NATIONAL CENTRE IN HIV EPIDEMIOLOGY AND CLINICAL RESEARCH

ANNUAL REPORT 2001

Contents

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What is NCHECR?

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 transmitted 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 two scientific areas:

- The Therapeutic Research Unit
- The Epidemiology Unit.

Foreword

This past year marks a decade and a half since the Commonwealth Government established the National Centre in HIV Epidemiology and Clinical Research through a grant to the University of New South Wales. I would like to highlight three areas in which there have been particularly important advances for NCHECR during 2001.

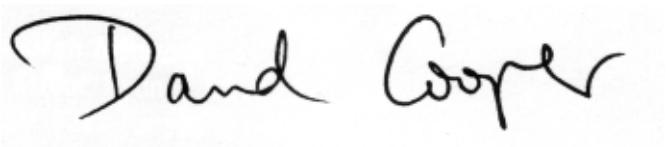
We have continued our efforts to provide Australian expertise in support of clinical and epidemiological research in the Asia-Pacific region, where HIV transmission and its consequences continue to present serious public health challenges. HIV-NAT, our clinical trials and research collaboration in Bangkok, has continued to flourish. Through a continually expanding research program, HIV-NAT has provided leadership in the development of appropriate antiretroviral therapy for Thailand, one of the developing countries of the region that has been most affected by HIV/AIDS. HIV-NAT is now sufficiently mature after five years to expand its horizons, and to move beyond a base of support that has in the past been predominantly provided by the pharmaceutical industry. Extensive planning during 2001 has led to the development of new research initiatives, for which funding is being sought from international public sector agencies. These initiatives are based on the experience in Thailand gained through HIV-NAT, but are intended to involve collaboration in other countries with more limited resources. They draw on NCHECR's combined clinical trial and epidemiology expertise to address both the challenges of providing antiretroviral therapy in resource-limited settings, and the increasingly recognised need for biomedical approaches to prevention such as vaccines and chemoprophylaxis. These developments will contribute to the urgent need for solutions to the HIV/AIDS epidemic in our region.

A second area of major achievement during 2001 was in the study and prevention of toxicity related to antiretroviral therapy. Although the benefits of antiretroviral agents have been extraordinary in reducing the morbidity and mortality due to HIV infection in richer countries, these advances have come at the cost of new forms of difficult-to-manage toxicity, most notably the lipodystrophy syndrome. Last year, data collection was completed and analysis begun on an international study, led by NCHECR and funded under the auspices of the European Medicines Evaluation Agency, to develop a case definition for lipodystrophy. We have also concluded randomised trials to test whether strategies such as switching antiretroviral drugs, or introducing new agents proven in other therapeutic areas (including diabetes and cardiovascular disease), can reduce the levels of lipodystrophy and its tragic consequences for the affected person.

David Cooper

The third key area of development during 2001 was the initiation of a program of therapeutic research in viral hepatitis. Although NCHECR had worked extensively on the epidemiological aspects of hepatitis C infection, we had engaged in a much more limited way with the clinical challenges of viral hepatitis. Collaboration with the Australian Liver Association led to the establishment of a combined working group during 2001, and its designation as the structure around which a research program on the natural history and treatment of viral hepatitis would be built. This program will draw on our strengths and infrastructure in clinical trial, epidemiology, biostatistics and data management, and combine with the hepatologists' expertise and clinical networks.

I wish to thank all of our staff including academic, administrative and project teams for the enormous commitment and efforts they have put into our programs in 2001. Moreover, the involvement and unwavering support of our Scientific Advisory Committee, chaired by Professor Peter McDonald; the University of New South Wales through the Dean, Professor Bruce Dowton and the Pro Vice-Chancellor for Research, Professor Elspeth McLachlan; and St Vincent's Hospital and Mater Health have been fundamental to our work and our success. I would like to acknowledge the crucial role played by our research collaborators in Australia and internationally, and express our appreciation to all participants in the studies that we have conducted.



Research highlights

Epidemiology Unit

Epidemiological programs at NCHECR involve surveillance and monitoring for public health purposes, as well as a range of collaborative research initiatives. Some key developments that took place during 2001 are indicated below.

Surveillance systems, analyses and methods

For the fifth year in succession, NCHECR published the *Annual Surveillance Report*, a comprehensive compilation of epidemiological information on the occurrence of HIV/AIDS, viral hepatitis and sexually transmitted infections in Australia. The *Report* for the first time was prepared under the guidance of an editorial advisory committee, chaired by Dr Jeremy McAnulty, and comprising representatives of key organisations with an interest in the material presented in the *Report*.

Important findings presented in the *Report 2001* were the ongoing fall in the occurrence of AIDS, due largely to the improved antiretroviral therapy of the past half-decade; the increased proportion of heterosexually acquired cases of HIV infection that had an association with a country of high prevalence; and the continuing high rates of hepatitis C transmission among people injecting drugs. The *Report* featured data for the first time from the Australia and New Zealand Liver Transplant Registry, which showed that hepatitis C had now overtaken hepatitis B as the leading indication for transplant of livers. Victoria reported an increased level of HIV diagnosis in 2000, but other jurisdictions did not detect a trend of this kind, despite continuing increases in self-reported unprotected anal intercourse with casual partners by gay men responding to the behavioural surveys conducted in collaboration with the National Centre in HIV Social Research.

During 2001, NCHECR worked with the States and Territories under the auspices of the Communicable Diseases Network Australia to continue implementation of enhanced surveillance for newly acquired hepatitis C infection. Through an analysis of published sources, estimation of the prevalence of hepatitis B infection in Australia was undertaken and found to be in the order of 100,000. Work began on improving surveillance for sexually transmitted infections, again under the auspices of the Communicable Diseases Network. Late in the year, there was an agreement with the Network that the National HIV Surveillance Committee, which has operated since 1989 under the ANCAHRD structure and its predecessors, should also come under the Network umbrella.

In collaboration with the immunovirology laboratory at St Vincent's Hospital in Sydney, work continued on development of the so-called "detuned" method of testing blood specimens for recently acquired HIV infection. With a new source of test kits having been identified, this potentially valuable surveillance tool can now be used more widely as a means of improving our understanding of recent patterns of HIV transmission.

During 2001 NCHECR became increasingly involved in epidemiological analyses of the occurrence of Creutzfeld-Jakob disease in Australia, through collaboration with the Melbourne-based National Registry.

John Kaldor

Social epidemiological research

A new collaborative project conducted with the National Centre in HIV Social Research led to the first 500 men to be enrolled in the HIM cohort, a vaccine preparedness study funded through a contract with the United States National Institutes of Health. The cohort is the first of its kind in Australia to incorporate routine screening for HIV infection and other sexually transmitted infections and blood-borne viruses.

Other collaborations with the National Centre in HIV Social Research continued on the study of non-occupational post-exposure prophylaxis for HIV prevention, which has now enrolled over 500 participants without a seroconversion having occurred, and the pH cohort of people with HIV infection, which is following over 400 participants.

Data collection for the national survey of sexual behaviour began, with some 5,000 (out of a total of 13,000) interviews completed during 2001.

Clinical epidemiological research

A central research theme at NCHECR for over 15 years has been the investigation and follow up of people detected as having newly acquired HIV infection. During 2001, a comprehensive review of study procedures in this important area was undertaken. As a result, an integrated database was developed, allowing more systematic analyses of relevant research questions to be carried out. International collaborations in this area included a new association with the Harvard group led by Professor Bruce Walker, which has a particular interest in early immunological responses and their therapeutic manipulation; and ongoing participation in CASCADE, a collaboration based in Europe that is studying clinical outcomes and their predictors in over 5,000 people with known date of HIV infection.

During 2001, the Australian HIV Observational Database was extended to include close to 2,000 patients being followed through 24 sites. Preliminary analyses were undertaken of an international study of cardiovascular endpoints in people with HIV infection.

Analyses of survival after specific AIDS-related illnesses found a general improvement in survival time, particularly following AIDS dementia complex, but no change in people who had non-Hodgkin's lymphoma.

An analysis was completed of liver fibrosis in patients with chronic hepatitis C infection recruited through the S100 scheme for funding expensive pharmaceutical agents, and found that age at infection, duration of infection, recent alcohol intake, mean ALT level and prior hepatitis B infection were independent predictors of the severity of liver fibrosis. A comprehensive meta analysis of progression rates in hepatitis C was published in *Hepatology*, and led to further work on the risk associated with specific prognostic factors.

Epidemiological research on pathogenesis and disease progression

The cohort of people with HIV infection whose disease progression is slower than average continued to be an important research resource in 2001. Preliminary analyses of HLA types were carried out and showed specific associations with nonprogression. Further work on the HIV *nef* region showed that there was potentially subtle variation in the viral sequences that could influence pathogenicity.

Recruitment continued for a collaborative study of non-Hodgkin's lymphoma in people without HIV infection. This study is investigating the role of immune stimulation, a hypothesis of particular interest in relation to lymphoma pathogenesis in people with immunosuppression.

Mathematical modelling

Empirical analyses were supplemented by mathematical models in a number of research areas addressed by NCHECR. One group of models took account of the role of sexually transmissible infections in showing how the impact of improved antiretroviral treatments in reducing HIV infectiousness may be counterbalanced by increases in unsafe sex. Modelling was also applied to the HIV epidemic in Victoria to gain insight into the apparent upturn in diagnosed cases seen in 2000.

Mathematical models can also provide projections of future disease occurrence. The Hepatitis C Virus Projections Working Group was re-established in 2001, with the goal of updating and expanding on the work carried out by the Working Group in 1998. Preliminary findings indicate a sharply increasing incidence of hepatitis C-related cirrhosis and liver cancer over the coming decades.

Another area in which NCHECR has made use of mathematical models has been in the estimation of the risk due to products that might be contaminated by the agent responsible for the new variant form of Creutzfeld-Jakob disease.

Epidemiological research in health services

With the trial of a medically supervised injecting centre getting underway in May 2001 in Kings Cross, NCHECR was extensively involved in developing and implementing the monitoring mechanisms that will be used to evaluate the centre. Under NCHECR's responsibility within the overall evaluation team are surveys of client behaviours and attitudes, counts of discarded syringes, and measurement of the prevalence of HIV and hepatitis C among people who inject in the Kings Cross area. The final evaluation report is due in the first half of 2003.

During 2001, NCHECR also contributed to a cost-effectiveness analysis of needle and syringe programs. Central to the analysis were a comprehensive international comparison of HIV and hepatitis C trends in cities with and without such programs, and an assessment of the impact of therapy on long-term outcomes in HIV and hepatitis C.

Therapeutic Research Unit

The principal objective of the Therapeutic Research Unit (TRU) has been to conduct clinical trials for the treatment of HIV in Australia. More recently it has taken on research into prophylactic vaccination for HIV infection, and expanded its research program into South-East Asia.

In addition to its central role in the design and implementation of clinical trials, the TRU plays a role in the development of evidence-based treatment policies and the delivery of education, training and capacity building in clinical research.

Table 1 provides a summary of recruitment in Australian clinical trials coordinated by NCHECR during 2001. Over 1,800 patients were participating in the 17 clinical trials shown. The network of 41 investigational sites in Australia and New Zealand contributed approximately 1,100 of these patients to this total, and the remainder were recruited at sites in other countries that are coordinated through NCHECR.

International project coordination

NCHECR's role in international projects has expanded considerably. Since 2000, it has undertaken regional coordination of the six-year ESPRIT study of the clinical effectiveness of interleukin-2, funded by the United States National Institutes of Health (NIH), and now the largest trial of HIV therapy in the world.

During 2001, work began on SMART, a large-scale study aimed at identifying the optimal strategy for using anti-HIV therapy. NCHECR is again playing the role of regional coordination, with funding via the NIH. This long-term trial, currently in its initial phases, could be expanded to incorporate approximately 20 investigational sites to recruit up to 200 patients with follow up extending across seven years.

The Lipodystrophy Case Definition Study was another major multinational project conducted during 2001. Entirely coordinated by NCHECR, this study collected over 100 data variables from approximately 800 patients in over 30 clinics on five continents in an effort to establish an objective case definition for lipodystrophy. Results will be available during 2002.

National initiatives

At a national level, NCHECR continued to develop and coordinate new research initiatives aimed at improving the care of people with HIV infection in Australia.

The CREST study was undertaken to provide access to testing for resistance to antiretroviral agents, which has become a standard of care in much of the developed world. In Australia and New Zealand no formal system had been implemented to develop capacity for laboratories with the ability to provide the tests, and there was no commitment to funding testing centrally. CREST compared two different approaches for the clinical interpretation of laboratory resistance reports, one centralised via a commercial organisation, and the other involving

Sean Emery

academic specialists at each participating site, and incorporating the development of a formal laboratory quality control program. A consequence of making the test more available in Australia was the familiarisation of care providers with the technology.

Investigations continued during 2001 into the management of the treatment-related metabolic complications in HIV infection that has come to be known as lipodystrophy. The MITOX study compared continued treatment with thymidine analogue HIV reverse transcriptase inhibitors against switching to the guanidine analogue HIV reverse transcriptase inhibitor (abacavir) in patients with peripheral lipoatrophy. After 24 weeks there was a modest but statistically significant improvement in peripheral fat gain for patients in the switch group. Longer-term follow up will further define this potentially important observation. The study is the first to show benefits in management of this treatment associated with complications for people with HIV infection.

For the third year in succession the TRU organised and ran a meeting of clinical research coordinators prior to the *13th Annual Conference Australasian Society for HIV Medicine Inc* in Melbourne. This satellite brought together approximately 50 research staff from the network of clinical sites in Australia and New Zealand to ensure that staff were updated on current and planned activities, and to provide education and training in clinical trial methodology. Funding provided for the meeting also assists research coordinators to attend the *Conference* itself.

During 2001, NCHECR also convened two meetings (in April and November) of the Combined Working Groups. These gatherings of up to 80 clinical investigators affiliated with NCHECR from Australia, New Zealand, Singapore and Malaysia provide a forum for developing and refining research protocols, sharing information on ongoing studies and generally networking. The meetings help define the clinical research agenda at NCHECR, as well as address issues of project management. The importance of these meetings was reinforced through the introduction of new working groups in viral hepatitis (a collaboration between NCHECR and the Australian Liver

Association), HIV neurology, and, for the first time, a separate working group for research coordinators.

Advances in data management

Given the large number of clinical studies in progress at any time, effective project management is of paramount importance to the efficient running of the trials network coordinated by NCHECR. In addition, the conduct of clinical trials has to adhere to the requirements of Good Clinical Research Practice. For these reasons NCHECR is moving toward a uniform system for data management in studies for which we are the primary data management centre. Previously data would only come to the TRU when staff from NCHECR visited sites to conduct monitoring visits. This caused delays in reporting trials, complicated project management and led to uncertainty about priorities among site personnel. Sites now complete and transmit study paperwork as soon as possible after a patient has completed a visit and data are available. In this way information can be entered into study databases at NCHECR on an ongoing basis, with continuous internal checks performed to assure data quality. Under the old system it was not unusual for the final statistical analysis to take up to nine months after the last patient had completed the last protocol-specified assessment. This contrasts with the one month it took to prepare a preliminary analysis recently for CREST, allowing study investigators to receive rapid feedback about the study results.

Another improvement to data management has come with the Lipodystrophy Case Definition Study, which used a case report form that was entirely internet-based. Each participating site around the world accessed a secure internet site with data entry forms customised to its needs, including language and pathology units. Internal quality checks were carried out during data entry, so that clearly invalid information could not enter the database. A formal evaluation of this system of data entry is underway.

Table 1: Therapeutic Research Unit projects in progress during 2001*

Project	Current recruitment	Recruitment objective
†QUEST	31	30
PULSE	52	26
PIILR	79	80
Mitox	111	100
INITIO	137	120
CREST I	338	330
SMART	na	na
STACCATO	na	na
CREST II	na	na
Lipodystrophy Case Definition	790	800
ROSEY	na	100
SILCAAT	114	125
ESPRIT	156	247
Avipox Therapeutic Trial	31	36
HRG 214	10	15
†IM682	14	40
†AMC#010	na	5
TOTALS	**1,863**	**2,054**

† = coordination only na = not applicable

* See the section on the Therapeutic Research Unit commencing on page 25 for further details

Teaching and training highlights

NCHECR is involved in a wide range of teaching and training activities (see page 52). During 2001, a total of four doctoral and eight Masters candidates whose research had been supervised by NCHECR staff were awarded their degrees.

Academic staff at NCHECR are also 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 2001, and a further 35 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.

Andrew Grulich

NCHECR was also involved in the coordination of several short courses during the year, and in contributing lectures to a variety of other postgraduate courses.

Service highlights

NCHECR staff were active during 2001 in a variety of advisory bodies, working groups and other committees that took them well beyond the immediate conduct of their research programs (see list on page 49). These forms of engagement with other public health and clinical agencies are considered to be core responsibilities for NCHECR staff. Through such involvements, NCHECR's research programs are continuously informed by real problems of policy and program implementation, and in turn NCHECR is able to contribute the expertise that is built on its research experience. Of particular note during 2001 was the election of Andrew Grulich to the Presidency of the Australasian Society for HIV Medicine, the peak professional body for HIV-related medical research in Australia.

Greg Dore

Another area in which several NCHECR staff made a particular contribution in 2001 was in the organisation of conferences. Greg Dore served as the Chair for one of the four streams of the 6th International Congress on AIDS in Asia and the Pacific held in Melbourne. David Cooper served as the Co-Chair of the Organising Committee of the International Workshop on Adverse Drug Reactions and Lipodystrophy held in Athens, Greece.

International activities

Many NCHECR studies have international dimensions, through multicentre patient recruitment or the transfer of specimens for analysis to partner laboratories in other countries. In addition to this form of collaboration, NCHECR has been increasingly active in supporting research and public health initiatives in developing countries.

Chris Duncombe

The largest scale commitment of this kind has been through HIV-NAT, a collaborative initiative of the Thai Red Cross, the Netherlands AIDS Treatment Evaluation Centre and NCHECR, which has been implementing clinical investigations in Thailand since 1996. NCHECR supports HIV-NAT in a number of ways, including the provision of technical expertise and personnel.

NCHECR has also been involved in advising on surveillance for HIV/AIDS and sexually transmitted infections in the countries of the Asian Region. During 2001, NCHECR staff provided technical assistance of this kind in Indonesia, Cambodia and China.

Epidemiology Unit*

The main achievements of the Epidemiology Unit are described in more detail below. We are indebted to many collaborating individuals and agencies around the world.

Surveillance systems

Case reporting for HIV and AIDS

The pattern of HIV infection and AIDS continued to be monitored by notification of newly diagnosed cases through State and Territory health authorities. The national case definition for HIV-1 infection was revised in late 2001 to include virological as well as immunological evidence of infection, and is awaiting formal adoption by the Communicable Diseases Network Australia.

Results of case reporting for HIV infection and AIDS to the end of 2000 were released in the *Annual Surveillance Report 2001*. Over the past seven years, AIDS incidence has dropped substantially from 955 cases in 1994 to 255 cases in 2000. The decline in AIDS incidence has occurred among people whose HIV infection was diagnosed at least three months prior to AIDS diagnosis, and has been attributed to the expanding use, from mid 1996, of combination antiretroviral treatments for HIV infection. In contrast, the number of AIDS cases in people whose HIV infection had been diagnosed within the preceding three months remained steady. This group accounted for approximately 40% of the annual number of AIDS diagnoses in 1998-2000.

There has been continuing concern about the possibility of a resurgence in the levels of HIV transmission, following evidence from behavioural surveys of an increasing prevalence of unprotected anal intercourse with casual partners among homosexually active men, and increasing rates of diagnosis of gonorrhoea. In Victoria, the number of new HIV diagnoses increased quite sharply from 1999 to 2000, but there was no further rise in 2001, and the trend was not mirrored in other parts of Australia. Similarly, there has been little change over time in the rate of diagnosis of newly acquired HIV infection (cases with a negative HIV antibody test or a clinical diagnosis of HIV seroconversion illness within 12 months of HIV diagnosis). HIV transmission occurred predominantly among homosexually active men.

Ann McDonald, Jenny Kemp, Melanie Middleton, Alison Leckie

Surveillance authorities endeavoured 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 138 cases of HIV infection newly diagnosed in 2000 with a returned exposure questionnaire, 75% reported a history of heterosexual contact only, 13% reported injecting drug use and exposure history remained undetermined in 12%, usually because the subjects did not wish to provide a comprehensive history of potential exposure. Among cases attributed to heterosexual contact only, 67% were people from countries of high HIV prevalence or their sexual partners.

Perinatal exposure to HIV was monitored in collaboration with the Australian Paediatric Surveillance Unit. Twenty children born to women with diagnosed HIV infection were reported in 2000. The mother's HIV infection was diagnosed prior to the child's birth in 17 cases. Almost all of these women reported use of interventions for reducing the risk of mother-to-child transmission, and none of the exposed children acquired HIV infection. Of the three children born prior to their mother's HIV diagnosis, two acquired HIV infection.

Investigators: Ann McDonald, Jennie Musto

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

Case reporting for hepatitis B and hepatitis C infection

The National Hepatitis C Surveillance Committee was established as a subcommittee of the Communicable Diseases Network Australia and New Zealand in 1999 to oversee the implementation of hepatitis C surveillance procedures at a national level. The

* Listed as investigators under each project are the NCHECR staff with primary responsibility for the area of work. As Head of the Epidemiology Unit, John Kaldor has involvement to varying degrees with all of the activities of the Unit, and is not listed separately on each project.

Committee's work has been coordinated by NCHECR. During 2001, the Network recommended that surveillance activities for hepatitis B be coordinated by the Committee, and to acknowledge this change, the new name National Viral Hepatitis Surveillance Committee was adopted.

The Committee's activities during 2001 included development of revised case definitions for hepatitis B and C notification, further development of enhanced surveillance mechanisms to detect newly acquired cases of hepatitis C (those with definitive evidence of infection within the previous two years), and discussion of mechanisms for improvement of hepatitis B surveillance in Australia. The extent to which agreed modifications to surveillance procedures for newly acquired hepatitis C infection were implemented during 2001 varied across jurisdictions, but the majority of States and Territories were able to improve their detection and description of incident cases, and the quality of national reporting was correspondingly strengthened. A preliminary analysis was undertaken of newly acquired hepatitis C cases diagnosed as having occurred during 2000. Injecting drug use continued to be reported as the responsible factor in the vast majority of cases.

Investigators: Greg Dore, Jenean Spencer, Monica Robotin

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

Surveillance for sexually transmissible infections

It has been recognised for some time that routine case reporting for sexually transmissible infections (STIs) in Australia provides, at best, a limited understanding of current patterns of incidence and prevalence. The Sexually Transmissible Infections Surveillance Committee, a subcommittee of the Communicable Diseases Network Australia, met for the first time in August 2001 to assist in the development of a national framework for STI control. The subcommittee is chaired by John Kaldor and includes representatives from each jurisdiction, along with key national organisations with an interest in STI control. During 2001, the subcommittee participated in two teleconferences and endorsed a plan to review and develop STI surveillance at a national level in Australia. State and Territory representatives agreed to provide documents related to procedures and outputs for STI surveillance. Significant progress was also achieved in drafting case definitions for sexually acquired chlamydia, donovanosis, gonorrhoea and syphilis for review by the Communicable Diseases Network Australia.

Investigators: Lesley Ashton, Jennie Musto

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

Monitoring HIV infection through sexual health clinics

People who attend sexual health clinics may be at increased risk of HIV infection through sexual contact compared with the general population. The pattern of testing for HIV antibody and new HIV diagnoses has been monitored through a network of metropolitan sexual health clinics in Australia since 1991. Information from this surveillance system to the end of 2000 was released in the *Annual Surveillance Report 2001*. Results of monitoring HIV infection at sexual health clinics in 2000 indicated that the low prevalence of HIV infection among heterosexually active men and women, documented among people seen prior to 2000, had been maintained. Overall, 29,565 people were seen at the collaborating clinics, 57% were tested for HIV antibody and 47 (0.2%) were newly diagnosed with HIV infection. Of 10,127 people with a history of heterosexual contact in Australia who were tested for HIV antibody, 13 (0.1%) were newly diagnosed with HIV infection. HIV prevalence was even lower among 1,007 female sex workers and 1,163 people with a history of heterosexual contact overseas. HIV prevalence was highest among homosexually active men (1.9%). Among 7,201 people retested for HIV antibody following a previous negative test, 14 (0.2%) were newly diagnosed with HIV infection.

Investigator: Ann McDonald

Collaborators: Network of sexual health clinics

Monitoring HIV infection among people entering Australian prisons

Because a substantial proportion of people entering Australian prisons have a recent history of injecting drug use, the monitoring of HIV test results in prison entrants may provide an indication of patterns of HIV transmission related to injecting. The extent and outcome of HIV antibody testing among people received into Australian prisons has been monitored, in collaboration with jurisdictional corrective services and prison health services, from 1991. Results to the end of 2000 were released in the *Annual Surveillance Report 2001*.

While the extent of HIV antibody testing at reception into prison has dropped from over 70% in the early 1990s to less than 60% in 2000, HIV prevalence among tested prison entrants has remained below 0.5% in all State and Territory corrections jurisdictions.

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 among injecting drug users at sentinel needle and syringe programs (NSPs) was carried out in October 2001. The number of survey sites was expanded from six to twenty-two in Queensland for 2001 to assess patterns of drug use and HIV and hepatitis C prevalence in regional areas of this State. New survey sites in Melbourne and Adelaide were also included. Around 2,500 clients at 53 NSPs completed the survey questionnaire and provided blood for HIV and hepatitis C testing.

Results from the 2000 survey were released in the *Annual Surveillance Report 2001*. Prevalence of HIV infection remained low (0.9%) among 2,523 injectors recruited from 35 sites in 2000. Consistent with previous surveys, HIV prevalence remained high among gay, male injectors (14%). Prevalence of hepatitis C virus remained stable at 53%. However, 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%), and 2000 (26%).

Margaret MacDonald was invited to address a meeting convened by the European Centre for Monitoring Drugs and Drug Addiction in November 2001 in Lisbon. The Australian experience with repeated surveys using dried blood spot testing and short questionnaires at NSPs was a key focus of the meeting, which was called to improve surveillance of drug-related infectious diseases in Europe.

Trends in type of drug last injected among survey participants were again reported in the Illicit Drug Reporting System (IDRS) Bulletin, October 2001, in collaboration with the National Drug and Alcohol Research Centre.

Investigators: Margaret MacDonald, Julian Zhou

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

Monitoring HIV, hepatitis B and hepatitis C prevalence among blood donors

Blood donors are required to sign a declaration to the effect that they have not been exposed to a range of factors that are linked to the transmission of HIV, hepatitis B and hepatitis C, and should therefore represent a group at low risk of infection. Monitoring infection rates in blood donors is important as a means of ensuring that the donation deferral criteria remain valid, and of identifying new patterns of transmission should they emerge. Cases of newly diagnosed HIV infection in blood donors are routinely notified to NCHECR through the Australian Red Cross Blood Service (ARCBS), as well as summaries of the number of blood donors tested for HIV antibody, broken down by State/Territory and year. Summaries of the number of diagnoses of hepatitis C infection among blood donors tested for hepatitis C antibody are also provided by the ARCBS.

For the first time in 2001, a report of the number of blood donors tested for hepatitis B surface antigen and the number positive was provided by the ARCBS.

In 1998-2000, 11 new diagnoses of HIV infection in blood donors were notified, giving a prevalence of 0.4 per 100,000 donations. In 2000, 105 blood donors were diagnosed with hepatitis B surface antigen, and 152 had hepatitis C antibody, resulting in prevalences of 11 and 16 per 100,000 donations, respectively.

Investigators: Jennie Musto, Ann McDonald

Collaborator: Australian Red Cross Blood Service

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

The extent of testing for HIV antibody and HIV diagnoses among entrants into the Australian Defence Force (ADF) is reported to NCHECR to provide information on another population that is considered to be at lower risk. The 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: Jennie Musto, Ann McDonald

Collaborator: Australian Defence Force

Occupational exposure to HIV, hepatitis B and hepatitis C infection among health care workers

A hospital network, established by the State and Territory health authorities and NCHECR, collects data on occupational exposures to HIV, hepatitis B virus and hepatitis C virus infection among health care workers.

Conversion of the database used for recording data, from the Epi Info computer program to a Microsoft Access database continued in 2001. Work focused on improving the reporting component. A survey of sites was carried out late in 2001 to determine data collection methods used during the conversion of the database.

Investigator: Margaret MacDonald

Collaborators: National HIV Surveillance Committee; Melbourne Diagnostic Unit, The University of Melbourne; State and Territory health authorities

Periodic Survey of risk behaviour in gay men

The Periodic Surveys provide a form of 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 2001, surveys were conducted in Sydney (2,134 completed questionnaires in February; 728 completed questionnaires in August), Melbourne (1,830 completed questionnaires in February), Queensland (1,570 completed questionnaires in June), and Adelaide (565 completed questionnaires in November).

A trend of increasing unprotected anal intercourse with casual partners was found in all capital cities for which data had been available prior to 2001. Analyses indicate that optimism about improved HIV treatments is associated with the increase in unprotected anal intercourse, and that at least some of the men engaging in unprotected anal intercourse, appear to be using HIV status to make decisions about condom use and strategic positioning (the decision to restrict oneself to either the insertive or receptive role during anal intercourse based on knowledge of one's own and one's partner's HIV status).

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 2001

An advisory committee, chaired by Dr Jeremy McAnulty, the nominated representative of the Communicable Diseases Network Australia, and including representatives from affected communities, clinicians and government agencies, was convened for the first time to guide the planning of the *Annual Surveillance Report*. Analyses presented in the *Report 2001* indicated that an estimated 12,440 people were living with HIV infection in Australia by the end of 2000, 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 nearly doubled between 1994 and 1997.

Brian Acraman, Garrett Prestage

HIV transmission continued to occur in Australia primarily among homosexual men. There was no evidence of a recent change in rates of transmission through male-to-male sexual contact or any increase in the very low rate of transmission through injecting drug use or heterosexual contact. Mother-to-child HIV transmission remains rare in Australia.

Hepatitis C was the most frequently reported notifiable infection in Australia in 2000. The increasing number of diagnoses of newly acquired hepatitis C infection, from 79 in 1996 to 444 in 2000, was probably due to improved surveillance methods. Transmission of hepatitis C continued to occur primarily among people who inject drugs. The *Annual Surveillance Report 2001* presented information provided by the Australia and New Zealand Liver Transplant Register showing that the primary cause of liver disease among the 192 people who had had a transplant in 1999-2000, was hepatitis C infection in 19% and hepatitis B infection in 16% of cases.

Diagnoses of both chlamydia and gonorrhoea increased substantially over the past five years to 91 and 31 per 100,000 population in 2000 respectively, whereas the rate of syphilis diagnoses remained relatively stable at 10 per 100,000 population. Indigenous people continued to be diagnosed with specific sexually transmissible infections at much higher rates than non-Indigenous people.

Investigators: Ann McDonald, Jennie Musto

Collaborators: Collaborating networks in surveillance for HIV/AIDS, viral hepatitis and sexually transmissible infections

Matthew Law

Australian HIV Surveillance Report

During 2001, the *Australian HIV Surveillance Report* provided quarterly updates of the number of new diagnoses of AIDS and HIV infection in Australia, the prevalence and incidence of HIV infection among people seen through a network of sexual health clinics and brief reports on topics of special interest in the epidemiology of HIV/AIDS, viral hepatitis and sexually transmissible infections.

In the January 2001 issue of the *Report*, South Australia reported on its experience with surveillance for newly acquired hepatitis C infection. New serological methods for detecting newly acquired HIV infection using a less sensitive or "detuned" HIV antibody assay were described in the April issue. In July, the *Report* presented an update on testing for resistance to antiretroviral agents, and the proceedings of a workshop on the status and trends in the epidemics of HIV/AIDS and sexually transmissible infections in Asia and the Pacific was published in the October 2001 issue.

Investigators: Ann McDonald, Yueming Li, 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

While AIDS has been a notifiable condition since it was first detected in Australia, reporting of AIDS and death following AIDS is not complete. To improve the completeness of AIDS notification in Australia, all AIDS cases and deaths following AIDS that have been 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 80% of deaths following AIDS had been notified. A review began during 2001 of deaths registered with the National Death Index as being HIV-related that could not immediately be matched to AIDS cases.

Investigators: Ann McDonald, Jennie Musto

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 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. Because such additional information is only available for a limited number of cases, surveillance for newly acquired infection provides a lower bound to the actual extent of HIV transmission.

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 2001, the NSW State Reference Laboratory for HIV/AIDS at St Vincent's Hospital, in collaboration with NCHECR, conducted pilot analyses based on cases of HIV infection newly diagnosed between January 1998 and August 2000. Of 570 cases, 180 (31.6%) were identified as having early infection using the "detuned" test, whereas 129 (22.6%) had some other evidence of newly acquired infection. The "detuned" testing strategy will be further evaluated to assess its value in monitoring patterns of HIV transmission.

Investigator: Ann McDonald

Collaborators: NSW State Reference Laboratory for HIV/AIDS; NSW Health Department

Estimation of hepatitis B prevalence in Australia

Consensus estimates and projections of the hepatitis C epidemic in Australia, calculated under the supervision of national working groups, have provided important information for public health policy in the areas of hepatitis C prevention and care. Similar estimates have not been available for hepatitis B infection in Australia. A project commenced in 2000 to estimate the prevalence of chronic hepatitis B infection in Australia. Information sources included the National Notifiable Diseases Surveillance System; reports of antenatal hepatitis B testing in New South Wales; a serological survey carried out on opportunistically collected specimens from children and adolescents throughout Australia; and published Australian studies of hepatitis B prevalence among people considered at higher risk, such as gay men, people who inject drugs, and Indigenous populations.

Several different estimation procedures were used. They were in general agreement that around 100,000 people were living with chronic hepatitis B in Australia (compared with approximately 160,000 people for chronic hepatitis C), and were therefore at risk of development of advanced liver disease complications. A large proportion of these cases are among people who have migrated from endemic regions such as China and South-East Asia.

Investigators: Greg Dore, Belinda O'Sullivan, Matthew Law

Collaborators: National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases; NSW Health Department; Central Sydney Area Health Service; Australian Red Cross Blood Service

Analyses of the National Creutzfeldt-Jakob Disease Registry

During 2001, the collaboration between NCHECR and the Australian National Creutzfeldt-Jakob Disease Registry continued. Statistical and epidemiological advice and support were provided by NCHECR for the analysis and interpretation of Registry data. Results of this collaboration included two papers submitted for publication during 2001. One was a description of a cluster of possible Creutzfeldt-Jakob Disease (CJD) cases in a regional Australian city, and the other was an analysis of 30 years of CJD incidence in Australia. In the latter, the epidemiology of CJD in Australia for 1970-1999 was described. 387 cases were confirmed over this time period, the majority of whom were sporadic cases. Over the 30 year period, the sporadic CJD incidence rate per million increased from 0.305 during 1970-1979 to 1.033 during 1990-1999.

An evaluation of the Registry's surveillance system was also undertaken in the context of the requirements for the Master of Applied Epidemiology. The review focused on the ability of the Registry to detect all cases of CJD in Australia, and in particular, to distinguish cases that may be of public health importance. The evaluation found that the CJD Registry is generally well prepared to face the potential challenges presented by CJD and the new variant form, vCJD. The few areas noted for possible improvement included evaluation of the system's sensitivity and improvement in the timeliness of reporting.

Investigators: Monica Robotin, Matthew Law

Collaborator: The Australian National Creutzfeldt-Jakob Disease Registry

Social epidemiological research

Risk factors for HIV seroconversion

This ongoing survey involves the interviewing of people with newly acquired HIV infection to identify characteristics that may be involved in the risk of transmission. Enrolment was ongoing during 2001, and some 20 people were interviewed. Community-based organisations in Australia continue to use data from this study to inform the development of prevention activities, for example a media campaign focusing on the risk associated with insertive anal sex. Discussions were held in 2001 to link recruitment with follow up procedures for participants in clinical trials of treatment for primary HIV infection.

Matthew Calvert

Investigators: Andrew Grulich, Olympia Hendry, Garrett Prestage

Collaborator: National Centre in HIV Social Research

Hepatitis C incidence studies

NCHECR has played a key advisory role on two cohort studies of hepatitis C incidence. The HITS study, based on repeat testing of people recruited within the New South Wales prisons system, has shown how difficult it is to carry out clinical and public health research in this context. The formal structure of the prison system and the mobility of prisoners within it has created formidable obstacles to the conduct of longitudinal research, despite the motivation of many within the system to help achieve the research goals. Although the study has so far found fewer cases of hepatitis C seroconversion than anticipated, it has helped to

define a prison health research agenda. The small number of seroconversions have also been of considerable interest immunologically.

The other cohort study, known as CU, has recruited injecting drug users from field settings in three parts of New South Wales. Both the recruitment rates and the levels of hepatitis C infection have been highest in Cabramatta, compared to the other two sites in the Northern Rivers and the Illawarra. Overall, the study recruited 347 participants to the end of 2001 and detected 50 seroconversions.

Investigator: Jenean Spencer

Collaborators: Andrew Lloyd, School of Medical Sciences, UNSW; Paul Haber, Drug and Alcohol Service, Royal Prince Alfred Hospital; George Marinos, Department of Gastroenterology, Prince of Wales Hospital; Rose Ffrench, Westfield Research Laboratories, Immunology Department, Sydney Children's Hospital; William Rawlinson, Department of Microbiology, Virology Division, Prince of Wales Hospital; Kate Dolan, National Drug and Alcohol Research Centre; Michael Levy, Population and Public Health Unit, Corrections Health Service; Kerry Chant, South Western Sydney Area Health Service; Rohan Jayasuriya, Department of Psychology, University of Wollongong; Lisa Maher, School of Medical Education, UNSW; Tim Sladden, Northern Rivers Area Health Service

Vaccine preparedness cohort study

The year 2001 saw the commencement of the Health in Men (HIM) 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. As planned, close to 500 men were enrolled. They underwent a socio-behavioural interview and had blood tested for HIV, hepatitis A and B and syphilis. Although NCHECR, in collaboration with the National Centre in HIV Social Research, has previously conducted large-scale socio-behavioural cohort studies, this is the first time that the study design has directly involved biological specimen collection. Analysis of data collected in 2001 will provide valuable information on such factors as the validity of participants' recall of hepatitis vaccine status and the prevalence of susceptibility to hepatitis A and B. From 2002, the cohort will provide data on incidence and risk factors for HIV, and other sexually transmissible infections. The study will continue enrolling until 2004, and follow up of participants will continue to 2005.

Investigators: Andrew Grulich, Garrett Prestage

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

Non-occupational post-exposure prophylaxis

There is continuing controversy over the efficacy of post-exposure prophylaxis (PEP) in the non-occupational setting, and policy debate over the conditions of access to therapy. To inform this debate, NCHECR has been conducting an observational study of the use of non-occupational PEP. By the end of the year over 500 participants had been enrolled in this study. None had seroconverted to HIV, whereas three to five infections would have been anticipated based on the types of exposures and expected HIV transmission rates. Use of nevirapine was found to have decreased dramatically during the year after a warning was issued by the United States Centers for Disease Control and Prevention in January of possible serious adverse effects. Discussions were held with international collaborators with regard to possible combined analyses, to help determine whether or not PEP is efficacious in preventing infection.

Olympia Hendry

Investigators: Andrew Grulich, Don Smith, Olympia Hendry, Belinda O'Sullivan

Collaborator: National Centre in HIV Social Research

National survey of sexual health and sexual behaviour

Interviewing for the first Australian national survey of sexual behaviour commenced in 2001, and over 5,000 people were interviewed. The remaining 8,000 interviews, and the analysis of results, will take place in 2002. Data from this survey will help build a comprehensive picture of the HIV risk profile of the Australian population.

Investigator: Andrew Grulich

Collaborators: National Centre in HIV Social Research; Australian Research Centre in Sex, Health and Society

Positive Health study

The Positive Health (pH) cohort study commenced in 1998 to track the impact of having HIV among people in New South Wales and Victoria.

In 2001, follow-up interviews were conducted involving over two thirds of the 425 participants enrolled in the study and an additional 30 participants were recruited. A third of the participants had been

hospitalised as a consequence of their HIV infection, including 11% who had been hospitalised at some time in the previous year. Fifty-one percent had previously reported a CD4 cell count of less than 200 (per microlitre), but this was the case in only 18% of cases at the time of the interview. Fifty-five percent of the total sample indicated that they had experienced some depression or anxiety in the previous year. Seventy-seven percent were currently taking combination antiretroviral therapy at baseline, and this had changed little at the time of their follow-up interview. Taking such treatments was associated with a reduced viral load, but not with an improved self-rating of health. Those taking combination antiretroviral therapies were also more likely to be taking complementary therapies.

Investigators: Garrett Prestage, Andrew Grulich, Olympia Hendry

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

Injecting drug use, hepatitis C and other drug-related harms in Australia: A qualitative study

Preliminary work was commenced on a project to identify factors and behaviours that influence transmission of blood-borne viruses among people who inject drugs, particularly the influence of location and situation. The project was funded through the Australian National Council on Drugs and ANCAHRD.

Ethnographic observation and in-depth interviews were commenced in 2001 with injectors from inner Sydney and South-Eastern Brisbane. Questions relating to place of injection at the last episode of shared syringe use were also added to the national needle and syringe program survey in October. Focus group interviews with injectors will be carried out in all States and Territories in 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

Clinical epidemiological research

Cohort studies of people with known duration of HIV infection

Cohorts of people with known duration of infection offer the best opportunity to understand the natural history of HIV infection, both early and late, and assess the effect of treatment and other factors on disease progression.

Since 1985, NCHECR has been involved in the recruitment and follow up of cohorts of people with newly acquired HIV infection, with data collected on treatment and disease progression as measured both clinically and through laboratory markers. A number of different investigations have been undertaken through these cohorts, including pathogenesis studies of early events in HIV infection, clinical trials and assessment of long-term outcomes. During 2001, NCHECR began a process of consolidating the information on these cohorts, which had been maintained in a number of different forms and under the responsibility of a diverse group of investigators. Aspects of this consolidation include upgrading the study database and strengthening support for recruitment and follow up.

Jan Guerin, Pat Grey

During 2001, collaboration was established with the Harvard group led by Professor Bruce Walker that has made significant contributions to understanding the immune response in HIV infection. Planning for joint pathogenesis and treatment studies in early HIV infection is well underway.

Investigators: Lesley Ashton, Jan Guerin, Don Smith, Tim Ramacciotti, Pat Grey, Kathy Petoumenos, Tony Kelleher

Collaborators: Partners AIDS Research Center (Massachusetts General Hospital) Harvard University, USA; Mark Bloch, Holdsworth House General Practice; Cassy Workman, AIDS Research Initiative; Robert Finlayson, Taylor Square Private Clinic; Robert McFarlane, 407 Doctors; Nicholas Medland, The Centre Clinic; Phillip Cunningham, John Zaunders, Centre for Immunology, St Vincent's Hospital, Sydney

CASCADE study

NCHECR continued its collaboration with CASCADE (Concerted Action on Seroconversion to AIDS and Death in Europe), a European-based multi-centre cohort study of over 5,000 people with known dates of HIV infection from 11 countries. Individuals enrolled through NCHECR in the Australian AIDS Prospective Study and the Primary Infection Cohort have been included in CASCADE, and their status was updated during 2000-2001.

A primary research focus of CASCADE is to characterise the long-term impact of the new antiretroviral treatments on disease progression. The collaboration also examines how laboratory measures can be used to predict clinical outcomes.

Investigators: Lesley Ashton, Jan Guerin, Tim Ramacciotti

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

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 four data transfers from the collaborating sites to NCHECR, most recently in September 2001. In total, 1,961 patients from 24 sites throughout Australia have now been recruited to the database.

Time trends in the use of antiretroviral treatment and changes in treatment strategies among AHOD patients were presented at the *13th Annual Conference Australasian Society for HIV Medicine Inc 2001*. The main findings were an increasing proportion of patients receiving combination therapy including a non-nucleoside reverse transcriptase. The proportion of patients receiving ritonavir in combination with another protease inhibitor has also increased, as has the proportion of patients interrupting treatment for more than three months. Summary biannual reports were published in June and December and data were also presented in the *Annual Surveillance Report 2001*.

Investigators: Kathy Petoumenos, Matthew Law

Collaborators: Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia

The Data Collection on the Adverse Events of Anti-HIV Drugs Study

The Data Collection on the Adverse Events of Anti-HIV Drugs (DAD) Study is a large, international, collaborative study aimed at assessing the medium to long-term effects of antiviral treatment of people with HIV in terms of possible increased risk of cardiovascular events. The study is coordinated through the Copenhagen HIV Programme in Denmark, and involves observational data from approximately 20,000 people with HIV from 11 cohorts in Europe, the United States and Australia followed for two years.

The Australian contribution to the DAD Study is based on eight sites in the Australian HIV Observational Database (AHOD). Anonymised data on 719 patients recruited into AHOD were forwarded to the coordinating office in Copenhagen in 2000, and the first follow-up transfer occurred in October 2001. Baseline analyses on 17,852 patients were presented at the *13th Annual Conference Australasian Society for HIV Medicine Inc 2001*. Antiretroviral treated subjects, particularly older subjects with preserved immunity, viral suppression and signs of lipodystrophy had increased rates of high cholesterol, low HDL and high triglycerides, and may be at increased risk of cardiovascular events.

Investigators: Kathy Petoumenos, Matthew Law

Collaborators: Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia)

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 of ADC.

In 2001, based on national AIDS notification data, there was further evidence that there has been a relatively smaller reduction in ADC incidence than has been seen 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, Bruce Brew, Yueming Li, Ann McDonald

Collaborators: State and Territory health authorities

Natural history of HIV-related opportunistic infections

The introduction of highly active antiretroviral therapy (HAART) has considerably altered the natural history of HIV-related opportunistic infections in Australia and other countries where there is widespread access to antiretroviral therapy. Previous NCHECR studies have documented the changing incidence and spectrum of HIV-related opportunistic infections in the era of HAART. In 2001, a further study was completed which examined survival following individual AIDS illnesses.

Based on national AIDS notification data median survival following AIDS has doubled in the era of HAART: from 20 months for AIDS cases diagnosed in 1993-1995 to 38 months for AIDS cases diagnosed in 1996-2000. The only major AIDS illness in which there has been no increase in survival is non-Hodgkin's lymphoma.

Investigators: Greg Dore, Yueming Li, Ann McDonald

Collaborators: State and Territory health authorities

Predictors of severity of hepatic fibrosis among people with chronic hepatitis C: Analysis of the S100 interferon database

When interferon was first funded by the Commonwealth Department of Health and Ageing under the S100 scheme, it was under the condition that information on demographic and clinical characteristics be forwarded to a centralised database at John Hunter Hospital, Newcastle. Enrolment data were collected on approximately 3,000 people from 61 hospital-based liver clinics from October 1994 through to December 1996.

In 2001, NCHECR investigators worked with the data base to complete a cross-sectional study in which potential predictors of severity of liver fibrosis were examined. Five factors were found to be independently associated with more severe liver fibrosis: age at infection; duration of infection; alcohol intake in previous six months; mean ALT level; and previous hepatitis B infection. There was no association with gender, ethnicity, source of infection, or chronic hepatitis B. These results will assist in the targeting of people for liver biopsy investigation and therapeutic intervention. Although there has been no new enrolment into the S100 database since 1997, further analyses will examine the progression of liver fibrosis among people under follow up through the data base.

Investigators: Greg Dore, Mark Danta (Master of Public Health student), Yueming Li

Collaborators: John Hunter Hospital, Newcastle; Network of liver clinics

Hepatitis C natural history

Although there have been many studies on the natural history of hepatitis C, conflicting conclusions have been drawn as to the rate of liver disease progression. In 2000, a systematic review of the natural history of chronic hepatitis C was undertaken to address this uncertainty. It was finalised and published in *Hepatology* during 2001. This review demonstrated that liver disease progression estimates varied widely by study methodology. The prevalence of cirrhosis 20 years after initial infection was found to be 25% in liver clinic-based studies, 28% in post-transfusion cohorts, 7% in community-based cohorts, and 4% in studies of people newly diagnosed on blood donor screening. For people infected with hepatitis C in late adolescence or early adulthood (as are the vast majority of cases in Australia) it appears that the overall rates of progression are likely to be slow.

Further analyses of the 57 studies considered in the review were conducted in 2001 to examine predictors of liver disease progression. Factors found to be significantly associated with more rapid liver disease progression were male gender, heavy alcohol consumption, elevated serum liver enzymes, and high-grade liver inflammation. Neither the age at acquisition of hepatitis C nor the mode of acquisition was associated with the rate of progression in multivariate models. These factors will be used to develop models to predict liver disease progression based on individual characteristics.

Based on estimates from the systematic review, a model was developed to estimate liver disease burden. This model predicted cirrhosis prevalence of 7% and 20% after 20 years and 40 years chronic hepatitis C, respectively. The corresponding estimates for hepatitis C-related mortality were 1% and 4% after 20 years and 40 years, respectively.

These reviews have important implications for guiding therapeutic intervention and for estimation and projection of health care services required for hepatitis C.

Investigators: Greg Dore, Matthew Law, Anthony Freeman

Collaborators: None

Epidemiological research on pathogenesis and disease progression

Australian long-term nonprogressor cohort

The Australian long-term nonprogressor cohort established in 1994 represents one of the largest studies of its kind in the world. Over 90 participants have been enrolled in the cohort, and the majority have had HIV infection for at least 15 years. Up until 2001approximately one-third of the cohort members had experienced disease progression as defined by a decline in CD4 counts to under 500 cells/μl or commencement of antiretroviral therapy. Analyses of observations on this cohort have shown that lower levels of HIV-1 sequence diversity, polymorphisms in the CCR 5 chemokine receptor, and the presence of *nef*-attenuated virus are independently associated with slower disease progression. On the other hand, detectable cytotoxic T lymphocyte (CTL) responses to

HIV antigens were associated with faster HIV-1 disease progression in this group.

Investigators: Lesley Ashton, Mee-Ling Munier

Collaborators: Graeme Stewart, Alison Clegg, Department of Clinical Immunology, Westmead Hospital; Nick Deacon, David Rhodes, National Centre in HIV Virology Research, Macfarlane Burnet Institute for Medical Research and Public Health; Rose Ffrench, Liz Keoshkerian, Westfield Research Laboratories, Sydney Children's Hospital; Claudette Satchell, Kate McGhie, St Vincent's Hospital, Sydney

Host genetic factors associated with long-term asymptomatic HIV-1 infection

The natural history of infectious diseases such as HIV-1 presents a major challenge in identifying single genes that can influence disease progression. Recent studies have suggested that certain genes such as those involved in cellular immunity (eg HLA genes) may ultimately influence rates of disease progression. Several groups have shown that expression of specific HLA genes may be associated with the manifestation of certain AIDS defining illnesses as well as faster or slower rates of disease progression.

Preliminary investigations in 2001 in the Australian long-term nonprogressor cohort have shown that HLA class I alleles B14, B35 and B57 are more frequently observed in people with long-term asymptomatic HIV infection and may have a central role in delaying HIV disease progression.

Investigators: Lesley Ashton, Mee-Ling Munier

Collaborators: John Sullivan, Andrew Geczy, Heather Dunkley, Australian Red Cross Blood Service; Claudette Satchell, Kate McGhie, St Vincent's Hospital, Sydney

HIV-1 species diversity in long-term nonprogressors

The *nef* gene of HIV has been shown to play an important role in controlling viral replication. Naturally occurring deletions within this region of the HIV-1 genome have been reported in a limited number of individuals with long-term asymptomatic HIV infection.

In order to examine the role of *nef* variations in long-term asymptomatic HIV-1 infection, amino acid sequence variations encoded within the *nef* genes of individuals (n=39) enrolled in the Australian long-term nonprogressor cohort were studied in 2001.

Conserved and hypovariable regions of the *nef* gene were identified. Regions previously reported to be associated with CD4 and MHC-I down-regulation remained conserved. However, a striking difference was observed between *nef* amino acid sequences from long-term nonprogressors with viral loads less than or equal to 2,000 copies/ml (95% had conserved sequence), and those with viral loads greater than 2,000 copies/ml (48% had variable sequence). These results provide further evidence that subtle changes occurring within the *nef*/LTR region of the HIV-1 genome are associated with increased levels of HIV-1 RNA and appear to contribute to disease pathogenesis.

Investigators: Lesley Ashton, Mee-Ling Munier

Collaborators: Nick Deacon, National Centre in HIV Virology Research, Macfarlane Burnet Institute for Medical Research and Public Health; David Rhodes, Amrad; Kate McGhie, Centre for Immunology, St. Vincent's Hospital, Sydney

Effects of chemokine co-receptors on HIV disease progression: An international meta-analysis of individual patient data

To address inconsistencies in the literature regarding an association between chemokine receptor gene polymorphisms and HIV disease progression, an international meta-analysis of individuals infected with HIV-1 was undertaken. Data were contributed by 19 groups of investigators from the United States, Europe and Australia. The analysis was finalised in 2001 and the data published in *Annals of Internal Medicine*.

Lesley Ashton

The overall findings from the analysis showed that both *CCR5-Δ32* and *CCR2b-64I* polymorphisms decreased the risk of progression to AIDS or death among seroconverters and seroprevalent patients, but had no clear protective effect on the risk of death after development of AIDS. In contrast, SDF-13'A homozygosity had no effect on the risk of AIDS, death or death after diagnosis of AIDS.

Investigator: Lesley Ashton

Collaborators: International Meta-Analysis of HIV Host Genetics, Department of Health and Human Services, National Institutes of Health, Bethesda, USA

HIV disease progression in people with haemophilia

As part of a Masters project, rates and determinants of HIV disease progression were examined in a hospital-based cohort of people with haemophilia type A

followed for more than 16 years after infection. Those who received antiretroviral therapy, particularly three drugs or more, were less likely to progress to AIDS or death. A higher CD4+ T-cell count at commencement of therapy was also strongly associated with delayed progression to AIDS or death, even after adjusting for the effect of antiretroviral therapy or age.

Investigators: Lesley Ashton, Masuma Khanam (Master of Public Health student)

Collaborators: Roger Garsia, Royal Prince Alfred Hospital; Jenny Learmont, Australian Red Cross Blood Service

Non-AIDS lymphoma case-control study

As lymphoma is one of the most common AIDS-related malignancies, researchers at NCHECR have taken an interest in this malignancy both in people with and without HIV. This study, funded by the NHMRC, is a large population-based study of the causes of this cancer. By the end of 2001, 700 cases and 700 controls had been enrolled in the study, and enrolment was completed. Discussions were held with international collaborators about testing of stored blood to examine the role of Epstein-Barr virus infection and immunity in lymphomagenesis. Analysis of other infective and immunological risk factors for non-AIDS lymphoma will occur in 2002.

Investigator: Andrew Grulich

Collaborator: NSW Cancer Council

Risk of cancer in people with HIV/AIDS

Cancer is a common cause of morbidity in people with HIV/AIDS. Research at NCHECR has focused on linkage studies to enable the determination of the spectrum of cancers that occur at increased rates. In 2001, we published results showing that rates of both Kaposi's sarcoma and non-Hodgkin's lymphoma had declined since the introduction of combination antiretroviral therapy, and that non-Hodgkin's lymphoma was now more common than Kaposi's sarcoma. Final analyses of the national linkage of HIV, AIDS and cancer data occurred in 2001. The fact that HIV, as well as AIDS, has been a notifiable infection in Australia since the early epidemic allowed us to examine rates of cancer before and after AIDS registration in this population. Apart from anal cancer, no cancer types occurred at increased rates in early HIV infection.

Investigators: Andrew Grulich, Yueming Li, Patty Correll, Matthew Law, Ann McDonald

Collaborator: Australian Institute of Health and Welfare

AIDS lymphoma case-control study

For some time, it has been postulated that the anti-herpes drug acyclovir may prevent the development of Epstein-Barr virus-related lymphoma in people with AIDS. In response to a small study published in 2002 that purported to find this relationship, we performed a re-analysis of data from our previously conducted study, the largest such study in the world. These data showed convincing data that high dose acyclovir does not in fact prevent the development of this AIDS-related cancer. Preparations for further recruitment to a new case-control study commenced in 2001. This study will examine the clinical and pathologic features of non-Hodgkin's lymphoma since the introduction of highly active retroviral therapy.

Investigators: Andrew Grulich, Monica Robotin

Collaborators: St Vincent's Hospital, Sydney; Prince of Wales Hospital; Royal Prince Alfred Hospital; Taylor Square Private Clinic; Albion Street Centre

Mathematical modelling

The competing effects of treatment and risk behaviour on HIV transmission among gay men in Australia

Previous mathematical models developed by NCHECR have suggested that two-, five-, and ten-fold decreases in HIV infectiousness through combination antiretroviral treatment reducing viral load could be counterbalanced among gay men in Australia by approximately 40%, 60% and 70% increases in rates of unprotected anal intercourse respectively.

This model was extended to assess in the impact of increased rates of sexually transmissible infections, which in turn could independently increase the risk of HIV transmission. It was assumed that increased unprotected anal intercourse resulted in a constant increased 2% (range 1% to 3%) of gay men being infected with a sexually transmissible infection, which carried a 3.5-fold (range 2- to 5-fold) increase in the risk of HIV transmission. Increases in HIV transmission were found to be more likely, with two-, five-, and ten-fold decreases in infectiousness as a result of treatment counterbalanced by approximately 30%, 50% and 65% increases in rates of unsafe sex.

Investigators: Matthew Law; Garrett Prestage; Andrew Grulich

Collaborator: National Centre in HIV Social Research

HIV incidence in Victoria

Following concerns about a possible increase in HIV transmission in Victoria in 2000, a mathematical transmission model was applied to estimate HIV incidence during the late 1990s. The transmission model was first calibrated to give HIV incidence estimates during the 1980s corresponding to those derived from back-projection analyses, which are considered to be reliable over this period before effective treatments altered the natural history of HIV disease to an extent that remains uncertain. HIV incidence was then estimated over the period 1995-2001 allowing for changes in antiretroviral treatments and risk behaviours. Based on this model, it was estimated that HIV incidence in Victoria decreased slowly during the 1990s to a nadir of 115 new HIV infections in 1997, followed by an increase to an estimated 130 HIV infections in 2000.

Investigator: Matthew Law

Collaborator: HIV Modelling Working Party

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. Membership of the group included statisticians, epidemiologists, clinicians, and representatives of the Commonwealth and State and Territory Health Departments and members of the affected community. NCHECR provided coordination for the group, as well as statistical and epidemiological support. Mathematical models of the hepatitis C epidemic in Australia were developed by the group, incorporating improved knowledge on numbers of injecting drug users and rates of hepatitis C disease progression which has become available since the first Hepatitis C Virus Working Group report in 1998. These models estimated that there were 210,000 people living with antibodies to hepatitis C in 2001, of whom 6,500 were living with cirrhosis. It was further estimated that there were 50 hepatitis C-related hepatocellular carcinomas during 2001, and 175 cases of decompensated liver cirrhosis during 2001, with both these incidence rates estimated to at least triple by 2020. The Working Group's final report will be published in the second quarter of 2002.

Investigator: Matthew Law

Collaborator: Hepatitis C Virus Projections Working Group

Transmissible spongiform encephalopathies

NCHECR provided epidemiological and statistical support to two projects aimed at assessing the risk of transmission of transmissible spongiform encephalopathies. First, in collaboration with the Therapeutic Goods Administration, risk assessments were performed of the potential for transmission of transmissible spongiform encephalopathies through blood-derived products, vaccines, and through ophthalmic surgery. This process involved using a simulation approach to put likely upper limits on the risk of a treated person receiving contaminated blood products in one year. Second, with the Australian Red Cross Blood Service a large national survey of blood donors aimed at providing information on travel and residency histories among donors was designed. A pilot study of data collection methodology was performed in 2001, with the full survey of some 10,000 blood donors scheduled for the second quarter 2002.

Investigator: Matthew Law

Collaborators: Australian Red Cross Blood Service; Therapeutic Goods Administration, Commonwealth Department of Health and Ageing

Epidemiological research on health services

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

Kathy Petoumenos, Janaki Amin

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 are included in the *Australian HIV Observational Database Biannual Report*, and the *Annual Surveillance Report*.

For 2001, the total number of people prescribed antiretroviral treatment was approximately 6,700, and just over 1,500 were prescribed prophylaxis for opportunistic infections.

Investigators: Kathy Petoumenos, Matthew Law

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

Survey of HIV and hepatitis C antenatal policy and practice

In Australia there are various policies and practices in regard to antenatal testing for HIV and hepatitis C. A previous study conducted by NCHECR in collaboration with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in the early 1990s found that approximately 20% of pregnant women were tested for HIV. There was no similar study on hepatitis C testing. In 2001, a study was completed in which specialist obstetricians, GP obstetricians, and public hospital obstetric units were surveyed as to their antenatal HIV and hepatitis C testing policies and practices. The proportion of private obstetricians, GPs and public hospitals with an antenatal testing policy for HIV was 62%, 42% and 42%, and for hepatitis C 70%, 41% and 39%, respectively. Universal offer of antenatal testing among private obstetricians, GPs and public hospitals was reported by 48%, 62% and 25% for HIV, and 56%, 47% and 27% for hepatitis C, respectively. During 1999, an estimated 33% of pregnant women were tested for HIV, and 37% for hepatitis C. Specific consent was obtained by private obstetricians, GPs, and public hospitals from 84%, 89%, and 94% of women tested for HIV, and from 72%, 79%, and 73% of women tested for hepatitis C, respectively. Based on reported numbers of women in antenatal care, prevalence rates were estimated at 0.23 per 1,000 and 13 per 1,000, for HIV and hepatitis C, respectively. Antenatal testing policy and practice continues to vary widely in Australia, but there has been an increase in antenatal HIV testing since the early 1990s. Prevalence of HIV among pregnant women continues to be low, while hepatitis C prevalence was consistent with estimates from previous antenatal prevalence studies.

The lack of specific consent and inadequate counselling for hepatitis C testing from a significant proportion of antenatal women suggests a need for specific hepatitis C education for obstetric practitioners. Considering the range of policies and practices, development of consensus guidelines for both HIV and hepatitis C antenatal testing also would appear to be a priority.

Investigators: Greg Dore, Jenean Spencer

Collaborators: Royal Australian and New Zealand College of Obstetricians and Gynaecologists; National Public Health Partnership; Australian Hepatitis Council; Australian Federation of AIDS Organisations; Maternity Alliance; Australian College of Midwives; National Association of People Living with HIV/AIDS; La Trobe University

Evaluation of the Medically Supervised Injecting Centre

In May 1999, the NSW 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:

Community opinion and experience of the MSIC and injecting drug use

During 2000, baseline data on community opinion of the MSIC and injecting drug use were obtained through phone interviews with Kings Cross residents and businesses and with a statewide sample of respondents. Participants were selected using randomly generated phone numbers. Preliminary data analyses were undertaken during 2001. The surveys will be repeated in mid 2002, after twelve months of service provision.

Counting discarded syringes

Recording of the number of syringes discarded in the street continued every six months for a one-month period in 2001. Counts were carried out by NCHECR researchers at selected sites in the 2011 postcode area, and by South Sydney Council in the main streets of Kings Cross. Data on syringes collected by Langton Centre Clean Up Team in Kings Cross on a daily basis are also being analysed.

HIV and hepatitis C infection and injecting behaviour

A survey of drug injectors at the MSIC and at two needle and syringe programs (NSPs) in Kings Cross, (Kirketon Road Centre and K2), was carried out in October 2001 as part of the national NSP survey. Additional items specifically related to the evaluation of the MSIC included history of overdose, treatment uptake, injecting health, and

experience of the MSIC. Data collected in 2001 will be compared with similar data previously collected from NSP clients at Kirketon Road Centre and K2 in October 2000, and with data to be collected at the three sites in October 2002.

Staff perception of the MSIC

Focus groups were carried out with two groups of MSIC staff in October and December 2001 to assess their perception of the service and its functioning.

Investigator: Margaret MacDonald

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

Margaret MacDonald

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. In 2001, the Commonwealth Department of Health and Ageing commissioned Health Outcomes International to undertake a study of the economic effectiveness of NSPs in Australia. NCHECR was sub-contracted to provide the epidemiological analyses that underpinned the evaluation of economic effectiveness. In the mid-1990s, NCHECR was involved in an international ecological analysis of the effectiveness of NSPs in HIV prevention. This study design was again used to estimate the effectiveness of NSPs in the prevention of both HIV and hepatitis C infection. Published studies of HIV and hepatitis C prevalence and incidence studies 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 cases of HIV infection, 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. Further analyses are underway to translate these estimates into economic terms.

Investigators: Greg Dore, Margaret MacDonald, Matthew Law

Collaborator: Health Outcomes International

HIV superinfection study

The question of whether or not infection with a second strain of HIV can occur in a person already infected with HIV remains uncertain. We have identified a subgroup of HIV positive participants in the previously conducted Sydney Men and Sexual Health study to look at this question. Individual behaviour in this subgroup varies from those who have never had unprotected sex since HIV infection, to those who report unprotected sex with many other partners. This makes them an ideal subgroup to study whether or not HIV superinfection can occur. During 2001, laboratory and statistical analysis of the data from this study was ongoing.

Investigators: Andrew Grulich, Garrett Prestage

Collaborator: National Centre in HIV Virology Research

Research ethics

Over the past few decades, an increasing awareness of issues of privacy protection, coupled with the introduction of large electronic databases and communications technology, has led to a profusion of regulations governing the use of personal information, including the use of health information for research purposes. These need to be taken into account in the conduct of epidemiological research. Researchers at NCHECR have for several years been closely involved with monitoring the introduction of new privacy regulations and laws. In 2001, a submission was drafted to the NHMRC regarding the introduction of new guidelines (the Section 95A guidelines) for considering the use of personal information in medical research. These guidelines make more explicit the balancing of privacy and public health interests in the ethical consideration of research applications by human research ethics committees. Our submission highlighted the need for a process of education for health researchers and health ethics committees before any new guidelines were promulgated. Issues relating to privacy were addressed in a review paper published in the *UNSW Law Journal*.

Investigator: Andrew Grulich

Collaborators: None

Therapeutic Research Unit

Primary HIV infection

Studies closed to recruitment

CHRN 015

An open-label study to determine the antiretroviral activity and safety of nelfinavir + zidovudine + lamivudine in patients with primary HIV infection.

Status: Trial closed July 2000. Patients now being followed long-term. Manuscript submitted.
Sites: 8
Enrolled/target: 28/24
Sponsor: Agouron
Contact: Pat Grey, Don Smith

Studies recruiting during 2001

QUEST

An open-label, randomised study of induction therapy with four antiretroviral drugs followed by maintenance therapy with three drugs, then placebo-controlled vaccination phase followed by treatment discontinuation in patients with primary HIV infection.

Status: Opened November 1998, enrolment closed November 1999. Amendment submitted December 1999 to add two vaccines to the study, then, discontinue treatment. Recruitment of non-QUEST seroconverters to vaccine phase to stop in December 2000.
Sites: 9
Enrolled: 31
Sponsor: GlaxoSmithKline
Contact: Pat Grey, Don Smith

Don Smith

PULSE

A randomised trial of combination therapy plus or minus hydroxyurea for primary HIV infection followed by a regimen of treatment interruption based on HIV-RNA load.

Status: Open January 2000
Sites: 8
Enrolled/target: 52/26
Sponsor: NCHECR / Bristol-Myers Squibb
Contact: Pat Grey, Don Smith

Antiretroviral therapy

Studies closed to recruitment

PIILR

An open-label, multicentre, randomised study of the reversibility of HIV-protease induced lipodystrophy in HIV-1 subjects.

Status: Study closed December 1999, follow up continuing, Results published.
Sites: 15
Enrolled/target: 79/80
Sponsor: GlaxoSmithKline / Boehringer Ingelheim / Gilead Sciences / NCHECR
Contact: Jeff Hudson, Don Smith

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 completed December 2000, study to finish December 2002.
Sites: 16
Enrolled/Target: 111/100
Sponsor: GlaxoSmithKline / NCHECR
Contact: Allison Martin, Don Smith

Studies recruiting during 2001

PIILR extension

Effect of stavudine discontinuation on lipodystrophy in PIILR participants.

Status: Recruitment completed, study completed June 2000.
Sites: 2
Enrolled: 19
Sponsor: GlaxoSmithKline / Boehringer Ingelheim / Gilead Sciences / NCHECR
Contact: Allison Martin, Don Smith

Mitox extension

A 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: 111/100
Sponsor: GlaxoSmithKline / NCHECR
Contact: Allison Martin

INITIO

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

Status: Recruitment closed March 2001.
Sites: 27 (25 in Australia and 2 in New Zealand)
Enrolled: 137
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: Closed to recruitment April 2000.
Sites: 41
Enrolled/target: 338/300
Sponsors: Virco / Roche / Boehringer Ingelheim / GlaxoSmithKline / Abbott / Bristol-Myers Squibb / Merck Sharpe and Dohme / Perkin-Elmer Biosystems / Australian Technology
Contact: Gillian Hales, Sean Emery

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, enrolment ongoing.
Sites: 18 sites worldwide
Enrolled/target: 170/200 at HIV-NAT
Sponsor: Boehringer Ingelheim
Contact: Chris Duncombe, Mark Boyd, Sean Emery

Robyn Munro, Wendy Lee, David Courtney-Rogers

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 a treatment-naïve HIV-1 infected patients with CD4+ cell count 100-500/ mm^3.

Status: Open April 2000, ongoing.
Sites: 15 in Thailand
Enrolled/target: 260/330
Sponsor: Ministry of Public Health, Thailand / Bristol-Myers Squibb (Thailand)
Contact: Chris Duncombe, Sean Emery

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, ongoing.
Sites: 54
Enrolled/target: 31/31
Sponsor: Bristol-Myers Squibb
Contact: Chris Duncombe, Sean Emery

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, ongoing.
Sites: 54 worldwide
Enrolled/target: 15/35
Sponsor: Bristol-Myers Squibb
Contact: Chris Duncombe, Sean Emery

Studies in preparation

SMART Study

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: Due to commence January 2002.
Sites: In year 1–10 sites, thereafter 31 sites
Target: 350 in Australia, 6,000 internationally
Sponsor: National Institutes of Health, USA
Contact: Fraser Drummond

STACCATO Study

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

Status: Due to commence February 2002.
Sites: 10 sites across Australia and New Zealand
Target: 600 patients internationally
Contact: Fraser Drummond

Lipodystrophy studies

Studies closed to recruitment

GEMFIBROZIL

A randomised study of gemfibrozil for the treatment of HIV-protease inhibitor-associated hypertriglyceridaemia.

Status: Open March 1999, recruitment completed December 1999. Manuscript in preparation.
Sites: St Vincent's Hospital, Sydney
Enrolled : 40
Sponsor: Abbott / NCHECR
Contact: John Miller

National Lipodystrophy Survey

A national, prevalence survey of lipodystrophic phenomena in patients with HIV.

Status: Recruitment complete November 1999. Manuscript in preparation.
Sites: 14
Enrolled: 1,348
Sponsor: Roche / Abbott / Bristol-Myers Squibb / NCHECR
Contact: John Miller

Studies recruiting during 2001

Lipodystrophy Case Definition Study

Changes in body shape and metabolism have recently become apparent in patients treated for HIV infection. Fat loss from the face, limbs and buttocks, and fat gain in the abdomen, base of the neck and breasts have been shown in both sexes. Increased fats in the blood and decreased insulin activity may be seen, sometimes with type-2 diabetes.

An objective case definition for HIV-associated LD syndrome(s) would assist researchers, industry and regulatory authorities.

Status: Open September 2000, completed September 2001.
Sites: 32
Enrolled: 790
Sponsor: European Medicine Evaluation Agency
Contact: Rebekah Puls

Fonnie Chan, Susan Phipps, Rebekah Puls

ROSIGLITAZONE (ROSEY)

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

Status: Open mid December, 2001, no enrolments to date.
Sites: 17 national sites
Sponsor: GlaxoSmithKline / Bristol-Myers Squibb / NCHECR
Contact: Dianne Carey, Allison Martin

Immune-based therapies

Studies recruiting during 2001

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.
Sites: 12
Enrolled/target: 114/125
Sponsor: Chiron Therapeutics / NCHECR
Contact: Sarah Pett, Sean Emery

ESPRIT

A randomised, open-label, Phase III, international study of subcutaneous recombinant interleukin-2 in patients with HIV infection and CD4 lymphocyte count greater than or equal to 300 cells/mm^3.

Status: Open October 2000.
Sites: 48 (24 in Australia; other sites in Argentina, Israel, Japan, Singapore and Thailand)
Enrolled/target: 711/1067 (156/247 in Australia)
Sponsor: National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA /

Division of AIDS, Centers for Disease Control and Prevention, USA / The Government Pharmaceutical Organisation, Thailand / Ministry of Public Health, Thailand / GlaxoSmithKline (Thailand) / Bristol-Myers Squibb (Thailand)
Contact: Sarah Pett, Sean Emery, Fonnie Chan, Chris Duncombe

Avipox vaccine study

A multicentre, double-blind, placebo-controlled, randomised evaluation of safety and immunogenicity of an avipox vector (rFPV) containing HIV genomic material (gag-pol) with or without co-expression of an immuno-enhancing cytokine gene (interferon-gamma).

Status: Recruitment commenced first quarter of 2001.
Sites: 11
Enrolled/target: 31/36
Sponsor: Virax Immunotherapeutics / ANCAHRD Clinical Trials and Research Committee
Contact: Alexander Aichelburg, Sean Emery

Gillian Hales, Alexander Aichelburg

HRG 214 study (PROBE)

A Phase I trial of the pharmacokinetics and safety of the Caprine antibody ^{PE}HRG214 in persons living with HIV.

Status: Open
Sites: 1
Enrolled/target: 10/15
Sponsor: Probe Pharmaceuticals Pty Ltd
Contact: Sarah Pett

Opportunistic infections, AIDS-related malignancies

Studies recruiting during 2001

IM862

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

Status: Recruiting
Sites: 4
Enrolled/target: 14/40
Sponsor: UNSW / Cytran
Contact: Kate Clezy

AMC #010

An open study of CHOP chemotherapy with, or without rituximab, for the initial treatment for HIV-related NHL.

Status: Open
Sites: 3
Target: 5
Sponsor: UNSW
Contact: Kate Clezy

Immunovirology laboratory

A major initiative at NCHECR during 2001 was the establishment of a laboratory with the capacity to support clinical and epidemiological studies, as well as its own research program. The laboratory evolved through a combination of the resources of St Vincent's Hospital and NCHECR, and incorporates the Research and Development component of the NSW State Reference Laboratory for HIV/AIDS, which had been associated with the Centre for Immunology at St Vincent's Hospital. A number of factors led to the establishment of the laboratory, including the return from post-doctoral studies in Oxford of Tony Kelleher who took up the position of Head, a convergence of interests between NCHECR and the Centre for Immunology, and the need for additional bench space as NCHECR's research program expanded. The laboratory moved to its current location and configuration in the Garvan Institute building next door to the main NCHECR offices in June 2001. NCHECR supports a component of the running costs of the laboratory, as well as three full time positions (including that of the Head), all other staff are St Vincent's employees.

The laboratory has the potential to capitalise upon its position, linkages and expertise. It will benefit from NCHECR's clinical research infrastructure, close links to the NSW State Reference Laboratory for HIV/AIDS (which will remain at St Vincent's Hospital), and the national network of primary care and specialist doctors interested in HIV infection. This structure provides access to large numbers of biological specimens from epidemiological surveys, natural history studies and clinical trials of therapeutic agents. Because these specimens have generally been collected in the context of well conducted formal studies, the associated clinical data are of high quality and reliability. Analysis of samples may take place in real time, or using material retrieved from a large, fully archived repository of cryopreserved samples.

The work of the laboratory can be divided into three major categories. First of all, much of the laboratory's activity is directed towards providing support of a routine nature to clinical trials and epidemiological studies, through processing of specimens. Secondly, the laboratory uses its expertise to develop or modify assays that are needed in such studies. Finally, the laboratory's senior scientists are responsible for their own research programs on pathogenesis.

Service and support

Virtually every clinical trial conducted by NCHECR during 2001 involved the collection of specimens which 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 operates 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 and genotypic resistance testing coordinated by NCHECR Working Groups, and programs for flow cytometry through international trials (INITIO and SILCAAT).

David van Bockel, Mee-Ling Munier, Tony Kelleher

An important recent development in evaluation of the effectiveness of therapy involves measuring the extent of immune reconstitution that can be induced by therapeutic modalities. Over the last year the laboratory has conducted monitoring of T-cell responses in the context of a number of clinical trials through extended immunophenotyping panels, and assays of T-cell function (including lympho-proliferation, IFN-gamma ELISpots and intracellular cytokine staining).

Investigators: Tony Kelleher, Mee-Ling Munier

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

Implementation and development of new laboratory assays in clinical and epidemiological investigations

In 2001 the laboratory developed several new assays for use in epidemiological surveys, clinical trials and natural history studies. In general, these assays were based on methods that have been reported from other laboratories, but that required validation or modification of some kind for use in the local setting.

Serological techniques for detection of antibodies to HHV8

A number of different approaches were under investigation during 2001. Among these tests, those that are determined to have the best performance will eventually be employed in investigations of HHV8 transmission and pathogenesis in cohort studies.

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

Collaborators: Claudette Satchell, Leakanna Leas, Kazuo Suzuki, John Zaunders, Philip Cunningham, St Vincent's Hospital, Sydney

Determination of proliferative responses of CD4+ and CD8+ T-cells

Current methods require the use of radioactive substances. Development work was undertaken for new assays that will allow simultaneous estimation of the proliferative response of CD4+ and CD8+ T-cells in response to antigen, without the use of radioactivity. Initial data indicate that the proposed assay is at least equivalent to the radioactivity-based assay currently employed in the laboratory with regard to assessment of CD4+ T-cell function.

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

Collaborators: Claudette Satchell, Leakanna Leas, Kazuo Suzuki, John Zaunders, Philip Cunningham, St Vincent's Hospital, Sydney

Optimisation of intracellular cytokine staining and ELISpot techniques for simultaneous determination of antigen specific CD4+ and CD8+ T-cell responses

Methods for these assays underwent further development and optimisation in preparation for use in the prophylactic vaccine trial due to start in late 2002.

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

Collaborators: Claudette Satchell, Leakanna Leas, Kazuo Suzuki, John Zaunders, Philip Cunningham, St Vincent's Hospital, Sydney

MHC-1 tetrameric technology

During 2001, the methods for synthesis and use of MHC class I tetramers were established in the laboratory. These methods will be employed in the study of antigen specific CD8+ T-cell responses in both clinical trials and natural history studies in 2002.

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

Collaborators: Claudette Satchell, Leakanna Leas, Kazuo Suzuki, John Zaunders, Philip Cunningham, St Vincent's Hospital, Sydney

Pathogenesis research

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

Laboratory surveillance for 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 2001. Analyses involved comparison of the trends in treatment uptake and the development of resistance. In contrast to results from North America and most of Europe, rates of resistance in transmitted virus are low. Rates of resistance to protease inhibitors have not increased. The rates of resistance to reverse transcriptase inhibitors have fallen since their peak in the mid 1990s prior to the advent of highly active antiretroviral therapy (HAART), and the type of mutations seen has changed.

In separate experiments a novel mutation within the reverse transcriptase gene giving rise to selective resistance to efavirenz was described.

Investigators: Tony Kelleher, Palanee Ammaranond (PhD student)

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

The role of *gag* mutations in antiretroviral resistance

This project is based upon observations made within the laboratory that there are viral mutations outside the regions coding for reverse transcriptase and protease that may impact upon HIV's susceptibility to antiretroviral drugs. A particular region of interest has been the *gag* gene, which codes for the proteins making up the core of the virus. We have described mutations at protease cleavage sites within Gag which 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.

Investigators: Palanee Ammaranond (PhD student), Tony Kelleher

Collaborators: Kazuo Suzuki, Leakena Leas, Philip Cunningham, St Vincent's Hospital; Sabine Piller, Darren Jones, Centre for Immunology, St Vincent's Hospital, Sydney

2LTR excision circles as a measure of viral turnover in people receiving suppressive therapy

Prior to integration into human cells, viral DNA may form DNA circles through ligation of the LTR regions of the HIV gene. These circles represent a by product of viral infection of cells, and have a longer half life than viral RNA which often falls to undetectable levels following therapeutic intervention with 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. A real time PCR assay was developed for the quantification of 2LTR circles from small quantities of blood cells that is now ready for further validation, and ultimately, application.

Investigators: Anna Swanson (Bachelor of Science (Honours) student), Tony Kelleher

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

Dendritic cell depletion, T-cell homeostasis 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. Markers of CD4+ T-cell activation and sub populations 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. The next step in this research will be to investigate the contribution of these changes to the immune deficits observed in primary HIV infection.

Investigators: Tony Kelleher, Mee-Ling Munier

Collaborator: John Zaunders, St Vincent's Hospital, Sydney

Definition of novel subset of CD4+ CTLs in peripheral blood following infection with HIV and EBV

In studies similar to those outlined above, it has become clear that changes to the distribution and phenotype of immunological cells occur early in the infective process and the abnormalities are maintained, often despite therapeutic intervention. In particular, subsets of CD4+ T-cells that contain all the machinery needed for cell mediated cytotoxicity are seen among the CD4+ T-cell population in early HIV infection, whereas they are normally only seen in CD8+ T-cell subsets. Work has begun to investigate the pathogenic role of this phenomenon, and the effect of antiretroviral therapy on the generation of this subset.

Investigator: Tony Kelleher

Collaborators: John Zaunders, St Vincent's Hospital, Sydney; Victor Appay, Andrew McMichael, MRC Human Immunology Unit, Institute of Molecular Medicine, John Radcliffe Hospital, Oxford, UK

Synthesis and use of class II tetramers

Most assays that enumerate T-cells are dependent on function. It is still unclear whether HIV-specific CD4+ T-cells are difficult to detect because they are deleted or lose functionality. The distinction is important not only in pursuit of a clear understanding of the pathogenesis of HIV infection, but also in the design of immunotherapy aimed at restoring these responses. One way to gain insight into this process is through the isolation of antigen-specific T using multivalent MHC-peptide complexes, often referred to as tetrameric complexes. Although MHC-I tetramers used in the study of antigen specific CD8+ T-cells have become available tools in several research laboratories, the reproducible synthesis of MHC-II tetramers, used for the study of CD4+ T-cells, has proven far more problematic. We have recently developed a novel strategy for protein expression and refolding of MHC-II tetramers. These constructs provide a powerful and novel tool for following the fate of antigen specific CD4+ T-cells *ex vivo*. Future studies with these constructs conducted in primary infection and in long-term nonprogression should allow insight to be gained into the immunopathogenesis of the functional deficit of HIV-specific CD4+ T-cells.

Investigator: Tony Kelleher

Collaborators: Jessica Wyer, Sharon Cunliffe, Andrew McMichael, MRC Human Immunology Unit, Institute of Molecular Medicine, John Radcliffe Hospital, Oxford, UK

Viral escape from HIV specific CTL responses in primary infection and long-term nonprogression

The phenomenon of viral escape from CTL mediated immune response during HIV infection has until recently been a subject of intense controversy. Although observations consistent with escape very early in the disease process have been confirmed, the possibility of delayed escape, especially in the face of robust CTL responses such as those seen in individuals with the genetic marker HLA-B27, has been more difficult to establish. In research carried out during 2001, we confirmed and expanded our original observations regarding delayed escape in HLA-B27+ individuals. We hypothesised that there were structural constraints on the virus in the region of the epitope, and proposed that they were overcome through the accumulation of compensatory mutations. Further investigation has provided strong evidence that both the escape and compensatory mutations are positively selected, thereby explaining this apparent anomaly in immune escape. Viral escape may play an important role in disease progression and limit strategies for vaccine prophylaxis and immunotherapy. Studies are now in progress to track the evolution of the CD8+ T-cell response immediately prior to the generation of escape mutants in HLA-B27+ individuals. Other studies commenced late in 2001 using sequences derived from entire viral genomes may 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

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 abnormalities in the metabolism of adipose tissue. During the last year, various techniques have been explored to isolate RNA from adipose tissue. During 2001, many of the difficulties in this technically challenging process were resolved. Another likely site of metabolic abnormalities is in monocytes. Techniques for the purification of these cells have been optimised and are part of the routine laboratory service.

Investigator: Paddy Mallon

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

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Australian Hepatitis Council, Sydney
Australian Infection Control Association, Sydney
Australian Institute of Health and Welfare, Canberra
Australian IV League, Canberra
Australasian Liver Association, Sydney
Australian National Council on AIDS, Hepatitis and Related Diseases, Canberra
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Australian Red Cross Blood Service, Sydney
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Commonwealth Department of Health and Ageing, Canberra
Communicable Diseases Network Australia, Canberra
Haemophilia Foundation Australia, Melbourne
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, Melbourne
Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Sydney
Royal Australian College of General Practitioners, Sydney

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AIDS Action Committee of the ACT, Canberra
Assisting Drug Dependents Inc, Canberra
Australian National University, Canberra
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The Canberra Hospital

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Blue Mountains Sexual Health Clinic, Katoomba
Bigge Park Medical Centre, Sydney
Bligh Street Clinic, Tamworth
Bureau of Crime Statistics and Research, Sydney
Centre for Immunology, St Vincent's Hospital, Sydney
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Concord Hospital, Sydney
Corrections Health Service, Sydney
Drug Intervention Services, Sydney
Eastern Sydney Division of General Practice, Sydney
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General Medical Practice, Strathfield
General Medical Practice, Lismore
General Medical Practice, Coffs Harbour
Gosford Sexual Health Clinic
Ground Zero Medical Centre, Sydney
HIV Service, Sydney Children's Hospital
Holdsworth House General Practice, Sydney
Immunology and Microbiology Department, The University of Newcastle
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
Neisseria Reference Laboratory, Prince of Wales Hospital, Sydney
NSW Cancer Council, Sydney
Northern Rivers Health Services, Lismore
People Living with HIV/AIDS (PLWHA), Sydney
Prince of Wales Hospital, Sydney
Royal Australian College of General Practitioners, NSW Branch, Sydney
Resource and Education Program for Injecting Drug Users, Redfern and Canterbury
Royal Hospital for Women, Sydney
Royal North Shore Hospital, Sydney
Royal Prince Alfred Hospital, Sydney
School of Medical Education, UNSW, Sydney
Sexual Health Clinic, Nepean Hospital, Penrith

Sexual Health Clinic, Port Kembla Hospital
Sexual Health Clinic, St George Hospital, Sydney
Sexual Health and Infectious Diseases Service (SHAIDS), Lismore
South Sydney Council
St George Hospital, Sydney
St George Needle Exchange, Sydney
St Leonards Medical Centre, Sydney
St Vincent's Hospital, Sydney
St Vincent's Hospital, Lismore
Strathfield Private Hospital, Sydney
Sydney Children's Hospital
Sydney Sexual Health Centre
Taylor Square Private Clinic, Sydney
The Exchange Services, Manly and Ryde
The Medical and Vein Centre, Coffs Harbour
Wentworth HIV and Sexual Health Service, Penrith
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Northern Territory AIDS Council, Darwin
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Blackall Terrace Specialist Centre, Nambour
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Caboolture Community Health Service
Cairns Base Hospital
Community Health Services, Maryborough
Dalby Hospital
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Gladstone Road Medical Centre, Brisbane
Gold Coast Hospital, Southport
Gold Coast Sexual Health Clinic, Miami
Inala Community Health Service, Brisbane
Kobi House, Toowoomba Base Hospital
Logan Youth Health Centre, Brisbane
Mackay Sexual Health Services
Nambour General Hospital
Open Youth Program, Townsville
Prince Charles Hospital, Brisbane
Princess Alexandra Hospital, Wooloongabba
Queensland Corrective Services Commission, Brisbane
Queensland AIDS Council (QAC), Brisbane
Queensland Needle and Syringe Program, Queensland Health, Brisbane
Queensland Positive People, Brisbane
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Special Health Services, Cairns
Sunshine Coast Intravenous AIDS Association (SCIVAA), Maroochydore
The Sexual Health Program, Cairns
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Salvation Army Crisis Centre, Melbourne

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The Carlton Clinic, Melbourne

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David J Beames BSc(Hons), PhD
Chief Executive Officer, Virax Holdings Limited, Melbourne

Mark Bebbington
Policy and International Manager, Australian Federation of AIDS Organisations, Sydney

David Boyle BSc, MSc, PhD
Senior Principal Scientist, CSIRO Animal Health Laboratory, Geelong, Vic

David A Cooper DSc, MD, FRACP, FRCPA, FRCP
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Robyn Elliott BSc(Hon), PhD
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Alistair Ramsay PhD
Professor of Medicine, Tulane Gene Therapy Consortium, Louisiana State University, New Orleans, USA

Ian Ramshaw MSc, PhD
Professor of Cell Biology, John Curtin School of Medical Research, Australian National University, Canberra

Kiat Ruxrungtham MD
Director, AIDS Research Centre, Chulalongkorn University Hospital, Bangkok, Thailand

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Roberta Withnall BSc
Consultant, Clinical Trials Unit, Medical Research Council, London, UK

The Australian HIV Observational Database Steering Committee

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David Baker MB ChB
General Practitioner, 407 Doctors, Sydney

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

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NCHECR Working Groups

The Antiretroviral Working Group

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Professor of Medicine (Neurology); Head, Department of Neurosciences and Neurology, St Vincent's Hospital, Sydney

John Cumming
Treatment Information Officer, AIDS Council of NSW, Sydney

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

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Mark Kelly MB BS
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John Quinn MB BS(Hons), PhD, FRACP, FRCPA
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Michael Rawlinson MB BS (to June)
Visiting Medical Officer, HIV/Sexual Health, Nambour General Hospital, Qld

Hugo Ree MB, FRCP, FACSHP (from June)
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Dennis Rhodes BM, BSc (to February)
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Resistance / Virology Working Group

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Toxicology/Pharmacology Working Group

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Oncology Working Group

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Immune-Based Therapies Working Group

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Chairs of Combined Working Groups

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Membership of external boards and committees

1st International AIDS Society Conference on HIV Pathogenesis and Treatment, International Scientific Committee of Abstract Reviewers

John Kaldor

2nd International Conference on Vaccine Development and Immunotherapy in HIV, Organising Committee

David Cooper

3rd Australasian Hepatitis C Conference, Scientific Program Committee, Epidemiology and Social Research Stream

Greg Dore, Chair

3rd International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV, Organising Committee

David Cooper, Co-Chair

5th Bangkok Symposium on HIV Medicine, Organising Committee

Chris Duncombe, Chair

5th International Congress on Drug Therapy in HIV Infection, Scientific Committee

David Cooper

6th International Congress on AIDS in Asia and the Pacific, International Scientific Advisory Committee

John Kaldor

6th International Congress on AIDS in Asia and the Pacific, Program Committee, Treatment and Care Theme

Greg Dore, Chair

13th Annual Conference Australasian Society for HIV Medicine Inc, Conference Committee

Andrew Grulich

AIDS Council of NSW

Fraser Drummond, Andrew Grulich; Board Members

AIDS Editorial Board

David Cooper, John Kaldor

AIDS Impact, 5th International AIDS Impact Conference on Biopsychosocial Aspects of HIV Infection, International Scientific Board

John Kaldor

ANCAHRD, Clinical Trials and Treatments Advisory Committee

David Cooper, *Ex-officio*

ANCAHRD, Hepatitis C Subcommittee, Second Hepatitis C Virus Projections Working Group

Greg Dore, John Kaldor, Matthew Law

ANCAHRD, Indigenous Australians' Sexual Health Committee

John Kaldor

ANCAHRD, National HIV Committee

Andrew Grulich

Australasian Epidemiological Association, 10th Annual Scientific Meeting, Scientific Program Committee

Matthew Law

Australasian Epidemiological Association, 10th Annual Scientific Meeting, Conference Organising Committee

John Kaldor

Australasian Society for HIV Medicine, *HIV Journal Club*, Editorial Committee

Bruce Brew, John Kaldor, Don Smith

Australasian Society for HIV Medicine, *HIV/Viral hepatitis: A guide for primary care*, Monograph Editorial Committee

Greg Dore, Andrew Grulich

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

Bruce Brew, Chair

Australasian Society for HIV Medicine, National Committee

Andrew Grulich, President

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, Chair

Australian Federation of AIDS Organisations, Vaccine Policy Reference Group

Andrew Grulich

Central Australian Disease Control Coordinating Committee, STD/HIV Subcommittee

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 Editor

John Kaldor

Commonwealth Department of Health and Ageing, Returns on Investment Advisory Committee

John Kaldor

Communicable Diseases Intelligence, Editorial Board

John Kaldor

Communicable Diseases Network Australia

John Kaldor

Eastern Hepatitis C Research Group

Tony Freeman, Convener

ESPRIT Executive Committee

David Cooper, Sean Emery

ESPRIT International Steering Committee

David Cooper, Co-Chair

ESPRIT International Steering Committee

Matthew Law

ESPRIT Toxicity Committee

Sarah Pett

Hepatitis C Council of NSW, Medical and Research Advisory Panel

Greg Dore, John Kaldor

HIV CONNECT Immunology Group

Tony Kelleher

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

David Cooper, Director

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

Andrew Grulich, Co-Chair

International AIDS Society Governing Council

John Kaldor

International AIDS Society Governing Council, Governance Subcommittee

John Kaldor

International Society of Neurovirology, Board of Directors

Bruce Brew, Invited member

Journal of Acquired Immune Deficiency Syndromes, Editorial Board

David Cooper

Journal of Epidemiology and Biostatistics, Editorial Board

John Kaldor

Journal of Ethiopian Medical Practice, International Advisory Board

Bruce Brew

Journal of HIV Therapy, Editorial Board

Don Smith

Journal of NeuroAID, Editorial Committee

Bruce Brew

Kings Cross Community Drug Action Team

Margaret MacDonald

Lipodystophy Case Definition Study, International Steering Committee

David Cooper, Matthew Law

Mapping Indigenous Risk Workshop, Organising Committee

John Kaldor

Monitoring the AIDS Pandemic, Steering Committee

John Kaldor

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Disease, Scientific Advisory Committee

John Kaldor

National Centre in HIV Social Research, Scientific Advisory Committee

John Kaldor

National Donovanosis Eradication Advisory Committee

John Kaldor

National Health and Medical Research Council, Expert Advisory Group on Transmissible Spongiform Encephalopathies

John Kaldor

National Health and Medical Research Council, Project Grants Committee

John Kaldor

National Health and Medical Research Council, Regional Grant Interviewing Committee

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National Serology Reference Laboratory, Scientific Advisory Committee

David Cooper

Neurology International Literature Review Advisory Board

Bruce Brew

Neuroscience of HIV infection, Scientific Program Committee

Bruce Brew

NSW Health Department, AIDS/Infectious Diseases Branch, NSW Users and AIDS Association, Tribes Funding Steering Committee

Margaret MacDonald

NSW Health Department, Chlamydia Campaign Advisory Committee

John Kaldor

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

Don Smith

NSW Health Department, HIV Health Promotion Committee

Andrew Grulich, Chair

NSW Health Department, HIV/AIDS and Infectious Diseases Social Research Advisory Committee

Andrew Grulich

NSW Health Department, Medically Supervised Injecting Centre Evaluation Committee

John Kaldor

NSW Health Department, Ministerial Advisory Committee on Hepatitis

John Kaldor

NSW Health Department, Research Ethics Committee

Andrew Grulich

NSW Health Department, Sexual Health Advisory Committee

John Kaldor

NSW Health Department, South Eastern Sydney Area Health Service, Management Committee, AIDS Dementia and HIV-Related Psychiatric Service

Bruce Brew

NSW Health Department, South Eastern Sydney Area Health Service, HIV/AIDS Ambulatory Care Services, Data Working Group

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

Bruce Brew

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

Bruce Brew

Repatriation Medical Authority

John Kaldor

Repatriation Medical Authority, Expert Committee to Examine Balkan Veteran Exposure to Depleted Uranium

John Kaldor

Repatriation Medical Authority, Subcommittee on Ionising Radiation Dose

John Kaldor

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

Don Smith, Executive Member

Sexually Transmitted Infections, Editorial Board

David Cooper

St Vincent's Hospital, Sydney, Research Ethics Committee

Matthew Law

St Vincent's Hospital, Sydney, Library Committee

Bruce Brew, Chair

Steering Group for the Commonwealth Chief Medical Officer Report on Communicable Disease

John Kaldor

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

Matthew Law

UNSW Centre for Public Health, Management Committee

John Kaldor

Venereology, Honorary Editorial Advisory Board

David Cooper

World Federation of Neurology, Cerebrospinal Fluid Research Group

Bruce Brew

World Federation of Neurology, Neuroimmunology and Virology Research Group

Bruce Brew

World Health Organisation, Trial Management Committee, PETRA study on perinatal HIV transmission in Africa

David Cooper

World Health Organisation Working Group on Interim Antiretroviral Treatment Guidelines in Resource Poor Settings

David Cooper

XIV International AIDS Conference, International Advisory Board

John Kaldor

Education and training

Students supervised by NCHECR staff

Supervisor(s) in brackets

Bachelor of Science (Honours) candidate

Anna Swanson

The use of 2LTR to monitor residual HIV-1 replication

(Tony Kelleher)

Bachelor of Science (Medicine) awarded

W 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, Chris Duncombe)

Bachelor of Science (Medicine) (Honours) candidate

Lily Wang

Apoptotic effects of quinolinic acid on human foetal astrocytes

(Bruce Brew, Gilles Guillemin)

Doctor of Medicine candidate

Jane Adcock

Functional magnetic resonance imaging in the localisation of speech dominance in epileptic patients

(Bruce Brew)

Doctor of Philosophy awarded

Tony Butler

Health status of prisoners

(John Kaldor)

Gregory Dore

Natural history of HIV-related opportunistic infections

(John Kaldor, Bruce Brew, David Cooper)

Rima Habib

Retrospective cohort study of cancer incidence and mortality among nuclear industry workers at Lucas Heights Science and Technology Centre

(John Kaldor)

Margaret MacDonald

Monitoring the prevalence of HIV, hepatitis B and hepatitis C in intravenous drug users

(John Kaldor)

Doctor of Philosophy candidates

Palanee Ammaranond

Evolution of HIV in response to antiretroviral therapy and immune mediated pressures

(Tony Kelleher, David Cooper)

Lucette Cysique

Changes in neuropsychological performance in AIDS dementia complex: Effect of HAART

(Bruce Brew)

Oliver Distler

HIV lipodystrophy syndrome

(David Cooper)

Paddy Mallon

Protease inhibitor related atherosclerosis in HIV

(David Cooper)

Ann Mijch (Monash University)

Measuring and managing HIV virological failure

(John Kaldor, co-supervisor)

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

Lipodystrophy in patients with HIV disease

(David Cooper, John Kaldor)

Louise Pemberton

Role of host and viral factors in the pathogenesis of AIDS dementia complex

(Bruce Brew)

Theresa Smit

Virological factors in AIDS dementia complex

(Bruce Brew)

Danielle Smith

Role of the kynurenine pathway in AIDS dementia complex

(Bruce Brew)

Rosie Thein

Quality of life and relationships with hepatitis C

(John Kaldor, Greg Dore)

Master of Applied Epidemiology (Disease Control) awarded

Jenean Spencer (Australian National University)

Development of hepatitis C surveillance and epidemiology

(John Kaldor, Greg Dore)

Master of Applied Epidemiology (Disease Control) candidate

Monica Robotin (Australian National University)

(Greg Dore, Andrew Grulich)

Master of Clinical Pharmacy candidate

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

Master of Medicine (STD/HIV) awarded

Elizabeth Sullivan (Sydney University)
Prevalence of sexually transmitted infections among antenatal women in Vanuatu, 1999-2000
(John Kaldor)

Master of Public Health by research candidate

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

Master of Public Health major project awarded

Shahzad Baig
Sexual behaviour and sexually transmitted infections among clients of a Sydney sexual health clinic
(Greg Dore)

Chhorvann Chhea
Knowledge, attitudes, behaviours, and practices towards HIV/AIDS among male seasonal workers in Phnom Penh, Cambodia
(Greg Dore)

Mark Danta (University of Sydney)
Factors associated with increased hepatic fibrosis in chronic hepatitis C: The Australian S100 interferon database
(Greg Dore)

Helen Fraser
A prevalence survey of lipodystrophy in HIV positive patients in Japan
(Matthew Law)

Jeff Jin
Trends in HIV testing among gay men in Australia
(Andrew Grulich)

Kathy Petoumenos
Antiretroviral treatment use in Australia: Findings from the Australian HIV Observational Database
(Matthew Law)

Master of Public Health major project candidates

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

Masuma Akter Khanam
The rate of disease progression and the effect of treatment in people with haemophilia and HIV infection
(Lesley Ashton)

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

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

Year 5 elective term Bachelor of Medicine candidates

John Tippett
Monitoring HIV-NAT Clinical Trials, Bangkok, Thailand
(David Cooper)

Kate Webber
Monitoring HIV-NAT Clinical Trials, Bangkok, Thailand
(David Cooper)

Year 5 elective term Bachelor of Science (Medicine) candidates

Fieke Cox (Academic Medical Centre, University of Amsterdam, The Netherlands)
Nephrotoxicity in HIV-infected patients after treatment with indinavir as part of combination antiretroviral therapy
(Mark Boyd, Chris Duncombe)

Jacqueline Tromp (Academic Medical Centre, University of Amsterdam, The Netherlands)
Nephrotoxicity in HIV-infected patients after treatment with indinavir as part of combination antiretroviral therapy
(Mark Boyd)

Oddeke van Ruler (Academic Medical Centre, University of Amsterdam, The Netherlands)
Nephrotoxicity in HIV-infected patients after treatment with indinavir as part of combination antiretroviral therapy
(Mark Boyd)

Pomme van Warmerdam (Academic Medical Centre, University of Amsterdam, The Netherlands)
Body composition changes in patients taking indinavir and ritonavir
(Chris Duncombe)

Pomme van Warmerdam (Academic Medical Centre, University of Amsterdam, The Netherlands)
Changes in lipodystrophy and other drug related adverse effects in HIV infected patients switched from combination nucleoside therapy to a nucleoside-sparing regimen
(Mark Boyd)

Course coordination

Case studies in epidemiology, Master of Public Health, UNSW, Sydney
Andrew Grulich

Epidemiology for public health, Master of Public Health, UNSW, Sydney
John Kaldor, Andrew Grulich

HIV/AIDS: Challenging and changing health care systems, Master of Public Health, UNSW, Sydney
Greg Dore

Intensive Training Session in HIV Medicine for Chinese Medical Practitioners, HIV Netherlands, Australia, Thailand (HIV-NAT), Thai Red Cross AIDS Research Centre, Bangkok, Thailand
Chris Duncombe

Japan ESPRIT Study Coordinator Training Course, NCHECR, Sydney
Sarah Pett

Teaching

Advanced HIV Nursing Course, Albion Street Clinic, Sydney
Don Smith

Advanced therapeutics, Master of Clinical Pharmacy, University of Sydney
Dianne Carey

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

Australasian Society for HIV Medicine, AIDS Treatment Project Australia, pharmaceutical industry short course on HIV/hepatitis C virus infection, Sydney
Paddy Mallon

Australasian Society for HIV Medicine community short course in HIV medicine, Sydney
Bruce Brew, Dianne Carey, Greg Dore, Sean Emery, Paddy Mallon

Australasian Society for HIV Medicine S100 Prescribers Project, Sydney
Greg Dore, Fraser Drummond, Andrew Grulich

Australasian Society for HIV Medicine short course in HIV/hepatitis C virus infection for prescribers, Sydney
Greg Dore, Paddy Mallon

Australian Red Cross Blood Service Course in Transfusion Medicine, "Creativity in Transfusion Medicine – Making the Complicated Simple", Melbourne
John Kaldor

Case studies in epidemiology, Master of Public Health, UNSW, Sydney
Andrew Grulich, John Kaldor

Clinic-based teaching for visiting Chinese medical practitioners, HIV-NAT, Bangkok, Thailand
Mark Boyd

Epidemiology for public health, Master of Public Health, UNSW, Sydney
Andrew Grulich, John Kaldor, Lesley Ashton

Epidemiology, Master of Applied Epidemiology (Disease Control), Australian National University, Canberra
John Kaldor

Goulburn Base Hospital Clinical Training Program
Greg Dore

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

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

HIV/AIDS studies, Master of Health Science (Honours) Health and Nursing, University of Western Sydney, Parramatta
Bruce Brew

HIV/AIDS: Challenging and changing health care systems, Master of Public Health, UNSW, Sydney
Lesley Ashton, Greg Dore, Andrew Grulich, Tony Kelleher

Immunology Allergy/Dermatology/Renal Disease Conference Plenary Session, Year 4-6 Medicine, UNSW, Sydney
David Cooper

Indonesia-Australia Specialised Training Project in HIV/AIDS Management and Development, UNSW, Sydney
Greg Dore, Andrew Grulich, John Kaldor

Intensive Training Session in HIV Medicine for Chinese Medical Practitioners, HIV-NAT, Bangkok, Thailand
Mark Boyd

Kings Cross Police Local Area Command Training Course for the Medically Supervised Injecting Centre (Public Order and Public Health), Sydney
Margaret MacDonald

Master of Medicine (Sexually Transmitted Diseases/HIV), University of Sydney
Bruce Brew, Dianne Carey, Greg Dore, Andrew Grulich, Tony Kelleher

Maternal and child health in resource-poor settings, Master of International Public Health, University of Sydney
Greg Dore

Methadone Prescribers Education Program, Sydney
Greg Dore

Microbiology for Medical Students, Year 3 Medicine, UNSW, Sydney
Gilles Guillemin

Neurology, Master of Medicine, University of Sydney
Bruce Brew

NSW Anaesthetists Continuing Education Meeting, Leura, NSW
Greg Dore

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

Post Registration Nursing Course in Alcohol and Other Drugs, Sydney Hospital and Sydney Eye Hospital
Bruce Brew

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

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 HIV/AIDS, Master of Medicine (Sexually Transmitted Diseases/HIV) and Master of Public Health, University of Sydney
Greg Dore

Research Coordinators Educational Satellite Meeting of *13th Annual Conference Australian Society for HIV Medicine Inc,* NCHECR Clinical Trials Network, Melbourne
Sean Emery, Andrew Grulich, Tony Kelleher

Sexual Health Counselling Course, Sydney Hospital
Andrew Grulich

Short Course in STD Medicine, Sydney Hospital
Greg Dore

Society of Hospital Pharmacists Continuing Education Meeting, Sydney
Dianne Carey

Sociology of Deviance, Sociology, UNSW, Sydney
Garrett Prestage

Sydney HIV Nurses Professional Development Program
Greg Dore

Sydney Sexual Health Centre Training Program
Greg Dore

Viruses and disease, Bachelor of Science, UNSW, Sydney
Gilles Guillemin

Tutoring

Advanced Trainees Infectious Diseases (Prince of Wales Hospital), UNSW, Sydney
Kate Clezy

Basic Physician Trainees (Prince of Wales Hospital), UNSW, Sydney
Kate Clezy

Clinical Medicine (Prince of Wales Hospital), Year 4 Medicine, UNSW, Sydney
Kate Clezy

Clinical Medicine (St Vincent's Hospital), Year 4 Medicine, UNSW, Sydney
Bruce Brew

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

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, Jennie Musto, Kathy Petoumenos

Funding for 2001

Commonwealth Department of Health and Ageing core grants

The Commonwealth Department of Health and Ageing provided an allocation in 2001 to fund the activities and administration of the National Centre. It also provided funding for the Clinical Trials and Research Committee (CTARC). For administrative purposes, these funds are allocated into the following categories:

Core allocation	2,865,957
Clinical Trials and Research Advisory Committee	430,073

Other Commonwealth Department of Health and Ageing grants

Hepatitis C surveillance activities	237,123
Long-term asymptomatic HIV infection in Australia	94,575
The Health and Treatments Study	68,304
Health in Men cohort study	45,120
Workshop on Regional Approaches to STI Management: Screening for STIs in primary health care: Theory and effectiveness	20,000
Epidemiological assessment of variant Creutzfeldt-Jakob disease and donor referral	7,389

Other grants and contracts from public sources

United States National Institutes of Health: HIV Vaccine Design and Development Team contract	4,365,465
*European Medicines Evaluation Agency: Lipodystrophy Case Definition Study	1,467,182
University of Minnesota: ESPRIT Study	1,038,925
United States National Institutes of Health: Protease Inhibitor Related Atherosclerosis in HIV	474,201
UNSW: Research infrastructure block grant	319,208
UNSW: Research quality funds	318,000
United Kingdom Medical Research Council: INITIO Study	267,791
NSW Health Department: Evaluation of the Medically Supervised Injecting Centre	226,513
NSW Health Department: Infrastructure support grant	100,000
NSW Health Department: Health in Men cohort study	80,935
NHMRC: Role of Kynurenine Pathway Metabolites in the Pathogenesis of AIDS Dementia Complex	57,056
UNAIDS: Thai TB Prophylaxis Trial	32,051
Health Outcomes International Pty Ltd: Return on Investments study on needle and syringe programs	30,000
European Medicines Evaluation Agency: Data Collection on Adverse Events of Anti-HIV Drugs	20,052
*Medical Research Council, UK: INITIO Trial, Lipodystrophy substudy	15,738
Donations to HIV research	2,267
Fred Hutchinson Cancer Research Centre, University of Washington: Immunology and Molecular Virology of Acute HIV Infection	1,472

Pharmaceutical industry funding

Bristol-Myers Squibb Pharmaceuticals (Australia)	917,263
GlaxoSmithKline Research and Development (UK)	882,673
Chiron Corporation	320,399
Roche	224,676
GlaxoSmithKline Australia Ltd	182,853
Merck Sharp & Dohme (Australia)	181,920
Boehringer-Ingelheim Pty Ltd	90,000
Cytran Inc.	44,952
Abbott Australia Pty Ltd	40,000
Ares-Serono International	31,815
Virax Immunotherapeutics	31,638
DuPont Pharmaceutical Company	22,401
Schering-Plough Pty Ltd.	17,112

* Industry funds administered through publicly-funded agencies

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Presentations at conferences and meetings

Conference presentations

Ammaranond P, Cunningham P, Suzuki K, **Grulich AE, Kelleher AD, Cooper DA**. Prevalence of drug resistance mutations in a primary infection cohort 1992-2000: No increase in protease resistance mutations and a decrease in RT resistance mutations. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Boyd M, Duncombe C, Ruxrungtham K, Khongphattanayothin M, Hassink E, Srasuebkul P, Sankote J, Reiss P, Stek P, Lang J, **Cooper DA**, Phanuphak P. Indinavir/ritonavir versus indinavir in combination with AZT/3TC for the treatment of HIV infection in nucleoside experienced patients: A randomised, open label comparative trial. *17th Annual meeting of the Royal College of Physicians of Thailand.* Pattaya, Thailand.

Boyd M, Duncombe C, Ruxrungtham K, Khongphattanayothin M, Hassink E, Srasuebkul P, Sankote J, Reiss P, Stek P, Lang J, **Cooper DA**, Phanuphak P. Indinavir/ritonavir versus indinavir in combination with AZT/3TC for the treatment of HIV infection in nucleoside experienced patients: A randomised, open label comparative trial. *National Conference on HIV/AIDS in Thailand.* Bangkok, Thailand.

Boyd M, Duncombe C, Ruxrungtham K, Khongphattanayothin M, Hassink E, Srasuebkul P, Sankote J, Reiss P, Stek P, Lang J, **Cooper DA**, Phanuphak P. Indinavir/ritonavir versus indinavir in combination with AZT/3TC for the treatment of HIV infection in nucleoside experienced patients: A randomised, open label comparative trial: 76 week follow up. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Brew BJ, Tisch S, **Law MG**. Lactate concentrations distinguish between nucleoside neuropathy and HIV distal symmetrical sensory polyneuropathy. *8th Conference on Retroviruses and Opportunistic Infections.* Chicago, USA.

Brew BJ, Tisch S, **Law MG**. Lactate concentrations distinguish between nucleoside neuropathy and HIV distal symmetrical sensory polyneuropathy. *Australian Association of Neurologists Annual Scientific Meeting.* Adelaide.

Chan FLF. The role of treatment therapy in HIV prevention. *4th Annual Global Tong-zhi Conference.* Taipei, Taiwan.

Cooper DA. AIDS Vaccine. *7th "Virology: A New Perspective" Conference.* Auckland, New Zealand.

Cooper DA. Antiretroviral therapy in resource-poor settings. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Cooper DA. Antiretroviral therapy toxicity: The second round, beyond lipodystrophy. *1st International AIDS Society Conference on HIV Pathogenesis and Treatment.* Buenos Aires, Argentina.

Cooper DA. HIV/hepatitis coinfection. *AIDS Vaccine 2001.* Philadelphia, USA.

Cooper DA. Immunotherapy of HIV disease. *15th Annual Meeting of Japanese AIDS Society.* Tokyo, Japan.

Cooper DA. Immunotherapy of HIV infection. *1st International AIDS Society Conference on HIV Pathogenesis and Treatment.* Buenos Aires, Argentina.

Cooper DA. Immunotherapy of HIV infection. *2nd International Conference on Vaccine Development and Immunotherapy in HIV.* San Juan, Puerto Rico.

Cooper DA. Perinatal HIV Trials. *4th Australian Update for Mothers, Infants and Children with HIV/AIDS.* Sydney Children's Hospital.

Cooper DA. The epidemiology of HIV lipodystrophy. *American Heart Association Scientific Sessions 2001.* Anaheim, USA.

Dore GJ, Li Y, McDonald AM, Ree H, **Kaldor JM**. The impact of highly active antiretroviral therapy on survival following individual AIDS-defining illnesses. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Dore GJ. Access to antiretroviral therapy in resource-poor settings: Antiretroviral therapy program implementation research. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Dore GJ. Epidemiology of hepatitis C in Australia. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Dore GJ. Ethics, HIV/AIDS research, treatment and care: Presentation of research proposal. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Dore GJ. Global epidemiology and natural history of hepatitis C. *Australian Sexual Health Conference.* Sydney.

Dore GJ. Is serious liver disease a common outcome of chronic hepatitis C?: Observations from the epidemiologist. *Asia Pacific Digestive Week.* Sydney.

Dore GJ. Update on hepatitis C. *The Royal Australasian College of Physicians Annual Scientific Meeting.* Sydney.

Emery SE. Australian HIV vaccine initiative. *International Conference on HIV Vaccines: An Annual Update.* Bangkok, Thailand.

Emery SE. HIV Vaccine Trials. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Emery SE. New Issues in antiretroviral therapy. *Argentinian National AIDS Conference.* Mendoza, Argentina.

Emery SE. Prospects for an HIV Vaccine. *Argentinian National AIDS Conference.* Mendoza, Argentina.

Freeman AJ, Dore GJ, Law MG, Lloyd AR, Marinos G, **Kaldor JM**. Progression to cirrhosis in chronic hepatitis C infection. *The Royal Australasian College of Physicians Annual Scientific Meeting.* Sydney.

Grulich AE, O'Sullivan BG, Correll PK, Smith D, Kippax S, **Hendry O**. Implementation of non-occupational post-exposure prophylaxis in Australia. *National HIV Prevention Conference.* Atlanta, USA.

Grulich AE, Prestage G, Cunningham P, Kippax S, Isaacs M, Rawlinson W, **Kaldor JM**. Seroprevalence and risk factors for human herpesvirus 8 in the SMASH cohort. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Grulich AE. Epidemiological aspects of anal cancer screening. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Grulich AE. HIV epidemiology: The current environment. *National Association of People Living with HIV and AIDS 8th National Conference.* Melbourne.

Grulich AE. The global HIV epidemic 20 years on. *Australian Medical Students Association Annual Conference.* Melbourne.

Grulich AE. The HIV vaccine programme: Epidemiological aspects. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Grulich AE. Trends in the Australian and global HIV epidemic. *4th Australian Update for Mothers, Infants and Children with HIV/AIDS.* Sydney Children's Hospital.

Guillemin GJ, Croitoru J, Smith DG, Dormont D, **Brew BJ**. Quinolinic acid upregulates chemokine production and chemokine receptor expression in astrocytes: Implications for brain inflammation and AIDS. *1st Australian Virology Conference.* Fraser Island, Qld.

Guillemin GJ, Croitoru J, Smith DG, Dormont D, **Brew BJ**. Quinolinic acid upregulates chemokine production and chemokine receptor expression in astrocytes: Implications for brain inflammation and AIDS. *6th International Congress of Neuro-immunology.* Edinburgh, UK.

Guillemin GJ, Kerr SJ, Smythe GA, Smith DG, Kapoor V, Armati PJ, Croitoru J, **Brew BJ**. Kynurenine pathway metabolism in human astrocytes: A paradox for neuronal protection. *6th International Congress of Neuroimmunology.* Edinburgh, UK.

Guillemin GJ, Moore A, Smith DG, Brown D, Breit S, **Brew BJ**. Expression of macrophage inhibitory cytokine 1 in human fœtal astrocytes and microglia. *6th International Congress of Neuroimmunology.* Edinburgh, UK.

Guillemin GJ, Smith DG, Brown D, Moore A, Breit S, **Brew BJ**. Macrophage inhibitory cytokine 1 in human brain cells and interaction with HIV Tat. *1st Australian Virology Conference.* Fraser Island, Qld.

Guillemin GJ, Smith DG, Croitoru J, **Brew BJ**. Expression of macrophage inhibitory cytokine 1 in human brain cells and its interaction with the kynurenine pathway and HIV-1 Tat. *1st Australian Virology Meeting.* Fraser Island, Qld.

Guillemin GJ, Smith DG, Williams KR, Smythe GA, Dormont D, **Brew BJ**. Amyloid peptide 1-42 induces human macrophages to produce the neurotoxin quinolinic acid. *11th St Vincent's Hospital Campus Research Symposium.* Sydney.

Guillemin GJ, Smith DG, Williams KR, Smythe GA, Dormont D, **Brew BJ**. Amyloid peptide 1-42 induces human macrophages to produce the neurotoxin quinolinic acid. *6th International Congress of Neuroimmunology.* Edinburgh, UK.

Kaldor JM. Prevalence of hepatitis B in Australia. *St Vincent's Hospital, Melbourne 9th National Symposium on Hepatitis B and C.* Melbourne.

Kaldor JM. Role of research in prisons health. *Public Health Association Annual Conference.* Sydney.

Kaldor JM. The occurrence of viral hepatitis in Australia and its region. *Indian Ocean Conference on Viral Hepatitis.* Perth.

Kelleher AD, Booth BL, Sewell AK, Oxenius A, Cerundolo V, McMichael AJ, Phillips RE, Price DA. The effect of ritonavir on the proteasome and processing of HIV-derived MHC Class I-restricted cytotoxic T lymphocyte epitopes. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Kelleher AD, Zaunders J, Appay V, Sutton J, Papagno L, Easterbrook P, Rowland-Jones S, McMichael J, **Cooper DA**. Large numbers of CD4+ T-cells in patients with HIV are perforin positive with an effector phenotype. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Kelleher AD. An overview of HIV. *4th Australian Update for Mothers, Infants and Children with HIV/AIDS.* Sydney Children's Hospital.

Kelleher AD. Assays for the assessment of CD4 responses to vaccines. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Kelleher AD. Clinical evaluation of immunotherapies in HIV disease. *4th Annual Immune Reconstitution and Surrogate Markers in HIV/AIDS Conference.* Baltimore, USA.

Kelleher AD. HIV and CTL: Viral evolution in response to CTL pressure, implications for immune control of virus replication. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Kelleher AD. HLA and HIV infection. *15th European Histocompatibility Conference.* Granada, Spain.

Law MG, Friis-Moller N, Reiss P, Kirk O, d'Armino Monforte A, Rickenbach M, Thiebaut R, Pradier C, Morfeldt L, Calvo G, Bartsch G, De With S, Philips A, Lundgren JD on behalf of the DAD Study Group. Cardiovascular risk in HIV patients – association with antiretroviral therapy. The DAD Study. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Law MG. Combination antiretroviral treatment and increased unsafe sex: Modelling the competing effects on HIV transmission among gay men in Australia. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Law MG. Modelling disease progression and survival in chronic hepatitis C infection. *Hepatitis C Symposium, Satellite Symposium of the The Royal Australasian College of Physicians Annual Scientific Meeting.* Sydney.

Law P, Dore GJ, Duncombe C, Mahanontharit A, **Boyd M, Law MG**, Lange J, Phanuphak P, **Cooper DA**. Impact of lamivudine therapy on hepatitis B serological and virological outcomes in Thai patients coinfected with human immunodeficiency virus. *HEP DART 2001: Frontiers in drug development for viral hepatitis.* Maui, USA.

MacDonald M, Wodak A, **Kaldor JM** on behalf of the Collaboration of Australian Needle and Syringe Programs. Hepatitis C prevalence and related risk behaviour among Australian injecting drug users. *12th International Conference on the Reduction of Drug Related Harm.* New Delhi, India.

MacDonald M, Wodak A, **Kaldor JM** on behalf of the Collaboration of Australian Needle and Syringe Programs. HIV, hepatitis C and related risk behaviour among injecting drug users reporting recent imprisonment. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

MacDonald M. Mucocutaneous exposures to blood and body fluids: What are the risks? *Sterilization by the Sea, 28th Annual Conference of Sterilizing Research and Advisory Council of Australia SA Inc.* Adelaide.

Mallon PWG, Ray J, **Cooper DA**. Therapeutic drug monitoring and virological outcome in heavily antiretroviral experienced HIV positive patients. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Mallon PWG, Suzuki K, Leas L, **Cooper DA**. Baseline genotypic analysis and virological outcome in heavily pre-treated HIV positive subjects with virological failure. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

McDonald AM, Cunningham P, Delpech V, **Kaldor JM**. Monitoring HIV transmission using a detuned HIV antibody testing strategy. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

McDonald AM, Cunningham P, Menzies R, **Kaldor JM**. Evaluation of surveillance for newly acquired HIV infection using the "detuned" HIV antibody testing strategy. *Communicable Diseases Control Conference.* Canberra.

McDonald AM, Kaldor JM. Recent trends in incident HIV infection in Australia. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

McDonald AM, Li Y, Cruickshank M, Elliott E, **Kaldor JM**, Ziegler JB. Use of interventions for reducing mother-to-child HIV transmission in Australia. *The Royal Australasian College of Physicians Annual Scientific Meeting.* Sydney.

Munier MC, Cunningham PH, **Cooper DA, Grulich AE**. Sensitivity and specificity of serological tests for human herpes virus-8 infection. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Musto J, Law MG, Buring M, **Kaldor JM**. Estimating the effect to which donor deferral protects the blood supply. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

O'Sullivan BG, Barton S, Levy M, Dolan K, Post J, Dwyer D, **Kaldor JM, Grulich AE**. HIV post-exposure prophylaxis in the prison setting. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

O'Sullivan BG, Correll PK, Smith D, Kippax S, **Hendry O, Grulich AE**. Implementation of guidelines for non-occupational post-exposure prophylaxis in NSW. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Pemberton L, Stone E, Boxmeer F, **Brew BJ**. The role of host factors in AIDS dementia complex pathogenesis. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Petoumenos K on behalf of the Australian HIV Observational Database. Antiviral treatments, CD4 counts and viral load in the Australian HIV Observational Database. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Pett SL, French M, Finlayson R, **Emery SE, Cooper DA** on behalf of the ESPRIT Study Group. Preliminary results of ESPRIT (evaluation of subcutaneous Proleukin, in a randomised international trial): Predictors of CD4+ T-cell response to IL-2 and dose reductions of IL-2. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Prestage G, Rawstorne P, Grierson J, Song A, Kippax S, **Grulich AE**. Use of health services among PLWHA. *13th Annual Conference Australasian Society for HIV Medicine Inc.* Melbourne.

Prestage G, Van de Ven P. Australian gay men of Asian descent. *6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Prestage G, Van de Ven P. Increases in unprotected anal intercourse with casual partners among HIV sero-negative gay men in Australia. *5th International AIDS Impact Conference on Biopsychosocial Aspects of HIV Infection.* Brighton, UK.

Smith D, Zaunders J, Kaufmann G, Cunningham P, Goh L, **Cooper DA**. Greater suppression of CD8 activation with 4 versus 3 drugs in early stages of primary HIV infection despite similar plasma virological decay rates. *1st International AIDS Society Conference on HIV Pathogenesis and Treatment.* Buenos Aires, Argentina.

Other presentations

Boyd M, Hassink E, Cox F, Tromp J, van Ruler O, Felderhof M, Mahanontharit A, **Duncombe C**, Ruxrungtham K, Stek M, Lange J, **Cooper DA**, Pahnuphak P. Nephrotoxicity in patients randomised to AZT/3TC combined with either indinavir 800mg tid or indinavir/ritonavir 800/100 mg bid: 64 week outcome. *3rd International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV.* Athens, Greece.

Brew BJ. HIV central nervous system complications in 2001. *Sydney General Practitioner HIV Study Group.*

Brew BJ. Neurological impairment and HIV disease. *Boehringer Ingleheim HIV Mental Health Seminar.* Sydney.

Cooper DA. AIDS Vaccine. *Bangkok Symposium 2001: HIV Medicine.* Thailand.

Cooper DA. Case studies. *Asia Pacific Postgraduate Forum, Evolving strategies in HIV management.* Hanoi, Vietnam.

Cooper DA. Clinical trials in developing countries. *amfAR Therapeutics Research in Asia Meeting.* Bangkok, Thailand.

Cooper DA. International AIDS Society Conference 2001. *St Vincent's Hospital HIV/Immunology/Infectious Diseases Unit Journal Club.* Sydney.

Cooper DA. Lipodystrophy. *Albion Street Clinic Research Unit Presentation Series.* Sydney.

Cooper DA. Major advances that matter: HIV medicine-lipodystrophy. *St Vincent's Hospital Grand Rounds.* Sydney.

Cooper DA. Managing antiretroviral toxicity. *Asia Pacific Postgraduate Forum, Evolving strategies in HIV management.* Hanoi, Vietnam.

Cooper DA. Switch Studies. *St Vincent's Hospital HIV/Immunology/Infectious Diseases Unit Journal Club.* Sydney.

Cooper DA. The Australian HIV Vaccine Initiative. *WHO-UNAIDS Vaccine Satellite Meeting, following the 6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Dore GJ. Antenatal screening and vertical transmission of HIV, hepatitis B and hepatitis C. *St George Hospital Obstetrics Department Meeting.* Sydney.

Dore GJ. Coinfection: HIV, hepatitis B and hepatitis C. *Bangkok Symposium 2001: HIV Medicine.* Thailand.

Dore GJ. Considerations around therapy for hepatitis C. *Forum for People Living with Hepatitis C.* Adelaide.

Dore GJ. Environmental risk and epidemiology of hepatitis C. *Cairns City Council Hepatitis C Forum.* Qld.

Dore GJ. Epidemiology and natural history of hepatitis C. *Queensland Hepatitis C Council Awareness Month.* Brisbane.

Dore GJ. Epidemiology of hepatitis C in Australia: Hepatitis C natural history and treatment. *South Australian Hepatitis C Awareness Week.* Adelaide.

Dore GJ. Hepatitis C: An Australian perspective. *Royal North Shore Hospital Gastroenterology Unit Meeting.* Sydney.

Dore GJ. Natural history and treatment of hepatitis C. *Forum for People Living with Hepatitis C.* Cairns, Qld.

Dore GJ. Natural history of hepatitis C and considerations for therapy. *National Hepatitis C Treatments Summit.* Adelaide.

Dore GJ. The changing epidemiology of HIV in the Asia Pacific region. *Bangkok Symposium 2001: HIV Medicine.* Thailand.

Emery SE. CREST Trial Update. *Roche Investigator Meeting.* Marbella, Spain.

Emery SE. HIV vaccine trials. *Australian Federation of AIDS Organisations Consultancy Group, HIV Vaccine.* Sydney.

Emery SE. Phase I/II trials. *WHO-UNAIDS Vaccine Satellite Meeting, following the 6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Emery SE. Prophylactic and therapeutic vaccines for HIV. *Sydney General Practitioner HIV Study Group.*

Ffrench R, Ruxrungtham K, **Kelleher AD**. Laboratory monitoring of vaccine immunogenicity. *WHO-UNAIDS Vaccine Satellite Meeting, following the 6th International Congress on AIDS in Asia and the Pacific.* Melbourne.

Freeman AJ. Progression to cirrhosis in chronic hepatitis C infection. *Sydney Liver Group.*

Grulich AE, O'Sullivan BG. An observational study of non-occupational post-exposure prophylaxis. *Canberra Hospital sexual health physicians meeting.*

Grulich AE. A national survey of sexual behaviour for Australia. *National Drug and Alcohol Research Centre.* Sydney.

Grulich AE. Anal intra-epithelial neoplasia and anal cancer in people with HIV. *NCHECR working groups meeting.* Sydney.

Grulich AE. Current trends in HIV in Australia. *AIDS Council of NSW Community Roundtable.* Sydney.

Grulich AE. Current trends in HIV in Australia. *Parliamentary Liaison Group on HIV/AIDS.* Canberra.

Grulich AE. Epidemic update. *NSW Health Department Forum on HIV.* Sydney.

Grulich AE. Epidemiological aspects of HIV vaccine trials. *AIDS Council of NSW community consultation.* Sydney.

Grulich AE. Epidemiological research and surveillance on HIV in Australia. *UNICEF delegation from Guizhou province, China, NCHECR.* Sydney.

Grulich AE. Infectious and immunologic causes of non-Hodgkin's lymphoma. *Queensland Institute of Medical Research Forum.* Brisbane.

Grulich AE. Infectious causes of non-Hodgkin's lymphoma. *First meeting of the InterLymph international collaborative group on lymphoma.* Bethesda, USA.

Grulich AE. Infectious causes of non-Hodgkin's lymphoma. *National Cancer Institute Viral Epidemiology Laboratory seminar.* Frederick, USA.

Grulich AE. Rising HIV infection rates: Are they real? *Australian Federation of AIDS Organisations Executive.* Sydney.

Grulich AE. Surveillance in high risk populations: Men who have sex with men. *UNICEF delegation from Guizhou province, China, NCHECR.* Sydney.

Grulich AE. The epidemiology of HIV in Australia. *UNICEF delegation from Guizhou province, China, NCHECR.* Sydney.

Grulich AE. The epidemiology of HIV in injecting drug users. *NSW Health Department Public Health Officer Trainee Bug Breakfast.* Sydney.

Grulich AE. Understanding new HIV infections. *AIDS Council of NSW Community Roundtable.* Sydney.

Grulich AE. Unprotected anal intercourse. *AIDS Council of NSW Community Roundtable.* Sydney.

Kaldor JM. Clinical studies in primary HIV infection. *NCHECR Primary HIV Infection Working Group.* Sydney.

Kaldor JM. Donor risk analysis for virus-positive donations. *Australian Red Cross Blood Service National Donor and Product Safety Committee.* Melbourne.

Kaldor JM. Is this an outbreak and if so what is the cause? *NSW Health Department Outbreak Investigation Workshop.* Sydney.

Kaldor JM. Principles of health surveillance. *Family Health International Workshop on Surveillance for HIV/AIDS.* Jakarta, Indonesia.

Kaldor JM. The changing incidence of liver cancer. *Australian Liver Association Workshop, Asia Pacific Digestive Week.* Sydney.

Kelleher AD. 007 license to kill revoked! CTL and viral evolution. *Johnson and Johnson seminar series.* Sydney.

Kelleher AD. An update on HIV. *Immunology Update, Eastern Sydney Division of General Practice Clinical Meeting.* Sydney.

Kelleher AD. Evolution of HIV under sustained cytoxic T-cell pressure. *Royal Prince Alfred Hospital Department of Clinical Immunology, Infectious Diseases and Rheumatology meeting.* Sydney.

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