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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.

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

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

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.
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.
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. 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 the Annual Surveillance Report 2002. AIDS incidence has steadily dropped from its peak of 954 cases in 1994 to 178 cases in 2001. The age-standardised 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

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.

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

**Study recruiter:** Gillian Hales

**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

**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

**ITC**
*Aivipox vaccine study*

A multicentre, double-blind, placebo-controlled, randomised evaluation of safety and immunogenicity of an aivipox 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/mm³.

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, Japan)
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/mm³.

Opportunistic infections and AIDS-related 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

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

**Sponsor:** National Cancer Institute, National Institutes of Health, USA / NCHECR

**Contact:** Kate Clezy

**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 treatment-naïve HIV-1 infected patients with CD4+ cell count 100-500/ mm³.

**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.

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

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-Thailand-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.

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

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

### 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 ß2-microglobulin 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.

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 co-infection, and therapeutic research in HIV/viral hepatitis co-infection. 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 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 one-month 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 community-based 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
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 open-label 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.

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.

Don Smith

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 Private Practice; Cassy Workman, AIDS Research Initiative; Robert McFarlane, 407 Doctors; Nicholas Medland, The Centre Clinic; 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

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.


Although the Program does not have any formal teaching responsibilities, it does undertake wide-ranging 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 injecting drug use or receipt of blood. 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


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

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**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

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**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 NCHER 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

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**Biostatistics and database support**

To ensure timely and appropriate statistical advice into all NCHCR projects, the four biostatisticians from the Program are each aligned with two or three of the NCHCR 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 NCHCR 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.

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 to 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, Leakan 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, Leakan 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 may 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 region 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

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.

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 doses 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.

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

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.

Chris Duncombe

Mark Boyd

Julian Elliott

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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.
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 S100 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.
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.

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.
Centre staff

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, FRCPath, 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 BPPharm, 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, MA(Dip) (Research) (from July)
Fonnie Chan BN, RN, GradCert(HSM), 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)
Allison McClymont BAppSc (to May)
Leanne 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

* 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, BSc, 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, DiplMLib, 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 BEd, GradDipEd, AssDiplHlthSc
Jo Groves BA
John Redmond
Yvette Toole
Philippa Wong BEd

* Supervised by Professor Bruce Brew

John Redmond, Janette Button, Ian Brodie
Researchers affiliated to NCHECR

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
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, Fulbright Scholarship) BA Psych, MA
Psych (from June)

World Health Organisation Fellows
Zaini Hussin (Department of Health, Kelantan,
Malaysia) MEpidBio, MD (August)
Ahmad Jusoh (Ministry of Health, Kuala Lumpur,
Malaysia) MPH, MD (August)
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

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
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

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

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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
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
Mickle 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

International
Academic Medical Centre, University of Amsterdam, The Netherlands
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
Buddhachinaraj 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 Immunocomprometidos (CAICl), 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
Concerted Action on Seroconversion and AIDS Death in Europe (CASCADE), London, UK
Denver Infectious Disease Consultants, USA
Department of HIV/GUM Research, Brighton, UK
Division of Statistics, School of Public Health, University of Minnesota, Minneapolis, USA
European Monitoring Centre for Drugs and Drug Addiction, Lisbon, Portugal
Family Health Institute, Family Health International (FHI), North Carolina
Fundacion Centro de Estudios Infectologicos (FUNCEI) - Clinica La Sagrada Familia, Buenos Aires, Argentina
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
Hospitai Cantonal Universitaire, Geneva, Switzerland
Hospital Gui de Chauliac, Montpellier, France
Hospital Haut-Leveque, Bordeaux, France
Hospital Pitie-Salpetriare, Paris, France
Hospital Rothschild, Paris, France
Hospital Neck, Paris, France
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 Interzional de Agudos San Juan de Dios, La Plata, Argentina
Hospital Interzional 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
Massachusetts General Hospital, Boston, USA
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, Bangkok, Thailand
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
Wellington Hospital, New Zealand
Wetherall Institute of Molecular Medicine, Oxford, UK
WHO Western Pacific Regional Office, Manila, Philippines

**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, Thailand
Virax Immunotherapeutics, Melbourne
Virco Laboratories Inc, Maryland, USA
Visible Genetics Inc, Toronto, Canada
Scientific Advisory Committee

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Annual Surveillance Report

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Canberra

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Russell Waddell MB BS, BSc, FACSHP (Chair from July)
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The Australian HIV Observational Database Steering Committee

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The Antiretroviral Working Group

Jennifer Hoy MB BS, FRACP (Chair)
Associate Professor and Head, Clinical Research Section, Infectious Diseases Unit, The Alfred Hospital, Melbourne
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>David Baker MB ChB</td>
<td>General Practitioner, 407 Doctors, Sydney</td>
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</tr>
<tr>
<td>Bruce Brew MB BS(Hons), MD, FRACP</td>
<td>Professor and Head, Department of Neurosciences and Neurology</td>
<td>St Vincent's Hospital, Sydney</td>
</tr>
<tr>
<td>Suzanne Crowe MB BS, FRACP, MD</td>
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<td>Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne</td>
</tr>
<tr>
<td>John Cumming GradDipPublicSectorManagement</td>
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<td>Sydney</td>
</tr>
<tr>
<td>Nicholas Doong MB BS, DipObs, MPH, FRACGP</td>
<td>General Practitioner</td>
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<tr>
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<td></td>
</tr>
<tr>
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</tr>
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</tr>
<tr>
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</tr>
<tr>
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</tr>
<tr>
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<td></td>
</tr>
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</tr>
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</tr>
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</tr>
<tr>
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<td></td>
</tr>
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</tr>
<tr>
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<td></td>
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</tbody>
</table>

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

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

NCHECR Working Groups ex officio

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

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 Cooper

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 Kaldor

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
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 Penh, 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 Micaleff
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 gonorrhoea 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)

Shelcee 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)

(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
(John Kaldor)

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

(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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core allocation</td>
<td>3,095,471</td>
</tr>
<tr>
<td>Clinical Trials and Research Advisory Committee</td>
<td>526,111</td>
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</table>

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

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

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
### Pharmaceutical industry funding

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

* Industry funds administered through publicly-funded agencies
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.


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

Brew BJ. Thalidomide hypertensive crisis and HIV infection. 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.


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. 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. 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.


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


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


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.


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.


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.


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.


Other presentations


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.


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: 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 in Asia Pacific - the role of Australia. Australasian Society for Infectious Diseases Inc. Rowland Flat, SA.

Cooper DA. NCHECR perspective on surgical approaches to lipodatrophy. Lipodatrophy Research Workshop. Sydney.

Cooper DA. Primary HIV Infection. HIV/Immunology/Infectious Diseases Unit Journal Club. 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. Modelling the natural history of hepatitis C. Roche National Hepatitis C Advisory Board. 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. Update on HIV/AIDS surveillance. NSW Ministerial Advisory Committee on HIV/AIDS. Sydney.


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. Recent developments in the epidemiology of HIV, hepatitis C and sexually transmissible infections in Australia. *AIDS Medical Unit, Queensland Health Department.* Brisbane.


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.


MacDonald MA, Wodak A, Kaldor JM for the Collaboration of Australian Needle and Syringe Programs. HIV, hepatitis C and related risk behaviour among injecting drug users at needle and syringe programs in NSW. *Statewide Needle and Syringe Program Workers’ Meeting.* Sydney.

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.


Mallon PWG. Major toxicities of antiretroviral therapy. *Bristol-Myers Squibb Australia HIV Advisory Board.* Melbourne.


Mallon PWG. Update on pathogenesis and management of HIV-associated lipodystrophy. *Albion Street Centre.* Sydney.


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. 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.


Sasson SC. IL-7 expands the naïve CD4+ T-cell subset via distinct mechanisms: Implications for immune reconstitution. UNSW School of Biotechnology and Biomolecular Studies. Sydney.


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.


Distler O, Liang JS, Cooper DA, Ginsberg HN, Deckelebaum RJ, Sturley SL. Direct effects of HIV protease inhibitors on lipid metabolism. 2002 Gordan Research Conference on Lipid Metabolism. Meriden, USA.


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.


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 centralised body composition data analysis on an objective case definition of HIV lipodystrophy. 4th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV. San Diego, USA.


Workman C, Hales G on behalf of the CREST Study Group. CREST- A randomised comparison of two resistance test platforms: genotype and virtual phenotype™. The 9th Conference on Retrovirus and Opportunistic Infections. Seattle, USA.


Peer reviewed


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