore was responsible for the Epidemiology and Social Research Stream of the 3rd Australasian Conference on Hepatitis C.



This list includes both full time and part time staff. Contributions listed in this Report relate only to individuals whose primary employment is with NCHECR.

### Director's office

#### **Director and Professor of Medicine**

David A Cooper DSc, MD, FRACP, FRCPA, FRCP

#### **Executive Assistant**

Janette Button

### **Deputy Director's office**

#### **Deputy Director and Professor of Epidemiology**

John M Kaldor PhD

#### **Epidemiology Group Coordinator\***

Jennifer Kemp

#### **Administrative Assistants\***

Adrienne Broe BA

Alison Leckie (to June)

Susan Lewis MA

Melanie Middleton BMedSci, MPH (to May)

Mark Thompson BBus (from July)

#### Surveillance Program

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

### **Therapeutic and Vaccine Research Program**

#### **Head and Senior Lecturer**

Sean Emery BSc(Hons), PhD

#### **Associate Professor**

Jennifer Hoy MB BS, GradDipEpiBio, FRACP (from April)

#### Lecturers

Alexander Aichelburg MD (to June)

Dianne Carey BPharm, MPH

Kate Clezy MB BS, FRACP

Fraser Drummond MB ChB, MRCA, DA(UK)

Paddy Mallon MB, BCh, BAO, BSc(Hons)

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

Rebekah Puls BSc(Hons), PhD

#### **Senior Research Associate**

Gillian Hales RN, BSc(Hons), PhD, GradCert(Higher Ed)

#### **Clinical Project Coordinators**

Cate Carey RN, BA, MApplSc (Research) (from July) Fonnie Chan BN, RN, GradCertHSM, MPH (to October)

Jaimie Cox BSc(Hons), PhD, MAPS (from June)

Allison Martin MSc

Susan Phipps RN, RM

### **TVRP Operations Manager**

Morgan Stewart RN, BA(Hons)

#### **Data Managers**

David Courtney-Rodgers

Wendy Lee

Robyn Munro

#### **Administrative Assistants**

 $Brooke\ Cordwell\ BSc(Biomed)\ (from\ July)$ 

Alison McClymont BAppSc (to May)

Leeanne McIlvenna

### **HIV Epidemiology and Prevention Program**

#### **Head and Associate Professor**

Andrew Grulich MB BS, MSc, PhD, DRACOG, FAFPHM

### Lecturers

Jonathan Anderson MB ChB, MSc(MedSci), Dip Ven,

DRCOG, MRCGP, FRACGP

Jan Guerin BSc(Hons) PhD

#### **Post Doctorate Research Fellow**

Claire Vajdic BOptom, PhD

#### Senior Research Associate

Garrett Prestage BA(Hons), PhD

#### Senior Research Officer

Ann McDonald BSc, MPH

#### **Research Assistants**

Olympia Henry BA, GradDip(Counselling) (to February)

Jeff Jin BMed, MPH (from March)

Melanie Middleton BMedSci, MPH (from May)

Wei Zheng BS, MPH

<sup>\*</sup> Staff working in the office of the Deputy Director and the Surveillance, HIV Epidemiology and Prevention, Viral Hepatitis, Primary HIV Infection and Biostatistics and Databases Programs

#### **Clinical Project Coordinator**

Harry Smith MA

#### **Project Officers**

Brian Acraman

Wayne Bleakley GradCert(Management) (from August) Paul Kelly

Hedimo Santana BA(Hons)

### **Viral Hepatitis Program**

#### **Head and Senior Lecturer**

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

#### Lecturers

Anthony Freeman MB ChB, BmedSci Gail Matthews MBChB, MRCP (UK) (from December)

#### Research Fellow

Margaret MacDonald RN, BSocSci, GradDipEpidemiol, PhD

#### **Research Assistants**

Megan Buddle RN (from March) Rosie Thein MB BS, MPH Jialun Zhou BMed, MPH

### **Primary HIV Research Program**

**Head and Senior Lecturer** 

Don Smith MB ChB, MD

### **Clinical Project Coordinator**

Pat Grey RN, BA, DipEd, GradDipAppSci, DipCounselling

#### Senior Data Manager

Tim Ramacciotti BA(Hons) (to November)

### **Biostatistics and Databases Program**

**Head and Senior Lecturer** 

Matthew Law MA, MSc, PhD

#### Senior Research Assistants

Janaki Amin BSc(Hons), MPH(Hons) Mark Clements BSc, PhD (to November) Kathy Petoumenos BSc, MA, MPH(Hons)

#### **Computer Systems Officers**

Terry Sharkey BSc

Noorul Absar BTech, GradDipInfSci

### **Laboratory Support Program**

#### **Head and Senior Lecturer**

Tony Kelleher BSc(Hons), MB BS(Hons), PhD, FRACP, FRCPA

#### **Research Assistants**

David van Bockel BBiotech(Hons) Mee-Ling Munier BSc, GradDipEpi, MSc

### Internationally-based staff

#### Senior Lecturer

Chris Duncombe MB BS (HIV-NAT, Thailand)

#### Lecturers

Mark Boyd BA, MB BS, FRACP, DTM&H (HIV-NAT, Thailand)

Julian Elliott MB BS, FRACP (NCHADS, Cambodia) (from July)

### \*Neurology Research

#### Senior Lecturer

Gilles Guillemin PhD

#### Research Assistant

Louise Pemberton BSc(Hons)

### **Finance and Administration**

#### Manager

Bronwen Turner BA

#### **Business Manager**

Annie Tung MPA

#### Librarian

Coralie Kronenberg BA, DipIMLib, AALIA

#### **Computer Systems Officer**

Lisa Howard DipIT (from September) Regina Linich (to January)

Charles Tran BCompSci

#### **Personnel Officer**

Jason Flello BA (to October)

#### **Administrative Assistants**

Ian Brodie BEc, GradDipEd, AssDipHlthSc

Jo Groves BA

John Redmond

Yvette Toole

Philippa Wong BEc



John Redmond, Janette Button, Ian Brodie



### **Honorary Visiting Fellows**

Bruce Brew MB BS, MD, FRACP Professor of Medicine St Vincent's Hospital, Sydney

Nick Crofts MB BS, MPH, FAFPHM
Deputy Director and Head
Epidemiology and Social Research Unit
Macfarlane Burnet Centre for Medical Research,
Melbourne

Alex Wodak MB BS, MRACP, FRACP, MRCP, FAFPHM Senior Staff Specialist and Director Alcohol and Drug Service St Vincent's Hospital, Sydney



# Training or postgraduate degree placements at NCHECR

#### **Bachelor of Science (Honours) students**

Anna Swanson BSc(Hons) (to July) Sarah Sasson BA

#### **Doctor of Philosophy students**

Palanee Ammaranond Bachelor Medical Technology, Master of Biotechnology Joanne Micallef BMedSc(Hons) (from February)

#### **Master of Applied Epidemiology Fellow**

Monica Robotin MB BS, FRACS

#### Master of Public Health student

Adeeba Kamarulzaman MB BS, FRACP (from August)

### **NSW Health Department Trainee Biostatistician**

Doug Lincoln BSc(Hons) (to July)

#### **Visiting Fellows**

Toshiaki Shijuku (Chiba University, Japan) BSc, MSc (to December) Patrick Unemori (University of California, San Francisco, Fullbright Scholarship) BA Pysch, MA Psych (from June)

#### **World Health Organisation Fellows**

Zaini Hussin (Department of Health, Kelantan, Malaysia)MEpidBio, MD (August) Ahamad Jusoh (Ministry of Health, Kuala Lumpur, Malaysia) MPH, MD (August)



Palanee Ammaranond, Joanne Micallef

# **Collaborating organisations**

#### **National**

Australian Liver Association, Sydney

Australasian Society for HIV Medicine, Sydney

Australia and New Zealand Transplant Registry (ANZDATA), Sydney

Australian Agency for International Development (AusAID), Canberra

Australian Defence Force, Canberra

Australian Federation of AIDS Organisations, Sydney

Australian Hepatitis Council, Sydney

Australian Injecting and Illicit Drug Users League, Canberra

Australian Institute of Health and Welfare, Canberra

Australian National Council on AIDS, Hepatitis C and Related Diseases, 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

Commonwealth Department of Health and Ageing, Canberra

Communicable Diseases Network Australia, Canberra Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases, Canberra

National Association of People Living with HIV/AIDS, Sydney

National Centre in HIV Social Research, Sydney

National Centre in HIV Virology Research, Melbourne

National Drug and Alcohol Research Centre, Sydney

National Serology Reference Laboratory, Australia, Melbourne

Royal Australian College of General Practitioners, Sydney

### **Australian Capital Territory**

ACT Corrective Services, Canberra

AIDS Action Committee of the ACT, Canberra

Assisting Drug Dependents Inc, Canberra

Australian National University, Canberra

Brindabella Imaging

Canberra Sexual Health Clinic

Communicable Disease Control Program, ACT

Department of Health and Community Care, Canberra

Interchange General Practice, Canberra

The Canberra Hospital

#### **New South Wales**

Area Public Health Units, NSW Health Department

AIDS Council of NSW (ACON), Sydney

Albion Street Centre, Sydney

Blue Mountains Sexual Health Clinic, Katoomba

Bigge Park Medical Centre, Sydney

Bligh Street Clinic, Tamworth

Bureau of Crime Statistics and Research, Sydney

Communicable Diseases Surveillance and Control

Unit, NSW Health Department, Sydney

Concord Hospital, Sydney

Corrections Health Service, Sydney

Darlinghurst X-Ray, Sydney

Drug Intervention Services, Sydney

Garvan Institute of Medical Research, Sydney

General Medical Practice, Burwood

Gosford Sexual Health Clinic

Greater Murray Area Health Needle and Syringe

Program, Albury

Ground Zero Medical Centre, Sydney

Holdsworth House General Practice, Sydney

Immunology and Microbiology Department, The

University of Newcastle

Indo-Chinese Outreach Network, Sydney

John Hunter Hospital, Newcastle

Kirketon Road Centre, Sydney

Leichhardt Family Medical Practice, Sydney

Lismore Base Hospital

Livingstone Road Sexual Health Centre, Sydney

Liverpool Hospital, Sydney

Medically Supervised Injecting Centre, Sydney

Multicultural HIV/AIDS Service, Sydney

Nepean Hospital, Penrith

Northern Rivers Area Health Services, Lismore

People Living with HIV/AIDS (PLWHA), Sydney

Port Kembla Hospital

Prince of Wales Hospital, Sydney

Resource and Education Program for Injecting Drug

Users, Redfern and Canterbury

Royal Australian College of General Practitioners,

NSW Branch, Sydney

Royal Hospital for Women, Sydney

Royal Newcastle Hospital

Royal North Shore Hospital, Sydney

Royal Prince Alfred Hospital, Sydney

School of Public Health and Community Medicine,

UNSW, Sydney

Sexual Health and Infectious Diseases Service

(SHAIDS), Lismore

South Sydney Council, Sydney

St George Hospital, Sydney

St George Needle and Syringe Program, Sydney

St Leonards Medical Centre, Sydney

St Vincent's Hospital, Sydney

Sydney Children's Hospital

Sydney Sexual Health Centre

SydPath, Sydney

Taylor Square Private Clinic, Sydney

The Cancer Council NSW, Sydney

The Exchange Services, Manly and Ryde

The Medical and Vein Centre, Coffs Harbour

Wentworth HIV and Sexual Health Service, Penrith

Western Area Adolescent Team, Mount Druitt

Western Sydney HIV/Hepatitis C Prevention Service,

Auburn, Blacktown and Parramatta

Westmead Hospital, Sydney

407 Doctors, Sydney

### **Northern Territory**

AIDS Council of Central Australia, Alice Springs Department of Correctional Services, Darwin Northern Territory AIDS Council, Darwin Royal Darwin Hospital

#### Queensland

AIDS Medical Unit, Queensland Health, Brisbane

Blackall Terrace Specialist Centre, Nambour

Brisbane Sexual Health Clinic

Brunswick Street Medical Centre, Brisbane

Cairns Base Hospital

Community Health Services, Maryborough

Drug Users Network Education and Support (DUNES)

Needle and Syringe Program, Miami

Gladstone Road Medical Centre, Brisbane

Gold Coast Hospital, Southport

Gold Coast Sexual Health Clinic, Miami

GRM International Pty Ltd, Brisbane

Inala Community Health Service, Brisbane

Kobi House, Toowoomba Health Services

Logan Youth and Family Services, Brisbane

Mackay Sexual Health Services

Mater Private Hospital, Brisbane

Nambour General Hospital

Prince Charles Hospital, Brisbane

Princess Alexandra Hospital, Wooloongabba

Queensland AIDS Council (QAC), Brisbane

Queensland Corrective Services Commission, Brisbane

Queensland Intravenous AIDS Association (QUIVAA), Brisbane

Queensland Needle and Syringe Program,

Queensland Health, Brisbane

Queensland Positive People, Brisbane

Royal Brisbane Hospital

Southcoast Radiology, Pindara Hospital

Special Health Services, Cairns

Sunshine Coast Intravenous AIDS Association

(SCIVAA), Maroochydore

West Moreton Sexual Health Service, Ipswich

#### South Australia

AIDS Council of South Australia, Adelaide

Clinic 275, Adelaide

Drug and Alcohol Services Council, Adelaide

Flinders Clinical Trials Pharmacy, Adelaide

Flinders Medical Centre, Adelaide

Hindmarsh Centre, Adelaide

Infectious Diseases Laboratories, Institute of Medical

and Veterinary Science, Adelaide

O'Brien Street Practice, Adelaide

Parks Community Health Centre, Adelaide

Perrett Medical Imaging, Adelaide

Royal Adelaide Hospital

Salisbury Shopfront Youth Information Service,

Adelaide

South Australian Voice for Intravenous Education (SAVIVE), AIDS Council South Australia, Adelaide

STD Services, Adelaide

The Care and Prevention Program, Adelaide

University

#### **Tasmania**

Prison Health Services Tasmania, Hobart

Public and Environmental Health, Department of Community and Health Services, Hobart

Royal Hobart Hospital

Sexual Health Branch, Launceston

Tasmanian Council on AIDS, Hepatitis and Related

Diseases, Hobart

The Link Youth Health Service, Hobart

#### Victoria

Austin Repatriation Medical Centre, Heidelberg

Cogstate Ltd, Melbourne

CSIRO Animal Health Laboratory, Geelong, Victoria

Health Exchange, Melbourne

Immunology and Microbiology Department, The

University of Melbourne

Macfarlane Burnet Institute for Medical Research and

Public Health, Melbourne

Melbourne Diagnostic Unit, The University of

Melbourne

Melbourne Inner Needle Exchange

Melbourne Sexual Health Centre

Middle Park Clinic, Melbourne

Monash Medical Centre, Melbourne

Northcote Clinic, Melbourne

People Living with HIV/AIDS (PLWHA), Melbourne

Positive Living Centre, Melbourne

Prahran Market Clinic, Melbourne

Royal Melbourne Hospital

South East Alcohol and Drug Services, Outreach and Prevention Program, Dandenong

Southern Hepatitis and AIDS Prevention Service, Frankston

The Alfred Hospital, Melbourne

The Carlton Clinic, Melbourne

The Centre Clinic, 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 Diseases Control Unit, Perth

Fremantle Hospital, Perth

Ministry of Justice, Strategic and Specialist Services Division, Perth

Princess Margaret Hospital for Children, Perth

Royal Perth Hospital

Western Australian AIDS Council, Perth

Western Australian Substance Users Association, Perth and Bunbury

Western Region AIDS and Hepatitis Prevention, Perth

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Agence Nationale pour la Recherche de SIDA (ANRS), Paris, France

AIDS Clinical Centre, International Medical Centre of Japan, Tokyo

AIDS Malignancy Consortium, Alabama, USA

Asia Regional office, Family Health International (FHI), Bangkok, Thailand

Auckland Hospital, New Zealand

Auckland Sexual Health Clinic, New Zealand

Buddhachinnaraj Hospital, Phitsanulok, Thailand

Bumrasnaradura Hospital, Bangkok, Thailand

Canadian Trials Network (CTN), Vancouver

Centers for Disease Control and Prevention, Atlanta, USA

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, Thailand

Chonburi Regional Hospital, Thailand

Christchurch Hospital, New Zealand

Columbia University, New York, USA

Community Research Initiative, New England, USA

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European Monitoring Centre for Drugs and Drug

Addiction, Lisbon, Portugal

Family Health Institute, Family Health International (FHI), North Carolina

Fundacion Centro de Estudios Infectologicos

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Gemeinschafts Praxis, Dusseldorf, Germany

Geneva Hospital, Switzerland

Harlem Hospital Centre, New York, USA

Harvard University, USA

HIV Netherlands Australia Thailand Research

Collaborative (HIV-NAT), Bangkok, Thailand

Hopital Cantonal Universitaire, Geneva, Switzerland

Hopital Gui de Chauliac, Montpellier, France

Hopital Haut-Levegue, Bordeaux, France

Hopital Pitie-Salpetriare, Paris, France

Hopital Rothschild, Paris, France

Hopital Necker, Paris, France

La Plata, Argentina

Hospital Central, Mendoza, Argentina

Hospital Clinic Provincial de Barcelona, Spain

Hospital de Enfermedades Infecciosas FJ Muniz, Buenos Aires, Argentina

Hospital General de Agudos Juan A Fernandez, Buenos Aires, Argentina

Hospital General de Agudos Ramos Mejia, Buenos Aires, Argentina

Hospital Interzonal de Agudos San Juan de Dios,

Hospital Interzonal General de Agudos Oscar Alende, Mar del Plata, Argentina

Hospital Italiano de Buenos Aires, Argentina

Hospital JM Ramos Meija, Buenos Aires, Argentina

Hospital Rawson, Bajada Pucara, Argentina

Hospital Universitario Clementino, Rio de Janeiro, Brazil

Hvidovre Hospital, Copenhagen, Denmark

Infectologia Hospital, Alejandro Posadas, Haedo, Argentina

International AIDS Society, Stockholm, Sweden

International AIDS Therapy Evaluation Centre, Amsterdam, The Netherlands

Istituto Superiore di Sanita, Rome, Italy

J W Goethe Universitat, Frankfurt, Germany

Kaplan Medical Centre, Rehovot, Israel

Kings College Hospital, London, UK

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Medical Research Council Clinical Trials Unit, (MRC), London, UK

Ministry of Health, Kuala Lumpur, Malaysia

Ministry of Public Health, Bangkok, Thailand

Miriam Hospital, Providence, USA

Montreal General Hospital, Canada

National Cancer Institute, Bethesda, USA

National Heart, Lung and Blood Institute, Bethesda, USA

National Institute of Allergy and Infectious Diseases, Bethesda, USA

Northwestern University Medical School, Chicago, USA

Osaka National Hospital, Japan

Partners AIDS Research Centre, MGH, Boston, USA

Ramathibodhi University, Bangkok, Thailand

Rambam Medical Centre, Haifa, Israel

Royal Free Hospital, London, UK

Royal Sussex County Hospital, UK

St Paul's Hospital, Vancouver, Canada

San Francisco General Hospital, USA

Sanpatong Hospital, Chiangmai, Thailand

Siriraj Hospital, Bangkok, Thailand

Srinagarind Hospital, Thailand

Swiss HIV Cohort Study, Geneva, Switzerland

Tan Tock Seng Hospital, Singapore

Tel Aviv Sourasky Medical Centre, Israel

Terry Beirn Community Programs for Clinical

Research in AIDS (CPCRA), Washington, USA

Thai Red Cross, Chulalongkorn University Hospital, Bangkok, Thailand

The Chaim Sheba Medical Centre, Ramat Gan, Israel

The Government Pharmaceutical Organisation,

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Toronto Hospital, Canada

UNAIDS, Geneva, Switzerland

University Malaya, Kuala Lumpur, Malaysia

University of Minnesota, Minneapolis, USA

University of Munich, Germany

University of Oxford, UK

University of Tokyo Institute of Medical Science, Japan

University of Washington, Seattle, USA

Vajira Hospital, Bangkok, Thailand

Waikato Hospital, New Zealand

Washington University School of Medicine, St Louis, USA

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Wetherall Institute of Molecular Medicine, Oxford, UK

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### Pharmaceutical and biomedical industry

Abbott Australasia Pty Ltd, Sydney Agouron Pharmaceuticals Inc, California, USA Australian Technology Partnership Pty Ltd, Sydney Becton Dickson Pty Ltd, Sydney Boehringer Ingelheim Pty Ltd, Sydney

Bristol-Myers Squibb Pharmaceuticals, Melbourne

Chiron Therapeutics, Emeryville, USA

CSL Ltd, Melbourne

Cytran, Kirkland, USA

Gilead Sciences, Melbourne

GlaxoSmithKline Australia, Boronia, Vic

IDT Australia Ltd, Boronia, Vic

Ingenix Pharmaceutical Services Inc, New Jersey, USA

F Hoffman-La Roche Ltd, Basel, Switzerland

Merck Research Laboratories, West Point, USA

Merck Sharpe and Dohme, Sydney

Perkin-Elmer Biosystems, Knoxville, Vic

Probe Pharmaceuticals Pty Ltd, Sydney

Quintiles Australia Pty Ltd, Melbourne

Roche Diagnostics Australia Pty Ltd, Sydney

Roche Products Pty Ltd, Sydney

Shire Pharmaceutical Development Inc, Bangkok,

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Virax Immunotherapeutics, Melbourne

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Visible Genetics Inc, Toronto, Canada



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#### Ian Ramshaw MSc, PhD

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#### Russell Waddell MB BS, BSc, FACSHP (Chair from July)

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#### **David Baker MB ChB**

General Practitioner, 407 Doctors, Sydney

#### Bruce Brew MB BS(Hons), MD, FRACP

Professor and Head, Department of Neurosciences and Neurology, St Vincent's Hospital, Sydney

#### Suzanne Crowe MB BS, FRACP, MD

Professor and Head, AIDS Pathogenesis Research Unit, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne

#### John Cumming GradDipPublicSectorManagement

Treatment Information Officer, AIDS Council of NSW, Sydney

### Nicholas Doong MB BS, DipObs, MPH, FRACGP General Practitioner, Sydney

Dominic Dwyer BSc(Med), MB BS, FRACP, FRCPA

Staff Specialist, Medical Virology and Clinical Microbiology, Centre for Infectious Diseases and Microbiology Laboratory Services, Institute for Clinical Pathology and Medical Research, Westmead Hospital, Sydney

#### John Dyer MB BS, FRACP (from January)

Senior Consultant, Department of Microbiology and Infectious Diseases, Flinders Medical Centre, Adelaide

#### Mark Kelly MB BS

Head of Research, Albion Street Centre, Sydney

#### **Tony Maynard FACBS**

Treatments Officer, Victorian AIDS Council/Gay Men's Health Centre, Melbourne

#### Graham Mills MB ChB, MTH, FRACP

Infectious Disease Physician, Respiratory and Infectious Diseases, Waikato Hospital, New Zealand

# Cathy Pell MB BS, CertFamPlanning, MMed(Sexual Health)

Specialist General Practitioner, Taylor Square Private Clinic, Sydney;

Research Coordinator, Sydney Sexual Health

#### Anna Pierce MB BS. FRACP

Clinical Research Fellow, Department of Infectious Diseases, The Alfred Hospital, Melbourne

#### John Quin MB BS(Hons), PhD, FRACP, FRCPA

Director of Clinical Immunology, HIV Medicine and Sexual Health, Liverpool Hospital, Sydney

#### Hugo Ree MB, FRCP, FACSHP

Senior Medical Officer and Consultant Physician, AIDS Medical Unit, Queensland Health, Brisbane

#### Gary Rogers MB BS, MGPPsych, FACPsychMed

Clinical Lecturer and Program Director, The Care and Prevention Program, Department of General Practice, University of Adelaide

#### Cassy Workman MB BS

General Practitioner, Ground Zero Medical Centre, Sydney;

Research Coordinator, Sydney Sexual Health

# Fraser Drummond MB ChB, MRCA, DA(UK) (Convenor)

**NCHECR** 

### **Primary HIV Infection Working Group**

#### Andrew Carr MD, FRACP, FRCPA (Chair)

Associate Professor and Staff Specialist, Department of Immunology and HIV Medicine, St Vincent's Hospital, Sydney

#### Mark Bloch MB BS

General Practitioner, Holdsworth House General Practice, Sydney

#### Philip Cunningham BAppSc(Med)

Senior Scientist and Operations Manager, NSW State Reference Laboratory for HIV/AIDS, Centre for Immunology, St Vincent's Hospital, Sydney

#### Stephen Delaney BSc, PhD, MASM

Community Representative, National Association of People Living with HIV/AIDS, Sydney

# Christopher Fairley MB BS, FRACP, PhD, FAFPHM, FACSHP

Professor and Director, Royal Women's Hospital Research Unit, Melbourne Sexual Health Centre

#### Robert Finlayson MB BS, DipVen, FACVen

General Practitioner, Taylor Square Private Clinic, Sydney

#### Nicholas Medland BA(Hons), MB BS, DipVen

Clinical Director, The Centre Clinic, Victorian AIDS Council/Gay Men's Health Centre, Melbourne

#### **Dean Murphy**

HIV Education Officer, Australian Federation of AIDS Organisations, Sydney

#### John Zaunders BSc

Senior Scientist, Centre for Immunology, St Vincent's Hospital, Sydney

# Patricia Grey BA, Post Grad Dip AppSc, CNS, Dip(Counselling) (Convenor)

**NCHECR** 

### Toxicology/Pharmacology Working Group

# Simon Mallal BMedSci(Hons), MB BS, FRACP, FRCPA (Chair)

Clinical Immunologist, Department of Clinical Immunology, Royal Perth Hospital

# Anthony Allworth MB BS, FRACP, FRCPA, FACTM, MASM

Director, Infectious Diseases Unit, Royal Brisbane Hospital

# Jonathan Anderson MB ChB, MRCGP, DRCOG, DipVen, MSc(MedSci)

General Practitioner, The Carlton Clinic, Melbourne

#### David Austin MB BS, FRACGP, MPM (to April)

General Practitioner, Holdsworth House General Practice, Sydney

#### **Alan Brotherton BA**

Manager, Information Services and Gay Men's Health, AIDS Council of New South Wales, Sydney

# **Paddy Mallon MB, BCh, BAO, BSc(Hons)** NCHECR

#### Debbie Marriott BSc(Med), FRACP, FRCPA

Senior Staff Specialist, Clinical Microbiology and Infectious Diseases, St Vincent's Hospital, Sydney

#### David Menadue BA, BAEd

Care and Support Spokesperson, National Association of People Living with HIV/AIDS, Melbourne

#### Anne Mijch MB BS, FRACP

Head, HIV/AIDS Services, Department of Infectious Diseases, The Alfred Hospital, Melbourne

#### Peter Piggott MB BS, FRACP (from May)

Head, HIV Medicine, Department of Thoracic Medicine and Respiratory Investigation, Royal North Shore Hospital, Sydney

#### Norman Roth MB BS, DipAvMed, DipVen, FACSHP

General Practitioner, Prahran Market Clinic, Melbourne

# David Sowden MB BS, BS DIP, RACOG, FRACP, FRCPA

Infectious Diseases Physician, Nambour General Hospital, Qld

# **Dianne Carey BPharm, MPH (Convenor)** NCHECR

### **Oncology Working Group**

#### David Goldstein MB BS, FRACP (Chair)

Senior Staff Specialist, Department of Medical Oncology, Prince of Wales Hospital, Sydney

#### Trish Bullen RN, RITN

Manager, Sexual Health Program, Macquarie Area Health Service, Dubbo, NSW

### Mitchell Chipman MB BS, FRACP

Medical Oncologist, Austin Hospital, Melbourne

# Andrew Grulich MB BS, MSc, DRACOG, FAFPHM, PhD

**NCHECR** 

#### Sam Milliken MB BS, FRACP, FRCPA

Lecturer and Staff Specialist, Department of Haematology, St Vincent's Hospital, Sydney

# Adrian Mindel MB BCh, MSc(CTM), MD, FRCP, FRACP, FACVen

Professor and Director, Sexually Transmitted Infections Research Centre, Westmead Hospital, Sydney

### Richard Murphy PhD (until April)

Treatments Officer, AIDS Council of NSW, Sydney

# Kate Clezy MB BS, FRACP (Convenor)

**NCHECR** 

### **Immune-Based Therapies Working Group**

#### Andrew Lloyd MB BS, MD, FRACP (Chair)

Associate Professor and Consultant Infectious Diseases Physician, Department of Infectious Diseases, Prince of Wales Hospital, Sydney

#### Michael Boyle BMedSci, MB BS, MD

Staff Specialist, Immunology and Infectious Diseases, John Hunter Hospital, Newcastle, NSW

#### Martyn French MB ChB, FRACP, MD, FRCPath, FRCP

Clinical Immunologist and Head, Department of Clinical Immunology and Biochemical Genetics, Royal Perth Hospital

#### Roger Garsia MB BS, PhD, FRACP, FRCPA

Director of Clinical AIDS Services and Staff Specialist in Immunology, Department of Clinical Immunology, Royal Prince Alfred Hospital, Sydney

# Tony Kelleher BSc(Hons), MB BS(Hons), PhD, FRACP, FRCPA

**NCHECR** 

#### Stephen Kent MB BS, FRACP, MD

Senior Research Scientist, Department of Microbiology and Immunology, The University of Melbourne

#### Sharon Lewin MB BS(Hons), FRACP, PhD

Physician, Victorian Infectious Diseases Services, Royal Melbourne Hospital

#### Kirsty Machon BAComm, MA

HIV Health Policy Officer, National Association of People Living with HIV/AIDS, Sydney

# Paul McQueen BSc, GradDipBiotech, PhD Biotech, MASM

Community Representative, National Association of People Living with HIV/AIDS, Sydney

#### Richard Moore MB BS, Dip RACOG, FRACGP, DipVen

Medical Practitioner, Carlton Clinic, Melbourne; Sessional HIV Specialist, Melbourne Sexual Health Centre;

Clinical Assistant, Alfred Hospital Infectious Diseases Unit, Melbourne

# Graeme Stewart BSc(Med), MB BS, PhD, FRACP, FRCPA

Associate Professor and Director of Clinical Immunology, Department of Clinical Immunology and Allergy, Westmead Hospital, Sydney

#### John Sullivan PhD

Principal Scientist, Australian Red Cross Blood Services, Sydney

# Sarah Pett BSc(Hons), MB BS(Hons), DTM&H, MRCP (UK) (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 (Peggy) Bain BSc(Psych), MClinPsych

Neuropsychologist, St Vincent's Hospital, Sydney

#### Catherine Cherry MB BS, FRACP

Infectious Diseases Physician, The Alfred Hospital, Melbourne

#### John Daye

Treatments Spokesperson, National Association of People Living with HIV/AIDS, Melbourne

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

### Steve Ellen MB BS, MMed(Psych), FRANZCP

Head, Consultation - Liaison Psychiatry, The Alfred Hospital, Melbourne

#### Catriona McLean BSc, MB BS, FRCPA, MD

Consultant Pathologist, The Alfred Hospital, Melbourne

#### Hassan Naif PhD

Head, Molecular Pathogenesis Laboratory, Centre for Virus Research, Westmead Millennium Institute, Sydney

#### Patricia Price PhD

Senior Lecturer, Department of Pathology, The University of Western Australia, Perth

#### Nitin Saksena BSc, MSc, PhD

Head, Retroviral Genetics Laboratory, Centre for Virus Research, Westmead Millennium Institute, 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 (Convenor)

Infectious Diseases Specialist, The Alfred Hospital, Melbourne

### **Viral Hepatitis Working Group**

#### William Sievert MD, FRACP (Chair)

Head of Hepatology, Monash Medical Centre, Melbourne

# 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

# Chris Burrell BSc(Med), MB BS, PhD, FRCPath, FRCPA

Professor of Virology, University of Adelaide

# **David A Cooper DSc, MD, FRACP, FRCPA, FRCP** NCHECR

#### Darrell Crawford MD, FRACP

Associate Professor of Medicine, Princess Alexandra Hospital, Brisbane

#### Sean Emery BSc(Hons), PhD

**NCHECR** 

#### Geoff Farrell MD, FRACP

Robert W Storr Professor of Hepatic Medicine, Westmead Millennium Institute, Sydney

#### John M Kaldor PhD

**NCHECR** 

#### Susan Kippax BA(Hons), PhD

Professor and Director, National Centre in HIV Social Research, UNSW, Sydney

#### Matthew Law MA, MSc, PhD (until April)

**NCHECR** 

#### Stephen Locarnini MB BS, BSc(Hons), PhD, FRCPath

Divisional Head, Research and Molecular Development, Victorian Infectious Diseases Reference Laboratory, 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

### Joe Sasadeusz MB BS, FRACP, PhD

Infectious Diseases Physician, Royal Melbourne Hospital and Alfred Hospital, Melbourne

#### Ingrid van Beek MB BS, MBA, FAFPHM

Director, Kirketon Road Centre, Sydney

#### **Jack Wallace**

Executive Officer, Australian Hepatitis Council, Canberra

**Greg Dore BSc, MB BS, FRACP, MPH, PhD (Convenor)**NCHECR

### **Research Coordinator Working Group**

### John Miller MSN (Chair to September)

Coordinator, HIV Clinical Trial Unit, St Vincent's Hospital, Sydney

### Claire McCormack BNurs, GradDipAdvNurse, GradDipClinEpi (Acting Chair from October; Chair from November)

Clinical Research Coordinator, The Alfred Hospital, Melbourne

#### Jeff Hudson RN (from November)

Trials Nurse, Burwood Road General Practice, Sydney

#### Sheena McLeod RN (from November)

Clinical Trials Nurse, Immunology and Infectious Diseases, St Vincent's Hospital, Sydney

#### Jenny Skett RN

Study Nurse, Royal Perth Hospital

#### Alan Walker BA, GradDipAppSci, MPH

Nurse Practice Coordinator, Nambour General Hospital, Qld

#### Helen Wood RN

Clinical Research Coordinator, The Centre Clinic, Melbourne

#### Janelle Zillman RN

Clinical Nurse, Infectious Diseases, Day Therapy Unit, Royal Brisbane Hospital

# Fonnie Chan RN, BN, GradCert HSM, MPH (Convenor to October)

NCHECR

# Cate Carey RN BA MApplSc(Research) (Convenor from November)

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#### NCHECR Working Groups ex officio

**David A Cooper DSc, MD, FRACP, FRCPA, FRCP** NCHECR

Sean Emery BSc(Hons), PhD

**NCHECR** 

#### John M Kaldor PhD

**NCHECR** 

#### Matthew Law MA, MSc, PhD

**NCHECR** 

# Peter McDonald MB BS, FRCPA, MRACP, FRACP, FASM

Professor of Microbiology and Infectious Diseases, Flinders University, Adelaide; Chair, ANCAHRD Clinical Trials and Research Committee

#### Don Smith MB ChB, MD

**NCHECR** 



# External boards, committees and advisory groups

3rd Australasian Conference on Hepatitis C Organising Committee, Epidemiology and Social Research Stream

Greg Dore, Convenor

4th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV Organising Committee

**David Cooper** 

5th Bangkok Symposium on HIV Medicine Antiretroviral Workshop Organising Committee

David Coope

8th World STI/AIDS Congress International Scientific Committee

John Kaldor

14th Annual Conference Australasian Society for HIV Medicine Conference Committee

Andrew Grulich, Co-Convenor

14th Annual Conference Australasian Society for HIV Medicine Epidemiology Stream Advisor

Margaret MacDonald

14th Annual Conference Australasian Society for HIV Medicine Basic Science Stream Advisor

Tony Kelleher

14th International Conference on the Reduction of Drug Related Harm International Advisory Panel Margaret MacDonald

42nd Interscience Conference on Antimicrobial Agents and Chemotherapy Organising Committee

David Cooper

Acute Infection Early Disease Research Program Data Base Working Group

John Kaldor

AIDS Council of New South Wales Board

Andrew Grulich

AIDS Editorial Board

**David Cooper** 

ANCAHRD Hepatitis C Subcommittee, Hepatitis C Virus Projections Working Group

Greg Dore, John Kaldor, Matthew Law

ANCAHRD, HIV/AIDS Committee

Andrew Grulich

ANCAHRD Indigenous Australians' Sexual Health Committee

John Kaldor

ANCHARD, Clinical Trials and Treatments Advisory Committee

David Cooper, Ex officio

AusAID Indonesia HIV/AIDS Prevention and Care Project Phase II, Technical Advisory Team

John Kaldor, Chair

Australasian Society for HIV Medicine HIV Journal Club Editorial Board

Andrew Grulich, Don Smith

Australasian Society for HIV Medicine National Committee

Andrew Grulich, President

Australasian Society for HIV Medicine NSW Hepatitis C Prescriber Trial Clinical Subcommittee

Greg Dore

Australasian Society for HIV Medicine, Hospital Practice and Research Standing Committee

Bruce Brew, Chair

Australasian Society for HIV Medicine Standing Committee on Hepatitis C

Greg Dore, Chair

Australasian Society for HIV Medicine Treatment Subcommittee

Don Smith

Australian Association of Neurologists, Behavioural Neurology Subcommittee

**Bruce Brew** 

Australian Association of Neurologists, NSW State Committee

Bruce Brew

Australian Federation of AIDS Organisations HIV Vaccine Policy Reference Group

Andrew Grulich

Australian Red Cross Blood Service National Donor Travel Survey Working Party

John Kaldoi

Central Sydney Area Health Service Expert Advisory Group for the Australian Study of Health and Relationships

John Kaldor

Cochrane Collaborative Review Group on HIV infection and AIDS, Biomedical Interventions Reviews Editorial Group

John Kaldor

Commonwealth Department of Health and Ageing Returns on Investment Advisory Committee

John Kaldor

Communicable Diseases Intelligence Editorial Board John Kaldor

Communicable Diseases Network Australia Steering Committee on Best Practice Management of Health Care Workers Infected with a Blood Borne Virus John Kaldor

Communicable Diseases Network Australia John Kaldor

**ESPRIT Executive Committee** 

Sean Emery

ESPRIT International Steering Committee

Matthew Law

**ESPRIT Toxicity Committee** 

Sarah Pett

Health Research Council of New Zealand

**Bruce Brew** 

Hepatitis C Council of NSW, Medical and Research Advisory Panel

Greg Dore, John Kaldor

HIV DART 2002: Frontiers in Drug Development for Antiretroviral Therapy Conference Organising Committee

**David Cooper** 

HIV Netherlands, Australia, Thailand (HIV-NAT), Thai Red Cross AIDS Research Centre

David Cooper, Co-Director

InterLymph International Collaborative Group on Lymphoma Research Infectious Causes of Lymphoma Subgroup

Andrew Grulich, Co-Chair

International AIDS Society Governing Council Governance Subcommittee

John Kaldor

International AIDS Society Governing Council John Kaldor

International Society of Neurovirology, Board of Directors

**Bruce Brew** 

INTIO Immunology Substudy Steering Committee Tony Kelleher

Journal of Acquired Immune Deficiency Syndromes Editorial Board

David Cooper

Journal of Epidemiology and Biostatistics Editorial Board John Kaldor

Journal of Ethiopian Medical Practice, International Advisory Board

**Bruce Brew** 

Journal of HIV Medicine Editorial Board

Andrew Grulich

Lipodystrophy Case Definition Study International Steering Committee

Matthew Law

Monitoring the AIDS Pandemic Steering Committee
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 Drug and Alcohol Research Centre Illicit Drug Reporting System Steering Committee

Margaret MacDonald

Neuroscience of HIV infection, Scientific Program Committee

**Bruce Brew** 

NHMRC Project Grants Committee Milestones Subcommittee

John Kaldor, Chair

NHMRC Project Grants Committee

John Kaldor

NHMRC Special Expert Advisory Committee on Transmissible Spongiform Encephalopathies

John Kaldor

NSW Department of Corrective Services Ethics Committee

John Kaldor

NSW Health Department Chlamydia Campaign Advisory Committee

John Kaldor

NSW Health Department Committee on AIDS Strategy, Post-exposure Prophylaxis Subcommittee Don Smith

NSW Health Department HIV Health Promotion Committee

Andrew Grulich, Chair

NSW Health Department Medically Supervised Injecting Centre Evaluation Committee

John Kaldor

NSW Health Department NSW Health Ethics Committee

Andrew Grulich

NSW Health Department Sexual Health Advisory Committee

John Kaldor

NSW Health Department Sexually Transmissible Infections Strategy Working Group

Andrew Grulich, John Kaldor

NSW Health Department, South East Health, HIV Dementia and Mental Health Advisory Committee Bruce Brew

NSW Health Department, Statewide Area Health Services, Planning and Management Committee, AIDS Dementia Complex and HIV-Related Psychiatric Conditions

**Bruce Brew** 

NSW Ministerial Advisory Committee on Hepatitis John Kaldor

NSW Users and AIDS Association Heroin Overdose Information and Education Initiative Expert Advisory Group

Margaret MacDonald

Qualifications Committee (Promotion to professor), UNSW

Bruce Brew

Repatriation Medical Authority John Kaldor

Royal Australian College of General Practitioners Training Program HIV/AIDS Special Skills Management Committee

Don Smith, Executive Member

Sexually Transmitted Infections Editorial Board David Cooper

Sixth International Congress on Drug Therapy in HIV Infection Scientific Committee

David Cooper

SMART Body Composition Substudy Team

Fraser Drummond

SMART Protocol Team

Fraser Drummond

South East Health HIV Minimum Data Set Working Group

Paddy Mallon

South East Health HIV/Hepatitis C Sexual Health Minimum Data Set Implementation Committee Paddy Mallon

South Eastern Sydney Public Heath Unit Sexually Transmitted Infections in Gay Men Action Group Andrew Grulich

St Vincent's Campus Institutional Biosafety Committee Tony Kelleher

St Vincent's Hospital Human Research Ethics Committee

Matthew Law, Paddy Mallon

STD/HIV Subcommittee of the Central Australian Disease Control Coordinating Committee

John Kaldor

Steering Group for CMO Report on Communicable Disease

John Kaldor

The Data Collection on Adverse Events of Anti-HIV Drugs Study International Steering Committee

Matthew Law

UNAIDS/World Health Organisation Consultation on Estimates, Modelling and Projections

John Kaldor

UNSW Faculty of Medicine Research Committee, Bachelor of Science (Medicine) Subcommittee Greg Dore

World Health Organisation Consultation on Estimation of Incidence and Prevalence of Sexually Transmitted Infections

John Kaldor

World Health Organisation Regional Task Force on HIV/AIDS Care and Treatment

**Greg Dore** 

XIV International AIDS Conference International Scientific Advisory Board

John Kaldor

XIV International AIDS Conference, Track B Rapporteur Team

**Greg Dore** 



Analysis and reporting on the 2001 round of HIV serological surveillance, World Health Organisation, Cambodia

John Kaldor

Estimated risk of lung cancer given personal smoking history, Slater & Gordon, Sydney

Mark Clements

Expert Panel on Global Burden of Hepatitis C, World Health Organisation, Geneva, Switzerland Greg Dore

HIV and STI surveillance in China, Family Health International, Beijing, China

John Kaldor

HIV behavioural surveillance, World Health Organisation, Kuala Lumpur, Malaysia

Margaret MacDonald

HIV/AIDS epidemiology in Cambodia, World Health Organisation, Phnom Phenh, Cambodia John Kaldor

Meta analysis for an appeal to TGA for adult growth hormone, Pharmwiz International (for Novo Nordisk), Sydney

Mark Clements

Modelling theoretical TSE risk for plasma products, Therapeutic Goods Administration, Canberra

Matthew Law

National survey of overseas travel undertaken by Australian blood donors from 1980-2002 and impact of further donor deferrals on the blood supply, Australian Red Cross Blood Service / Commonwealth Department of Health and Ageing, Sydney

Matthew Law

OzFoodNet Review, Commonwealth Department of Health and Ageing, Sydney

John Kaldor

RCPA Serology Quality Assurance Program, RCPA Quality Assurance Programs Pty Limited, Sydney Matthew Law

SMART Neurology sub-study, Community Programs for Clinical Research on AIDS, Chicago, USA Bruce Brew

STI/HIV/AIDS surveillance in the Pacific, World Health Organisation, Suva, Fiji

John Kaldor

Technical consultant on antiretroviral therapy, World Health Organisation, China, Vietnam, Laos Chris Duncombe



## Students supervised by NCHECR staff

Supervisor(s) in brackets

### **Bachelor of Science (Honours) awarded**

#### **Anna Swanson**

Design and optimisation of a real time PCR assay for the detection of HIV-1 2-LTR episomal DNA (Tony Kelleher)

#### Bachelor of Science (Honours) candidate

#### **Sarah Sasson**

Modulation of IL-7 and IL-7 receptor following therapeutic intervention in HIV-1 infection (Tony Kelleher)

### Bachelor of Science (Medicine) candidate Phillip Law

Prevalence of human immunodeficiency virus/hepatitis B and/or C virus coinfection and the impact of antiretroviral therapy on hepatitis outcomes (David Cooper)

### Bachelor of Science (Medicine) (Honours) candidate Lily Wang

Quinolinic acid and astrocyte apoptosis (Bruce Brew)

#### **Doctor of Medicine candidate**

#### Patrick Unemori

Pathogenesis of HIV-associated lipodystrophy (Paddy Mallon)

### Doctor of Philosophy candidates Janaki Amin

Disease progression in chronic hepatitis C (Greg Dore, Matthew Law)

### Palanee Ammarannond

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

#### Jonathan Anderson

Clinical aspects of anal intra-epithelial neoplasia (Andrew Grulich)

#### **Oliver Distler**

HIV lipodystrophy syndrome (David Cooper)

#### Jeff Jin

Epidemiology of sexually transmissible infections in gay men in Sydney (Andrew Grulich, John Kaldor)

#### **Paddy Mallon**

Protease inhibitor related atherosclerosis in HIV (David Cooper)

#### Joanne Micallef

Risk factors and natural history of hepatitis C (Greg Dore, John Kaldor)

#### Ann Mijch (Monash University)

Measuring and managing HIV virological failure (John Kaldor)

**John Miller** (Clinical School of Medicine, St Vincent's Hospital)

Lipodystrophy in HIV disease (David Cooper, John Kaldor)

#### **Robert Owe-Young**

The blood brain barrier in AIDS dementia complex (Bruce Brew)

#### **Louise Pemberton**

Host and viral factors in the pathogenesis of AIDS dementia complex (Bruce Brew)

#### **Kathy Petoumenos**

The Australian HIV Observational Database (Matthew Law, John Kaldor)

#### Toshiaki Shijuku

Impact of insertion in p6gag on viral fitness, gag processing and antiretroviral drug resistance (Tony Kelleher)

Therese Smit (The University of Sydney)

Viral divergence in the brain and AIDS dementia complex pathogenesis (Bruce Brew)

#### **Danielle Smith**

Kynurenine pathway inhibition and the pathogenesis of AIDS dementia complex (Bruce Brew)

#### **Rosie Thein**

Quality of life and hepatitis C (Greg Dore, John Kaldor)

# Master of Applied Epidemiology (Disease Control) candidate

Monica Robotin (Australian National University)

Communicable disease epidemiology and surveillance (Greg Dore, Andrew Grulich)

# Master of Arts in Clinical Drug Dependence Studies candidate

Mark Denoe (Macquarie University)
Experiences of needle syringe program pharmacies in
South East Health
(Margaret MacDonald)

#### Master of Clinical Pharmacy candidate

**Scott Elsegood** (The University of Sydney) Nelfinavir concentration study (Dianne Carey)

# Master of Medicine (Sexually Transmitted Diseases/HIV) treatise candidate

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 Public Health major project awarded Jenny Gates

Risk factors for hepatitis C among NSW prison inmates (John Kaldor)

#### Bikarna Gosh

Predictors of blood-borne viral coinfection among injecting drug users (Greg Dore)

#### Wei Zheng

Implementation of non-occupational post-exposure prophylaxis in Australia (Andrew Grulich)

#### Jialun Zhou

Hepatitis C antibody prevalence and risk behaviour among young injecting drug users at sentinel needle and syringe programs, 1995-2000 (Margaret MacDonald)

### Master of Public Health major project candidates Robert Baldwin

A hepatitis C survey: Mid-North Coast of New South Wales (Greg Dore)

#### Anna Doab

Hepatitis C treatment knowledge, attitudes and barriers among current injecting drug users (Greg Dore)

Marianne Jauncey (The University of Sydney)
Retrospective cohort of newly acquired hepatitis C infection at Kirketon Road Centre
(Greg Dore)

#### **Shellee Korn**

Incidence of hepatitis C in a cohort of HIV + patients of an inner-city practice and rate of uptake of hepatitis A and B vaccination within the same cohort (John Kaldor)

#### Jennie Musto

Estimating the effect to which donor deferral protects the blood supply (John Kaldor)

#### Mohd Habibur Rahman

HIV and hepatitis C infection and related risk behaviour among injecting drug users at Barisal Southern Divisional City of Bangladesh (Margaret MacDonald)

#### **Tim Ramacciotti**

The role of antiretroviral treatment in primary HIV infection (John Kaldor)

### Master of Public Health by research candidates Leng Boonwatt

Factors associated with risk taking behaviours for hepatitis C transmission among NSW prison inmates (Margaret MacDonald)

#### Adeeba Kamarulzaman

Natural history of HIV disease in Malaysia (Greg Dore, John Kaldor)

#### **Alison King** (Griffith University)

An investigation of the goals of patients and staff at Gorman House non-medical residential detoxification unit (Margaret MacDonald)

#### **Suzanne Polis**

Vertical transmission of hepatitis C virus to infants born to mothers who are affected with hepatitis C virus (John Kaldor)

### **Course coordination**

5th Bangkok Symposium on HIV Medicine, Thailand (Mark Boyd, Chris Duncombe)

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: Challenging and changing health care systems, Master of Public Health, UNSW, Sydney (Greg Dore)

Regional physicians HIV medicine training course, Bangkok, Thailand (Mark Boyd, Chris Duncombe)

### **Teaching**

5th Bangkok Symposium on HIV Medicine, Thailand. (David Cooper, Greg Dore, Sean Emery)

Advanced HIV Nursing Course, Albion Street Centre, Sydney

(Gillian Hales, Don Smith)

Advanced Therapeutics - Infectious Diseases, Master of Clinical Pharmacy, The University of Sydney (Dianne Carey)

AIDS in the World, Master of International Public Health, The University of Sydney (John Kaldor)

An epidemiological approach to the critical appraisal of clinical evidence, short courses to the pharmaceutical industry, Sydney/Melbourne (Andrew Grulich, John Kaldor)

Case Studies in Epidemiology, Master of Public Health, UNSW, Sydney (Greg Dore, Andrew Grulich, John Kaldor)

Confusional States and Dementia Interactive Session (St Vincent's Hospital), Year 6 Medicine, UNSW, Sydney (Bruce Brew)

Day Program in Hepatitis C, Australasian Society for HIV Medicine, Sydney (Greg Dore)

Educational Satellite Meeting for Clinical Trial Nurses/Coordinators, NCHECR (Dianne Carey, Sean Emery, Paddy Mallon, Rebekah Puls) Epidemiology for Public Health, Master of Public Health, UNSW, Sydney (Andrew Grulich, John Kaldor)

Headache Interactive Session (St Vincent's Hospital), Year 6 Medicine, UNSW, Sydney (Bruce Brew)

Hepatitis C Rural Education Program, Australasian Society for HIV Medicine, Bathurst, NSW (Greg Dore)

HIV Medicine Interactive Session (St Vincent's Hospital), Year 6 Medicine, UNSW, Sydney (David Cooper)

HIV Nursing Practice Workshop, Albion Street Centre, Sydney (Don Smith)

HIV Therapy: Metabolic Complications of HIV Therapy and Immune Therapy, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney (Paddy Mallon)

HIV/AIDS: Challenging and Changing Health Care Systems, Master of Public Health, UNSW, Sydney (Greg Dore, Sean Emery, Andrew Grulich, John Kaldor, Tony Kelleher)

HIV/STDs, Master of Public Health, The University of Sydney (Greg Dore)

Immunology of HIV Infection/HIV, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney (Tony Kelleher)

Indonesian Training Course in Health Promotion, UNSW, Sydney (Greg Dore)

Introductory Program on HIV and Viral Hepatitis, St Vincent's Hospital, Sydney (Greg Dore)

Maternal and Child Health, Master of International Public Health, The University of Sydney (Greg Dore)

Metabolic Complications, from Laboratory to Patient: Course in HIV Clinical Management, Stanford, USA (David Cooper)

Neurological Complications of HIV Infection, Master of Health Science (HIV Studies), University of Western Sydney (Bruce Brew)

Neurology, Master of Medicine, The University of Sydney

(Bruce Brew)

Pharmacology, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney (Dianne Carey)

Post Registration Nursing Course in Alcohol and Other Drugs, Sydney Hospital and Sydney Eye Hospital (John Kaldor)

Post Registration Nursing Course in Epidemiology and Evidence Based Practice in Infection Control, Sydney Hospital and Sydney Eye Hospital (John Kaldor)

Post Registration Nursing Course in HIV Infection and Disease, Sydney Hospital and Sydney Eye Hospital (Bruce Brew, Dianne Carey)

Post Registration Nursing Course in Infection Control, Sydney Hospital and Sydney Eye Hospital (Dianne Carey, John Kaldor)

Post Registration Nursing Course in Ophthalmology, Sydney Hospital and Sydney Eye Hospital (John Kaldor)

Post Registration Nursing Course in Sexual Health and Venereology, Sydney Hospital and Sydney Eye Hospital (Dianne Carey, Greg Dore, John Kaldor)

Public Health Aspects of STDs/HIV, Master of Medicine (Sexually Transmitted Diseases/ HIV), The University of Sydney (Andrew Grulich)

Public Health Aspects of STDs, Master of Medicine (Sexually Transmitted Diseases/HIV) /Master of Public Health/Master of International Public Health, The University of Sydney (John Kaldor)

Quantitative Immunology, Master of Science and Technology/Master of Statistics, UNSW, Sydney (Tony Kelleher)

Research Skills for Public Health, Master of Public Health, UNSW, Sydney

(Janaki Amin, Dianne Carey, Pat Grey, Margaret MacDonald, Garrett Prestage, Tim Ramacciotti, Don Smith, Wei Zheng)

Sexual Health Medicine 1, Master of Medicine (Sexually Transmitted Diseases/ HIV), The University of Sydney

(Tony Kelleher, Don Smith)

Sexual Health Medicine 2, Master of Medicine (Sexually Transmitted Diseases/HIV), The University of Sydney

(Greg Dore, Sean Emery, Andrew Grulich)

Short Course in HIV for Treatment Officers and Community Workers, Australasian Society for HIV Medicine/AIDS Treatment Project Australia, Sydney (Paddy Mallon)

Short Course in HIV Medicine and Day Program in Hepatitis C, Australasian Society for HIV Medicine, Sydney

(Dianne Carey, Paddy Mallon)

Short Course in HIV Medicine for Pharmaceutical Representatives, Australasian Society for HIV Medicine/AIDS Treatment Project Australia, Sydney (Paddy Mallon, Sarah Pett)

Short Course in HIV Medicine, Australasian Society for HIV Medicine, Sydney (Dianne Carey, Sean Emery, Andrew Grulich)

Short Course in STI Medicine, The Australasian College of Sexual Health Physicians, Sydney (Greg Dore)

Study Coordinator Meeting, Australasian Society for HIV Medicine, Sydney (Paddy Mallon)

Training Session for Treatment Officers, AIDS Council of New South Wales, Sydney (Dianne Carey, Sarah Pett)

Undergraduate teaching, School of Sociology, UNSW, Sydney (Garrett Prestage)

## **Tutoring**

Clinical examination, Royal Australasian College of Physicians, Sydney (Paddy Mallon)

Clinical Medicine (St Vincent's Hospital), Year 2 Medicine, UNSW, Sydney (Tony Kelleher)

Clinical Medicine (St Vincent's Hospital), Year 3 Medicine, UNSW, Sydney (Bruce Brew, Greg Dore)

Clinical Medicine (St Vincent's Hospital), Year 4 Medicine, UNSW, Sydney (Bruce Brew) Clinical Tutorials, Part 1 candidates, Royal Australasian College of Physicians, Sydney (Bruce Brew)

Epidemiology for public health, Master of Public Health, UNSW, Sydney (Janaki Amin, Margaret MacDonald, Ann McDonald, Kathy Petoumenos)

Population and Community Health, Year 4 Medicine, UNSW, Sydney (Andrew Grulich)

Statistics for public health, Master of Public Health, UNSW, Sydney (Janaki Amin)

Undergraduate tutoring, School of Sociology, UNSW, Sydney (Garrett Prestage)



## **Commonwealth Department of Health and Ageing core grants**

The Commonwealth Department of Health and Ageing provided an allocation in 2002 to fund the activities and administration of NCHECR. It also provided funding for the Clinical Trials and Research Committee (CTARC). For administrative purposes, these funds are allocated into the following categories:

Core allocation	3,095,471
Clinical Trials and Research Advisory Committee	526,111

# Other Commonwealth Department of Health and Ageing grants

Hepatitis C surveillance activities	242,340	
Health in Men cohort study	38,630	
Workshop on Regional Approaches to STI Management: Screening for STIs in primary health care:		
Theory and effectiveness	14,280	

# Other grants and contracts from public sources

United States National Institutes of Health: HIV Vaccine Design and Development Team contract	6,806,700
University of Minnesota: ESPRIT Study	1,159,565
UNSW: Research quantum funds	366,277
UNSW: Research infrastructure block grant	333,403
United Kingdom Medical Research Council: INITIO Study	277,385
United States National Institutes of Health: Protease Inhibitor Related Atherosclerosis in HIV	274,533
Social & Scientific Systems: SMART Study	247,847
NSW Health Department: Reporting support grant	125,814
NHMRC: The Kynurenine Pathway chemokines and MIC-1 in the Pathogenesis of	
AIDS Dementia Complex	80,660
European Medicines Evaluation Agency: Data Collection on Adverse Events of Anti-HIV Drugs	68,779
NHMRC: 2002 Public Health Australia Fellowship for Dr Claire Vajdic	53,707
University of California: CSF consortium for the study of HIV brain disease	48,593
*Medical Research Council, UK: INITIO Trial, Lipodystrophy substudy	48,455
NSW Health Department: Health in Men cohort study	35,065
Health Outcomes International Pty Ltd: Return on Investments study on needle and syringe programs	24,924
NSW Health Department: Monitoring of prevalence, incidence and risk factors for	
sexually transmissible infections among gay men in Sydney	23,600
Ohio State University: Biological Response modifiers in AIDS malignancies	8,052

# Pharmaceutical industry funding

Roche Products Pty Ltd	635,516
Bristol-Myers Squibb Pharmaceuticals (Australia)	455,034
Chiron Corporation	217,515
GlaxoSmithKline Research and Development (UK)	216,588
GlaxoSmithKline Australia Ltd	131,045
Virax Immunotherapeutics	121,088
Johnson & Johnson Research Pty Ltd	40,504
Boehringer-Ingelheim Pty Ltd	25,350
Merck Sharp & Dohme (Australia)	20,000
DuPont Pharmaceutical Company	4,798

<sup>\*</sup> Industry funds administered through publicly-funded agencies



Annie Tung, Bronwen Turner



# Presentations at conferences and meetings

### **Conference presentations**

**Amin J, Law MG, Cooper DA, Dore GJ.** Predictors of hepatitis C coinfection and disease progression in the CAESAR Study. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Amin J**, Moore A, **Law MG**, Carr A, **Emery SE**, **Cooper DA**. OZCombo 1 and 2 long-term follow-up. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

Boyd M, Duncombe C, Khongphattanayothin M, Srasuebkul P, Hassink E, Ruxrungtham K, Sangkote J, Reiss P, Stek M, Lange JMA, Cooper DA, Phanuphak P. HIV-NAT 005: A randomised, open-label trial of indinavir 800mg TID versus indinavir/ritonavir 800/100mg BID in combination with AZT/3TC for the treatment of HIV infection in nucleoside experienced patients: Results of 112 weeks of follow-up. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.



Charles Tran, Lisa Howard

**Boyd M.** HIV lipodystrophy: Experiences from Thailand and Singapore. *XIV International AIDS Conference*. Barcelona, Spain.

**Brew BJ**, Fulham M, Garsia R. Factors associated with AIDS dementia complex. *The 9th Conference on Retroviruses and Opportunistic Infections*. Seattle, USA.

**Brew BJ.** Analysis of CSF parameters in highly active antiretroviral treatment. *10th Conference on neuroscience of HIV Infection*. Dusseldorf, Germany.

**Brew BJ.** Analysis of CSF parameters in highly active antiretroviral treatment. *4th International Symposium on Neurovirology.* Dusseldorf, Germany.

**Brew BJ.** CSF markers in HIV-1 associated dementia. 10th Conference on neuroscience of HIV Infection. Dusseldorf, Germany. **Brew BJ.** CSF markers in HIV-1 associated dementia. *4th International Symposium on Neurovirology.* Dusseldorf, Germany.

**Brew BJ.** Dementia in HAART. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

Cardiello P, Ananworanich J, Monhaphol T, Mahanontharit A, Van Heeswijk R, Burger D, **Boyd M, Duncombe C,** Ruxrungtham K, Lange JMA, **Cooper DA.** Pharmacokinetics of once daily saquinavir hard gel caps and saquinavir soft gel caps boosted with ritonavir in HIV-1 positive Thai patients. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

Cardiello P, Srasuebkul P, Hassink E, Mahanontharit A, Samor T, Worarien W, **Duncombe C, Boyd M,** Ruxrungtham K, **Cooper DA,** Lange JMA, Phanuphak P. Safety and efficacy of saquinavir soft gel caps ritonavir plus dual nucleosides in patients undetectable viral load after three years of treatment. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

Clements MS, Prestage GP, Grulich AE, Van de Ven P, Kippax S, Law MG. Modelling the effect of decreasing antiretroviral treatment use among homosexual men on HIV incidence. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**Cooper DA.** Biomedical prevention. *XIV International AIDS Conference.* Barcelona, Spain.

**Cooper DA.** Clinical setting, definitions and clinical studies of HIV-associated lipodystrophy. *Australian Health and Medical Research Congress.* Melbourne.

**Cooper DA.** Lipodystrophy syndrome. *12th International Symposium on HIV and Emerging Infectious Diseases.* Toulon, France.

**Cooper DA.** Future directions in therapy. *14th* Annual Conference Australasian Society for HIV Medicine. Sydney.

**Cooper DA.** HIV/AIDS research collaboration in Asia Pacific. *amfAR Satellite Symposium on TREAT Asia.* Barcelona, Spain.

**Cooper DA.** Management of metabolic complications. 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy. San Diego, USA.

**Dore GJ, McDonald AM,** Li Y, **Kaldor JM, Brew BJ.** Marked improvement in survival following AIDS dementia complex in the era of HAART. *XIV International AIDS Conference.* Barcelona, Spain.

**Dore GJ.** Defining and changing the natural history of hepatitis C infection. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Dore GJ.** Epidemiology of acute hepatitis *C* infection in Australia: Implications for management. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Dore GJ.** Hepatitis C: Maintaining your health. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Dore GJ.** Needle and syringe programs have a role in stopping the hepatitis C epidemic. *St Vincent's Hospital 10th National Symposium on Hepatitis B and C.* Melbourne.

**Dore GJ.** Quality of life and hepatitis C: Defining the components. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Drummond FM,** Hoy J, **Phipps S, Cooper DA.** The SMART (Strategies for Management of Antiretroviral Therapy) Study. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Elliott JH,** Mijch A, Hellard M, Oelrichs R, Street A, Korman T, Read T, O'Reilly M, Crofts C. HIV in Vietnamese Australians associated with injecting drug use. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Emery SE,** Birch C, Crowe S, Hoy J, Workman C, **Kelleher AD,** McKenna P, **Cooper DA, Law MG, Hales G.** CREST: A randomised comparison of two resistance test platforms: genotype and virtual phenotype interim results. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Emery SE.** Ozvax - preparation for phase III. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

**Freeman AJ,** Ffrench RA, Post JJ, Harvey CE, Gilmour SJ, White PA, Marinos G, Rawlinson WD, van Beek I, Lloyd AR. Virus-specific IFN production is associated with high risk injecting behaviour among HCV-resistant subjects. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Freeman AJ,** Post JJ, Harvey CE, White PA, Pan Y, White PA, Marinos G, Rawlinson WD, van Beek I, Ffrench RA, Lloyd AR. Cellular immunity in people resistant to HCV infection. *American Association for the Study of Liver Disease Conference*. Boston, USA.

Grulich AE, Jin FY, Prestage GP, Kaldor JM, Nakamura T, Van de Ven P, Kippax S. Hepatitis A and B in the Health in Men cohort. *HIV/AIDS, Hepatitis and Related Diseases Social Research Conference*. Sydney.

**Grulich AE,** O'Sullivan BG, **Zheng W,** Kippax S, **Smith DE.** Non-occupational post-exposure prophylaxis: Update and relevance in sexual assault. *Australasian Sexual Health Conference.* Perth.

**Grulich AE, Prestage GP, Middleton M,** Van de Ven P, **Kaldor JM.** Prevalence and risk factors for hepatitis A, B and syphilis in a community-based sample of homosexual men in Australia. *Australasian Sexual Health Conference*. Perth.

**Grulich AE.** Are we on the verge of a resurgent epidemic in gay men? *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Grulich AE.** The epidemiology of HIV and STIs in gay men in Australia. *Australasian Sexual Health Conference*. Perth.

**Guerin J** on behalf of the PHAEDRA Study Group. The PHAEDRA cohort: A mechanism for recruitment and follow-up of people diagnosed with acute and early HIV infection. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

Guerin J, Ashton LJ, McGhie K, Satchell C, Cunningham PH, Stewart G, Carr A, Cooper DA, Kaldor JM on behalf of the Long-term Nonprogressor Study Group. The Australian long-term nonprogressor cohort: 1994-2002 an update on the characteristics associated with asymptomatic HIV-1 infection and their role in predicting disease progression. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**Guillemin GJ,** Croitoru-Lamoury J, Dormont D, **Brew BJ.** Involvement of quinolinic acid in chemokine production and chemokine receptor expression in human foetal astrocytes. *10th International Study Group for Tryptophan Research Conference.* Padova, Italy.

**Guillemin GJ,** Smith DG, Brown D, Breit S, **Brew BJ.** Expression of macrophage inhibitory cytokine 1 (MIC-1) in human brain cells and its interaction with the kynurenine pathway. *10th International Study Group for Tryptophan Research Conference*. Padova, Italy.

**Guillemin GJ,** Smith DG, Kapoor V, Armati PJ, **Brew BJ.** Expression kynurenine pathway enzymes in human macrophages and microglia. *10th International Study Group for Tryptophan Research Conference*. Padova, Italy.

**Guillemin GJ,** Smith DG, Williams KR, Smythe GA, Dormont D, **Brew BJ.** Quinolinic acid in the pathogenesis of Alzheimer disease. *10th International Study Group for Tryptophan Research Conference*. Padova, Italy.

**Guillemin GJ.** Overview of kynurenine pathway involvement in neuroinflammation. *10th International Study Group for Tryptophan Research Conference.* Padova, Italy.

Jin FY, Prestage GP, Kaldor JM, Nakamura T, Van de Ven P, Kippax S, Grulich AE. Hepatitis A, B and syphilis in the Health in Men cohort. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

Jin FY, Prestage GP, Law MG, Kippax S, Van de Ven P, Rawstorne P, Kaldor JM, Grulich AE. Predictors of recent HIV testing in homosexual men in Australia. HIV/AIDS, Hepatitis and Related Diseases Social Research Conference. Sydney.

**Kaldor JM, Vajdic CM.** Surveillance for sexually transmissible infections in Australia: An update on the work of the national committee. *Australasian Sexual Health Conference*. Perth.

**Kaldor JM.** Epidemiology of hepatitis C in Australia. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Kaldor JM.** HIV infection in the Asia-Pacific region. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**Kaldor JM.** Update on patterns and trends in HIV/AIDS in Australia. *Anwernekenhe III Conference*. Melbourne.

**Kaldor JM.** Epidemiological issues. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

**Kelleher AD.** Designing a phase III HIV prophylactic vaccine trial: Clinical and laboratory aspects. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

**Kelleher AD.** T-cell homeostasis. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Law MG** on behalf of the Hepatitis C Virus Projections Working Group. Estimates and projections of the hepatitis C virus epidemic in Australia. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Law MG, Dore GJ, Freeman AJ, Kaldor JM.** Population level models of liver disease progression. *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Law MG, Emery SE.** Selective exclusion of treatment arms in multi-arm randomised clinical trials. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

Law MG, Friis-Moller N, Reiss P, Kirk O, d'Arminio Monforte A, Weber R, Thiebaut R, Fontas E, Morfeldt L, Calvo G, Bartsch G, De Wit S, Sabin C, Lundgren JD for the DAD Study Group. The DAD Study: Modelling risk of cardiovascular events in HIV. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**MacDonald MA** on behalf of the Collaboration of Australian Needle and Syringe Programs. Hepatitis C and related risk behaviour among young Australian injectors. *6th Annual ANEX NSP Conference*. Melbourne.

MacDonald MA, Law MG, Kaldor JM, Hales J, Dore GJ. Effectiveness of needle and syringe programs for preventing transmission of HIV and HCV infection. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

MacDonald MA, Law MG, Kaldor JM, Hales J, Dore GJ. The role of needle and syringe programs: Evidence for their impact on HCV and HIV infection. *Needle and Syringe Program Satellite Meeting*. Melbourne.

MacDonald MA, Wodak A, Kaldor JM on behalf of the Collaboration of Australian Needle and Syringe Programs. HIV, HCV and related risk behaviour among IDU reporting recent imprisonment. 13th International Conference on the Reduction of Drug Related Harm. Ljubljana, Slovenia.

**MacDonald MA, Zhou J,** Wodak A, **Kaldor JM** on behalf of the Collaboration of Australian Needle and Syringe Programs. HCV and HIV among young Australian injectors. *3rd Australasian Conference on Hepatitis C.* Melbourne.

Mallon PWG, Munier MLC, McGhie K, Zaunders J, Kelleher AD, Cooper DA, Carr A. Disrupted expression of lipid transport genes in monocytes of individuals with HIV-associated lipodystrophy – an additional risk for cardiovascular disease? 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

Martin A, Carey DL, Law MG, Emery SE.
Competitive recruitment in the ROSEY Study.
International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop. Sydney.

**McDonald AM** on behalf of the Collaborative Group on sentinel surveillance in sexual health clinics. HIV incidence among homosexually active men seen at sexual health clinics in Australia, 1993–2001. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**McDonald AM, Clements MS,** Cunningham PH, **Kelleher AD,** Delpech V, **Kaldor JM.** Monitoring HIV transmission in Australia using a "detuned" HIV antibody testing strategy. *XIV International AIDS Conference*. Barcelona, Spain.

**McDonald AM,** Cunningham PH, Delpech V, **Clements MS, Kaldor JM.** Monitoring HIV transmission in Australia using a "detuned" HIV antibody testing strategy. *19th NRL Workshop on Serology.* Melbourne.

McDonald AM, Cunningham PH, Delpech V, Clements MS, Kaldor JM. Monitoring HIV transmission using a "detuned" HIV antibody testing strategy. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**Pemberton LA, Brew BJ.** The relationship between CSF levels of S-100 and the presence and severity of AIDS dementia complex. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Pemberton LA, Brew BJ.** The relationship between CSF levels of S-100 and the presence and severity of AIDS dementia complex. *The 12th St Vincents and Mater Health Sydney, Research Symposium.* Sydney.

**Petoumenos K** on behalf of the Australian HIV Observational Database. Causes of death in the Australian HIV Observational Database. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Petoumenos K** on behalf of the Australian HIV Observational Database. The use of electronic data transfers to manage the Australian HIV Observational Database. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

**Petoumenos K, Lincoln D, Dore GJ** on behalf of the Australian HIV Observational database. Coinfection with hepatitis B and hepatitis C in the Australian HIV Observational Database. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Pett SL, Emery SE,** Bebchuk J, Neaton J, French M, Finlayson R, Chan FLF, Cooper DA on behalf of the ESPRIT Study Group. ESPRIT: Interleukin-2 dose and CD4+ cell count changes. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Pett SL, Emery SE, Chan FLF,** French M, Finlayson R, **Cooper DA** on behalf of the ESPRIT Study Group. Recruitment and retention strategies in large multicentre, international phase III studies with long-term follow-up, the ESPRIT (Evaluation of subcutaneous Proleukin, in a randomised international trial) experience. *International Clinical Trials Symposium, HIV vaccines: where to from here? Workshop.* Sydney.

**Pett SL, Emery SE,** French M, Finlayson RJ, **Law MG, Cooper DA** for the ESPRIT Study Group. ESPRIT: A survey of the baseline neuropsychiatric (NP) abnormalities in the Australian cohort. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Prestage GP,** Grierson J, Rawstorne P, Jewitt J. Research on living with HIV. *Ruralink NSW HIV Rural Forum.* Nelson Bay, NSW.

**Prestage GP, Grulich AE,** Van de Ven P, Kippax S. Sexually transmissible infections testing behaviour among HIV negative men in the Health in Men (HIM) cohort. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Prestage GP.** HIV prevention – The role of behavioural research among gay men in Australia. *16th Japan AIDS Conference.* Nagoya, Japan.

**Prestage GP, Grulich AE,** Van de Ven, P, Kippax S. Sexual health among men in the Health in Men (HIM) cohort. *Health in Difference 4 Conference*. Sydney.

**Prestage GP, Grulich AE,** Van de Ven P, Kippax S. Circumstances of last occasion of anal intercourse with casual partners among men in the Health in Men (HIM) cohort. *HIV/AIDS, Hepatitis and Related Diseases Social Research Conference*. Sydney.

**Prestage GP,** Rawstorne P, Grierson J. Differences in access to services and community support within the Positive Health cohort. *HIV/AIDS, Hepatitis and Related Diseases Social Research Conference.* Sydney.

**Puls RL**, Carr A, **Emery SE**, Miller J, **Law MG**, **Cooper DA**. Use of electronic media to coordinate an international clinical study. *International Clinical Trials Symposium*, *HIV vaccines: where to from here? Workshop*. Sydney.

**Puls RL, Law MG,** Freund J, Gallagher D, Punyanitya M, Kalnins S, Carr A on behalf of the HIV Lipodystrophy Case Definition Study Group. The effect of central reading of body composition data analysis on an objective case definition for HIV lipodystrophy. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Ramacciotti TPT, Smith DE,** Zaunders JJ, Cunningham PH, **Kelleher AD, Kaldor JM.** Durable immune and virologic response to immediate treatment during primary HIV infection (PHI). *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Robotin MC, Law MG,** Millken S, Garsia R, Goldstein D, Dolan G, **Grulich AE.** A population-based study of AIDS-non-Hodgkin's lymphoma in the era of HAART. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Robotin MC.** Australia needs to strengthen its surveillance system for incident hepatitis C infection. 2002 Training Programs in Epidemiology and Public Health Interventions Network Second International Conference. Madrid, Spain.

**Robotin MC.** Enhanced surveillance for newly acquired hepatitis C in Australia. Are we there yet? *3rd Australasian Conference on Hepatitis C.* Melbourne.

**Robotin MC.** Is Australia prepared to detect Creutzfeldt-Jakob disease? *Master of Applied Epidemiology Conference 2002: Responding to new challenges in a changing world.* Canberra.

Sasson SC, Zaunders JJ, Kelleher AD. IL-7 expands the naïve CD4+ T-cell subset via distinct mechanisms: Implications for immune reconstitution *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Smith DE.** Should we treat primary HIV infection? 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

**Vajdic CM,** Kricker A, Giblin M, McKenzie J, Aitken J, Giles G, Armstrong BK. Sun exposure predicts risk of ocular melanoma in Australia. *XXIXth International Congress of Ophthalmology.* Sydney.

**Zheng W,** O'Sullivan B, Kippax S, **Smith DE, Grulich AE.** Non-occupational post-exposure prophylaxis for HIV: Results of the first three years. *HIV/AIDS, Hepatitis and Related Diseases (HHARD) Conference.* Sydney.

**Zheng W, Smith DE,** Kippax S, **Grulich AE.** Epidemiologically targeted non-occupational post-exposure prophylaxis (NPEP) in Australia, 1998-2002. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Zhou J, MacDonald MA,** Wodak AD, **Kaldor JM** and the Collaboration of Australian Needle and Syringe Programs. Hepatitis C virus prevalence and risk behaviours among young injecting drug users at sentinel needle and syringe programs in Australia, 1995-2001. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

## Other presentations

**Ammarannond P.** Feedback from XIV International AIDS Conference Barcelona, Spain. *Ministry of University Affairs*. Bangkok, Thailand.

**Brew BJ.** Evidence for change in AIDS dementia complex. *Cerebrospinal Fluid Consortium Meeting*. Bellagio, Italy.

**Brew BJ.** HAART and neurocognitive improvement. *Mental Health Research Issues in HIV Infection and Aging.* Washington, USA.

**Brew BJ.** HIV and central nervous system complications. *Sydney General Practitioner HIV Study Group.* Sydney.

**Brew BJ.** Magnetic resonance spectroscopy and AIDS dementia. *Sydney General Practitioner HIV Study Group.* Sydney.

**Clements MS.** Effect of antiretroviral treatment during HIV seroconversion. *Concerted Action on Seroconversion to AIDS and Death in Europe Meeting.* Santorini, Greece.

**Clements MS.** Lung cancer mortality prediction using multi-state population smoking models. *Department of Medical Epidemiology, Karolinska Institutet.*Stockholm, Sweden.

**Clements MS.** Lung cancer mortality prediction using multi-state population smoking models: Précis of a PhD thesis. *NHMRC Clinical Trials Centre, The University of Sydney.* Sydney.

**Clements MS.** Lung cancer mortality: Will female rates continue to rise and will this be affected by smoking initiation and cessation? *The Cancer Council New South Wales.* Sydney.

**Cooper DA.** Chemoprophylaxis of HIV Infection. *HIV/Immunology/Infectious Diseases Unit Journal Club.* Sydney.

**Cooper DA.** HIV and lipodystrophy. *St Vincent's Hospital Diabetes Centre Meeting.* Sydney.

**Cooper DA.** HIV/AIDS: A Global Public Health Emergency. *Sydney University Reunion 1972*. Pokolbin, NSW.

**Cooper DA.** HIV in Asia Pacific - the role of Australia. *Australasian Society for Infectious Diseases Inc.* Rowland Flat, SA.

**Cooper DA.** NCHECR perspective on surgical approaches to lipoatrophy. *Lipoatrophy Research Workshop.* Sydney.

**Cooper DA.** Primary HIV Infection. *HIV/Immunology/Infectious Diseases Unit Journal Club.* Sydney.

**Cooper DA.** Treatment works. *International Roundtable on Increasing Access to HIV Treatment in Resource-Poor Settings.* Canberra.

Dixon J, Lowth A, **MacDonald MA.** Harm minimisation strategies and programs South East Health. *Drug Use in the Gay and Lesbian Community: Strategies for Action Meeting.* Sydney.

- **Dore GJ.** Australian experience. *Macfarlane Burnet Institute for Medical Research and Public Health Symposium on Treatment of Hepatitis C for Current Injecting Drug Users.* Melbourne.
- **Dore GJ.** Clinical management of hepatitis C and HIV/HCV coinfection. *Haemophilia Foundation of Australia Annual General Meeting*. Melbourne.
- **Dore GJ.** Clinical management of HIV and hepatitis C coinfection. *Royal Prince Alfred Hospital HIV/AIDS Seminar.* Sydney.
- **Dore GJ.** Evidence-base for decision making on hepatitis C treatment and care. *Queensland Hepatitis C Council Hepatitis C, Families and Communities Forum.* Brisbane.
- **Dore GJ.** Hepatitis C/HIV coinfection. *HIV Pharmacist Group.* Sydney.
- **Dore GJ.** Hepatitis C: Transmission, natural history and management. *HIV and Sexual Health Services*. Gosford, NSW.
- **Dore GJ.** HIV and hepatitis coinfection. *5th Bangkok Symposium on HIV Medicine*. Thailand.
- **Dore GJ.** HIV, hepatitis B and C coinfection. *Sydney General Practitioner HIV Study Group.* Sydney.
- **Dore GJ.** Management of HIV and hepatitis C coinfection. *HCV/HIV Coinfection Forum for People with Haemophilia*. Brisbane.
- **Dore GJ.** Management of HIV and hepatitis C coinfection. *HCV/HIV Coinfection Forum for HIV/AIDS Service Providers*. Brisbane.
- **Dore GJ.** Modelling the natural history of hepatitis C. *Roche National Hepatitis C Advisory Board.* Sydney.
- **Dore GJ.** Natural history of hepatitis C: Rating on evidence not misconception. *Australian Life Underwriters and Claims Association Inc Meeting.* Sydney.
- **Dore GJ.** Natural history of hepatitis C: Research to rating real life. *Swiss Re Life and Health Risk Management Meeting.* Sydney.
- **Dore GJ.** Nucleotide antiretroviral therapy: HIV/HBV coinfection. *Gilead Satellite Symposium.* Sydney.
- **Dore GJ.** Opportunistic infections and prophylaxis. *Macfarlane Burnet Institute for Medical Research and Public Health HIV/AIDS Treatment and Care in Developing Countries Symposium.* Melbourne.
- **Dore GJ.** Treatment of hepatitis C among current injecting drug users: Putting it on the agenda. *Hepatitis C Council of Queensland Annual General Meeting.* Brisbane.

- **Dore GJ.** Update on HIV/AIDS surveillance. *NSW Ministerial Advisory Committee on HIV/AIDS*. Sydney.
- **Emery SE.** HIV vaccine update. *Albion Street Centre*. Sydney.
- **Freeman AJ,** Ffrench RA, Post JJ, Gilmour SJ, White PA, Rawlinson WD, van Beek I, Lloyd AR. HCV-resistant subjects demonstrate virus-specific IFN production and CTL. *Blood Borne Viruses Symposium*. Melbourne.
- Freeman AJ, Law MG, Kaldor JM, Dore GJ.
  Predicting liver disease progression in individuals with chronic hepatitis C infection. *Blood Borne Viruses Symposium*. Melbourne.
- **Grulich AE, Vajdic C.** Epidemiological aspects of anal intraepithelial neoplasia. *Albion Street Centre.* Sydney.
- **Grulich AE, Vajdic C.** Epidemiological aspects of anal intraepithelial neoplasia. *Combined meeting of NCHECR Oncology Working Group and NCHECR Immune-Based Therapy Working Group.* Sydney.
- Grulich AE, Zheng W, Smith DE, Kippax S. Epidemiologically targeted non-occupational post-exposure prophylaxis in Australia, 1998-2002. Workshop on post-exposure prophylaxis, 14th Annual Conference Australasian Society for HIV Medicine. Sydney.
- **Grulich AE.** Critical appraisal. *The Diabetes Centre Journal Club.* Sydney.
- **Grulich AE.** Simian virus 40 and risk of non-Hodgkin's lymphoma. *North Atlantic Treaty Organisation/International Agency for Research on Cancer Workshop on perspectives of epidemiological research in non-Hodgkin's lymphoma: The Interlymph collaborative project. Lyon, France.*
- **Grulich AE.** Infectious causes of cancer. *Department of Public Health, The University of Sydney Seminar Series.* Sydney.
- **Grulich AE.** The use of non-occupational post-exposure prophylaxis in Australia. *Satellite meeting on non-occupational post-exposure prophylaxis*. Barcelona, Spain.
- **Grulich AE.** Trends in HIV in Melbourne and Sydney. *AIDS Council of New South Wales community round table.* Sydney
- **Grulich AE.** Update: The Barcelona AIDS Conference. *AIDS Council of New South Wales community round table.* Sydney.
- **Hales G.** CREST update. *HIV Resistance Testing Workshop.* Melbourne.

**Kaldor JM, McDonald AM.** Late presentation of HIV infection in Australia. *NSW Health Department, HIV/AIDS Health Promotion Plan 2001-2003 Forum Series, HIV Testing and Late Diagnosis Forum.* Sydney.

**Kaldor JM.** CIPRA prevention proposal. *HIV-NAT Retreat*. Bangkok, Thailand.

**Kaldor JM.** Recent developments in the epidemiology of HIV, hepatitis C and sexually transmissible infections in Australia. *AIDS Medical Unit, Queensland Health Department.* Brisbane.

**Kaldor JM.** Recent trends in HIV diagnosis in Australia. *Victorian Ministerial Advisory Committee on AIDS, Hepatitis C and Related Diseases, Forum on HIV/AIDS and STIs.* Melbourne.

**Kaldor JM.** Serological surveys for HIV infection: Where are we in 2002? *Workshop on Surveillance for HIV/AIDS, STIs and Risk Behaviour.* Beijing, China.

**Kaldor JM.** Surveillance systems for HIV/AIDS, STIs and behaviour. *Workshop on STI/HIV/AIDS Surveillance in the Pacific.* Fiji.

**Kelleher AD.** An update of the HVDDT program review of preclinical data and clinical trial protocol. *NCHECR Combined Working Groups Meeting*. Sydney.

**Kelleher AD.** Assessment of CTL and NK cell function. *Institute of Clinical Pathology and Medical Research Immunopathology Workshop.* Sydney.

**Kelleher AD.** Prevalence of resistant mutants over the last decade in recently transmitted virus. *St Vincent's Hospital HIV/Immunology/Infectious Diseases Journal Club.* Sydney.

**Law MG** on behalf of the Australian HIV Observational Database. Trends in antiretroviral treatment and patient outcomes in the Australian HIV Observational Database. *HIV/AIDS Treatments and Health Issues Forum, NSW HIV/AIDS Health Promotion Plan 2001-2003 Seminar Series.* Sydney.

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**MacDonald MA.** Increased hepatitis C prevalence among young injectors in the Needle and Syringe Program surveys. Is it real? *National Expert Advisory Committee on Illicit Drugs Meeting.* Adelaide.

**MacDonald MA.** Surveillance in high risk populations: Injecting drug users. *UNICEF delegation from Guizhou Province, China, NCHECR.* Sydney.

**Mallon PWG.** HIV pharmacology and therapeutic drug monitoring. *Parramatta Sexual Health Centre Journal Club.* Sydney.

**Mallon PWG.** Major toxicities of antiretroviral therapy. *Bristol-Myers Squibb Australia HIV Advisory Board.* Melbourne.

**Mallon PWG.** Management of metabolic abnormalities. *Facing the future – moving ahead in HIV.* Sydney.

**Mallon PWG.** Management of metabolic toxicities. *Bristol-Myers Squibb Australia HIV Advisory Board.* Melbourne.

**Mallon PWG.** Update on pathogenesis and management of HIV-associated lipodystrophy. *Albion Street Centre.* Sydney.

**McDonald AM.** Country update on HIV/ADS surveillance: new developments and recent trends. *Annecy Group.* Paris, France.

**McDonald AM.** Trends in new diagnoses of HIV infection in Australia, July 1997 – June 2002. *Gay Community Periodic Surveys – Report Back.* Melbourne.

**Pett SL.** ESPRIT enrolment update for the Sydney Regional Coordinating Centre. *7th International Standing Committee ESPRIT meeting.* Barcelona, Spain.

**Pett SL.** Therapeutic research on HIV at the NCHECR. *UNICEF delegation from Guizhou Province, China, NCHECR.* Sydney.

**Pett SL.** "Salvage therapy." XIV International AIDS Conference. Barcelona, Spain.

**Pett SL.** ESPRIT enrolment update for the Sydney Regional Coordinating Centre. *6th International Standing Committee ESPRIT meeting.* Seattle, USA.

**Pett SL.** Interlukin-2 and beyond, the future of immunotherapy for HIV-1 infection. *Albion Street Centre.* Sydney.

**Prestage GP.** Adelaide Gay Community Periodic Survey: Findings and implications. *AIDS Council of South Australia Community Forum.* Adelaide.

**Prestage GP.** HIV research and education: The role of the 'partnership' in Australia. *Terrence Higgins Trust Community Forum.* London, UK.

**Prestage GP.** Melbourne Gay Community Periodic Survey: Findings and implications. *Victorian AIDS Council Community Forum.* Melbourne.

**Prestage GP.** Queensland Gay Community Periodic Survey: Findings and implications. *Queensland AIDS Council Community Forum.* Brisbane.

**Prestage GP.** The role of HIV research in the HIV response of Australia's gay communities. *Osaka MASH Community Forum.* Osaka, Japan.

**Prestage GP.** The role of HIV research in the HIV response of Australia's gay communities. *Tokyo MASH Community Forum.* Tokyo, Japan.

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van Bockel D. Tetramer manufacture. *Vaccine Vector Group Workshop*. Werribee Park, Victoria.

### Poster presentations

Amin J, Carr A, Hill A, Emery SE, Law MG, Cooper DA. Haematological changes in patients randomised to highly active antiretroviral therapy regimens containing either zidovudine or stavudine. 4th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV. San Diego, USA.

**Ammaranond P,** Cunningham PH, Oelrichs R, Suzuki K, Harris C, Leas L, **Grulich AE, Cooper DA, Kelleher AD.** No increase in protease resistance and a decrease in reverse transcriptase resistance mutations in primary HIV infection: 1992-2001. *XIV International AIDS Conference*. Barcelona, Spain.

**Ammaranond P,** Cunningham PH, Oelrichs R, Suzuki K, Harris C, Leas L, **Grulich AE, Cooper DA, Kelleher AD.** No increase in protease resistance and a decrease in reverse transcriptase resistance mutations in primary HIV infection: 1992-2001, *9th Conference on Retroviruses and Opportunistic Infections.* Seattle, USA.

Bain M, **Brew BJ**, Coltheart M. Progressive peripheral dysgraphia in early posterior cortical atrophy. *The* 8th International Conference on Alzheimer's Disease and Related Disorders. Stockholm, Sweden.

Bloch MT, **Carey DL**, Ray JE, Graham GG. Indinavir regimens and inter-patient pharmacokinetic variability. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

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Pharmacokinetics of lower doses of saquinavir soft gel caps (800 and 1200 mg bid) with itraconazole compared to 1400 mg sqv bid without itraconazole in HIV-1 positive Thai patients. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

Carey DL, Martin A, Clements MS, Emery SE, Workman C, Rogers GD, Cooper DA, Carr AD on behalf of the ROSEY study investigators. ROSEY: Demographics and baseline clinical measures. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

**Chan FLF, Pett SL, Emery SE,** Finlayson R, French M, **Cooper DA** on behalf of the ESPRIT Study Group. Baseline characteristics of the patients participating in the ESPRIT Study. *14th Annual Conference Australasian Society for HIV Medicine*. Sydney.

Clements MS, Law MG, Pedersen C, Kaldor JM on behalf of the CASCADE Collaboration. Effect of antiretroviral treatment during HIV-seroconversion. 14th Annual Conference Australasian Society for HIV Medicine. Sydney.

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**Grey P,** Cunningham PH, Quan D, Bloch M, Macfarlane R, **Cooper DA, Smith DE.** Time to suppression of viral load <50 copies/mL in patients on antiretroviral therapy during acute and early primary HIV infection. *14th Annual Conference Australasian Society for HIV Medicine.* Sydney.

**Grulich AE,** O'Sullivan BG, **Zheng W,** Kippax S, **Smith DE.** The introduction of non-occupational post-exposure prophylaxis in Australia. *XIV International AIDS Conference.* Barcelona, Spain.

**Guillemin GJ,** Smith DG, Armati PA, **Brew BJ.** Expression kynurenine pathway enzymes in human macrophages and microglia. *10th International Study Group for Tryptophan Research Conference*. Padova, Italy.

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**McDonald AM** on behalf of the Collaborative Group on sentinel surveillance in sexual health clinics. Monitoring hepatitis C infection through sexual health clinics in Australia. *3rd Australasian Conference on Hepatitis C.* Melbourne.

McGhie K, Henner I, **Munier MLC**, Zaunders JJ, **Kelleher AD**. Evaluation of peripheral blood mononuclear cell (PBMC) enumeration techniques for HIV clinical trials: flow cytometric versus manual counts. *The 12th St Vincents & Mater Health Sydney, Research Symposium*. Sydney.

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**Prestage GP, Grulich AE,** Rawstorne P, Song A, Grierson J. What distinguishes Australian people living with HIV/AIDS not currently on combination antiviral treatment? *XIV International AIDS Conference*. Barcelona, Spain.

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