

Never Stand Still The Kirby Institute Medicine Kirby Institute ANNUAL REPORT 2012



THE KIRBY INSTITUTE for infection and immunity in society

ANNUAL REPORT 2012

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KIRBY INSTITUTE PROGRAMS 2012

THE ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH PROGRAM

The Aboriginal and Torres Strait Islander Health Program was established in 2007. The program works collaboratively to close the gap in health between Aboriginal and Torres Strait Islander and non-Indigenous people, with a central focus upon sexual health and blood borne viruses. In doing so, the program engages in strategies that are designed to enhance the capacity of Aboriginal and Torres Strait Islander communities in health improvement.

The program has four main domains of activity that it conducts in partnership within Aboriginal and Torres Strait Islander communities:

- Research aimed at increasing knowledge about ways to prevent and manage blood-borne viral and sexually transmissible infections in Aboriginal and Torres Strait Islander communities;
- Surveillance to support programs and policy related to the control of these infections in Aboriginal and Torres Strait Islander communities:
- Capacity building, to ensure that there is a strong workforce in research and service delivery in Aboriginal and Torres Strait Islander communities;
- Information dissemination to and from Aboriginal and Torres Strait Islander communities about key new developments and best practice in the control of blood-borne and sexually transmitted infections.

The program works closely with the National Aboriginal Community Controlled Health Organisation, its State and Territory-based affiliate organisations and Aboriginal Community Controlled Health Services to make a difference to the health of indigenous communities.

James Ward, who founded the program, moved to a senior position in Alice Springs with Baker IDI but has maintained strong collaboration with the program and ongoing leadership of a number of its projects. The program published the annual surveillance report on blood-borne viral and sexually transmitted infections in Aboriginal and Torres Strait Islander people, which is designed to provide a comprehensive update to meet the planning and evaluation needs of communities. Australia's largest randomised cluster trial ever conducted in Aboriginal health, named STRIVE and funded by the NHMRC, completed its first year of activity and transitioned into the second year, undertaking quality improvement for sexual health clinical services in nearly 70 remote communities across central and northern Australia. Work progressed through 2012

in SHIMMER, a quality improvement project in Aboriginal Community Controlled Health Services in NSW with State government support. REACCH, a Centre for Clinical Research Excellence in Aboriginal Community Controlled Health taking place at four community controlled services across the country, collected comprehensive data on uptake and outcome of testing for sexually transmissible infections and hepatitis B. The ARCfunded project GOANNA, the first national survey of young Aboriginal and Torres Strait Islander people regarding sexual and injecting related knowledge, risk behaviour and health service access, completed its second full year of data collection, through a variety of community events across the country. Ongoing projects in which the program played in major role in 2012 were NHMRC-funded studies of point-of-care testing for sexually transmissible infections in remote communities (TTANGO) and a large cluster randomised trial of chlamydia screening (ACCEPt).

THE BIOSTATISTICS AND DATABASES PROGRAM

The Biostatistics and Databases Program has a collaborative biostatistical research role across many of the Kirby Institute's programs and activities. A key activity in this area in 2012 was extensive statistical analyses of the ENCORE and SECONDLINE clinical trials (TVRP), for DSMB activities and final reporting. The final statistical analyses of the PREDICT study (HIVNAT) were conducted and published. Study databases were developed for trachoma surveillance (SEPHH) and the REACT study (SHP). The program also started a new role to provide training for, and coordination of, NHMRC and ARC grant applications.

During 2012 groundwork was laid for the development of a number of new collaborative studies. A case-control study of TB diagnosis in HIV-positive adults in Asia, examining socioeconomic risk factors for infection, was commenced. A case-control study of risk factors for suicide in HIV-positive adults in Australia was also begun. A trial of scabies treatment in Fiji was initiated. Finally, the extensive approvals required for a linkage study of the Health in Men and Positive Health studies with the National Death Index and hospitalisation databases was put in place. All these studies are expected to provide exciting research outputs in 2013 and beyond.

2012 was an active year for research outputs in a number of areas. Methodological work included an adaptive Markov chain Monte Carlo for epidemic modelling of HPV; the use of semiparametric regression models in HIV prevention research; and reclassification metrics to evaluate survival prediction

equations in HIV-positive patients. Analyses of observational cohort data showed that in HIV-positive adults successfully treated with antiretrovirals, life expectancy approached that of the general population, and that long-term CD4 count responses showed no evidence of declining in older patients. A diabetes risk prediction model was also developed for HIV-positive patients that should aid identification and patient management of pre-diabetes. Predictors of lost to follow-up were examined in HIV-positive patients receiving treatment in Asia, and found the optimal definition of lost to follow-up was no clinical contact for 180 days. Advanced statistical analysis of HIV surveillance data indicated a reduced impact of antiretroviral treatment among injecting drug users. Finally, hepatitis C treatment outcomes in routine care in Australian clinics were evaluated.

Professor Matthew Law, head of the Biostatistics Program, has been at the Kirby Institute for almost twenty years. His group plays a key support role to other academic programs but has also independent research activities in cohort studies, mathematical modelling, linkage studies and complex statistical analyses.

THE HIV EPIDEMIOLOGY AND PREVENTION PROGRAM

The HIV Epidemiology and Prevention Program (HEPP) conducts research into the transmission and prevention of HIV and sexually transmissible infections (STIs), and on the natural history of HIV. We work in partnership with communities most affected by HIV, particularly the gay community and those people living with HIV. HEPP works across the spectrum of biomedical, behavioural and structural prevention, because effective HIV prevention acknowledges the complexities of everyday life for at-risk communities. Their work includes behavioural risk surveillance, studies of risk behaviour, and studies of use of biomedical preventive interventions. Researchers in HEPP conduct a range of work on the intersection of infection, immunity and cancer to inform our knowledge of how we might prevent cancer in people with HIV. A particular focus is the prevention of anal cancer in gay men.

Highlights of 2012 for the HIV Epidemiology and Prevention Program include the commencement of enrolment into the NHMRC funded Opposites Attract project. Opposites Attract is a five year cohort study of HIV transmission in HIV serodiscordant gay couples. The study is examining the effect of HIV treatment and HIV viral load on sexual risk behaviour and the rate of HIV transmission. Data from the study will be critical in informing the development of biomedical HIV prevention policies in Australia. Complementing Opposites Attract is the TAXI-KAB study which is collecting baseline information about gay men's knowledge, attitudes and beliefs about recent changes in biomedical prevention of HIV and in HIV testing procedures and technologies. These data will be key to assessing any changes in understanding of these issues over coming years. The first three year funding period of the national HIV Seroconversion Study was completed in June, with nearly 500 recently diagnosed individuals having been enrolled into the study. The study report was launched in Melbourne at the annual ASHM conference. The next funding period will commence at the start of 2013. Recruitment for the NHMRC-funded Study of the Prevention of Anal Cancer neared completion, and baseline data were presented at the 28th International Papillomavirus Conference in Puerto Rico.

Professor Andrew Grulich heads the HIV Epidemiology and Prevention Program with a focus on cohort studies in at risk populations linked to behavioural and biomedical prevention of HIV and sexually transmitted infections. These types of research are central to the evaluation of biomedical preventions strategies such as vaccines, microbicides and chemoprophylaxis. Professor Grulich is also a world authority on the serious emerging issue of cancer in HIV. Andrew has been at the Kirby Institute for 20 years.

THE IMMUNOVIROLOGY AND PATHOGENESIS PROGRAM

The activities of the IVPP during 2012 can be divided into three categories. All involve substantial, daily interaction with the Immunovirology group at St Vincent's Centre for Applied Medical Research, which is collocated with IVPP.

A substantial proportion of laboratory-based activity involved provision of routine or semi-routine laboratory support, essential for the successful conduct of clinical trials and epidemiological studies conducted by the Kirby Institute. This section of the laboratory continued to perform well in external QA programs. The laboratory acted as the central global laboratory for flagship Kirby Institute studies such as SECOND-LINE, ENCORE, MARCH, and ATAHC II. Collaborative strategies were further developed to streamline the conduct of the laboratory aspects of these large complex trials. The laboratory completed extensive optimisation and verification studies of DNA-based viral tropism assay which was then successfully transferred to the NSW State HIV Reference Laboratory at St Vincent's. The laboratory played a substantial role in the development of an external QA program for viral tropism that was used to qualify laboratories both in Australia and overseas for conduct of assays for the MARCH Study. The laboratory also completed all the central resistance and viral load testing for the SECOND-LINE study and has commenced performing similar assays for ENCORE.

The second critical component of the program was the continued conduct of clinical trials and natural history studies in pathogenically informative populations of patients with HIV-infection such as those with primary infection and long term non-progressors. These cohorts continued to provide valuable material for productive collaborations particularly with Stephen Kent's group at the University of Melbourne and Martyn French's group at Royal Perth Hospital. Further, the primary infection database continued to provide data to the European collaborative effort CASCADE. Each of these collaborations resulted in several peer reviewed publications in 2012. In addition, these cohorts were used for a range of studies conducted within the program including studies providing insight into new regulatory pathways of T-cell function involving micro-RNAs which in turn appear to impact on rates of progression of HIV-infection. This work was accepted for publication during 2012 and attracted editorial commentary in the European Journal of Immunology.

Senior scientists and academics within the program were responsible for their own research projects on pathogenesis and development of therapeutics. In 2012, a paper demonstrating the utility of a patented, simple T cell assay as assisting the diagnosis of latent TB was published. These results were derived from twin studies conducted in Sydney and Bangkok, in collaboration with HIV-NAT. In addition, the initial analyses

of the first year of the PINT study, which provided new insights into dynamics of establishment and maintenance of the viral reservoir, were published in two separate manuscripts. Samples from this trial were a major focus of on going work in the laboratory in 2012. Further, insights into the mechanisms underlying the maintenance of the viral reservoir were sought from the elucidation of the relative infection rates of various T-cell subsets and their turnover rates. Developmental work for the characterisation of viral DNA load and phylogenetic profiles of virus-infected, antigen-specific CD4+ T-cells was carried out. This sophisticated work is only possible using a combination of molecular and cellular assays developed within the laboratory. These and other studies involving identification of lymphocyte subsets were aided by an upgrade of our flow cytometer to a 3 laser machine capable of analysing 15 parameters simultaneously. This was achieved through the award of an equipment grant, allowing a machine purchased in 2003 to remain state of the art.

During 2012 the first in vivo testing of our unique siRNAs that induce prolonged transcriptional gene silencing of HIV-1 in a Hu-SCID mouse model were completed with our Japanese collaborators. These experiments provided very encouraging data regarding the ability of these constructs to suppress viral replication when delivered by retroviral constructs. Further, the results of elegant molecular and confocal microscopy demonstrating that these constructs work in the nucleus in concert with Ago1 were published. The proposed development of these constructs was supported through the award of an NHMRC project grant to commence in 2013.

In 2012 Dr Stuart Turville and his HIV Biology Group had their work on the visualisation of the mechanisms of viral interaction with filopodia on dendritic cells and how this allows increased infection of CD4+ T cells was published in *Plos Pathogens*. The further development of this work was supported by the NHMRC with the funding of a project grant lead by Stuart to commence in 2013. Stuart was also successful in attracting funding for the upgrading of the DeltaVision Elite microscope housed within the St Vincent's AMR PC3 laboratory. This upgrade, which will occur early in 2013, will allow high through-put, and high resolution imaging of the interactions between virus and subcellular compartments in live cells in real time.

At the end of 2012, the laboratory took delivery of sophisticated confocal endo-microscope from Optiscan. It will be used with collaborators at the Garvan Institute of Medical Research and St Vincent's Hospital to visualise dynamic changes in the integrity of mucosal surfaces and for the monitoring real time of mucosal immune responses in vivo.

The overall quality of the work generated by the program and its ability to collaborate effectively to produce high quality clinically important results was recognised through the awarding of a highly prestigious NHMRC program grant to commence in 2014 through to a group of investigators, including the head of the IVPP.

Professor Tony Kelleher is head of the Immunovirology and Pathogenesis Program, and works closely at a laboratory level with colleagues from SVH. The program provides lab support across the organisation, as well as conducting world-class research, presently focussed on the design and development of novel assays, and the study of micro RNAs, fine mapping of T-cell function, and the transcriptional gene silencing of HIV by siRNA.

Dr Stuart Turville

Dr Turville's research career started with a BSc Hons (First class and John Elliot Prize for Best Thesis in Animal Biology) and followed with an Australian Postgraduate Award for PhD studies at the University of Sydney on the mechanism of HIV transmission in dendritic cells.

JUSTICE HEALTH RESEARCH PROGRAM

The Justice Health Research Program was established at the Kirby Institute in January 2011. Designed to complement the KI approach to health and human rights, particularly among marginalised populations, the program has a particular focus on Australia's offender population. The Justice Health Research Program undertakes research into a broad range of health issues affecting offender populations including communicable diseases, access to hepatitis C treatment in prison, Aboriginal health, mental health, sexual health, tobacco smoking, impulsivity, and alcohol use.

2012 saw the Justice Health Research program grow in terms of projects and staff joining the team. The program received NHMRC funding to look at the sexual health, attitudes to sex and reproductive health of young offenders in the community and custody (the JOSH study). The JOSH study complements the highly productive Sexual Health and Attitudes of Australian Prisoners (SHAAP) survey of adult offenders. Funding was received in 2012 from the Lowitja Institute to examine the community's attitudes to the treatment of offenders using a Citizen's Juries approach pioneered by the late Professor Gavin Mooney.

The program continues to hosts the NHMRC capacity building grant in Indigenous offender health, which has a cohort of Aboriginal researchers across Australia examining a range of issues including justice reinvestment, alcohol programs for Aboriginal men in custody, youth trajectories into crime, the health needs of Aboriginal prisoners, and the role of social support and families in post-release integration. Paul Simpson joined the team as the Indigenous Offender Health Capacity Building Group (IOHR-CBG) coordinator, and has also commenced working on collaborative projects looking at justice reinvestment and transgender prisoner policies.

Other NHMRC funded projects that continued during 2012 included the Hepatitis C, Prisons and Treatment Opportunities (HePATO)' study, and the AusAID funded study 'Strengthening China's response to HIV, TB and HIV/TB co-infection in labour camps (*lao jiao suo*) in Guangxi Autonomous Region: developing a prevention model to inform national policy'.

Joanne Reekie also joined the program working on a range of projects as support statistician.

Professor Tony Butler is the inaugural head of the Justice Health Research Program. He has researched health issues in the criminal justice system for more than a decade. Professor Butler's research focus includes the surveillance of bloodborne viruses and sexually transmissible infection among prison entrants nationally, work on establishing the National Prisoner Health Indictor Project, conducting Australia's largest epidemiological survey of prisoners' mental health and research into traumatic brain injury among prisoners. He is a key member of a group undertaking research into smoking cessation among prisoners.

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THE PUBLIC HEALTH INTERVENTIONS RESEARCH GROUP

The Public Health Interventions Research Group (PHIRG) undertakes a diverse range of projects that focus on the evaluation of strategies to prevent infectious disease. The program collaborates extensively, both within the Kirby Institute and externally, and emphasises research that benefits the health of disadvantaged populations in Australia and the Asia-Pacific Region. Much of their work also has a strong capacity-building component. The group is currently involved in projects related to the control of HIV, sexually transmissible infections, viral hepatitis, tuberculosis, scabies and trachoma. Countries of activity include Australia, Papua New Guinea, Indonesia, Cambodia and Fiji.

In 2012, Bette Liu undertook and published a linkage study that demonstrated a strong downward trend in chronic hepatitis B infection among pregnant women in the Northern Territory, where the neonatal vaccination program was commenced more than twenty years ago. The program also completed the largest study ever undertaken of hepatitis B infection in New South Wales by country of birth. Also completed, as part of a collaboration with the Royal Women's Hospital in Melbourne, was the first survey in the world to demonstrate a decline in human papillomavirus infection following the implementation of the national vaccination program. In conjunction with the other Kirby Institute programs, PHIRG continued work on national trachoma surveillance and; its second annual surveillance report from was also released. Andrew Vallely, on secondment to the Papua New Guinea Institute of Medical Research, continued to build the research program on male circumcision in Papua New Guinea and its link to sexual health, culminating in several published reports. He also embarked on new projects in sexually transmitted infection and the control of human papillomavirus and its complications. The project, evaluating interferon gamma release assay for diagnosis of children with suspected tuberculosis in PNG, was published in 2012. Through a successful competitive application, AusAID provided renewed funding for the Field Research Training Program (FRTP) in Indonesia and Cambodia, which is designed to assist emerging public health researchers to develop skills and experience in longitudinal health studies. Bradley Mathers was awarded a NHMRC early career fellowship, to commence in 2013.

Professor John Kaldor is an NHMRC Senior Principal Research Fellow and Professor of Epidemiology.

THE SEXUAL HEALTH PROGRAM

The Sexual Health Program leads and supports research into the epidemiology, surveillance, microbiology, clinical management and prevention of sexually transmissible infections (STIs). The program is also involved in research into the behaviour and sexual health of priority populations for STI control such as youth, men who have sex with men (MSM), sex workers, Aboriginal and Torres Strait Islander people, prisoners and travellers.

The program works closely with several programs within the Kirby Institute. Other collaborators include: a national network of 25 specialist sexual health services; research laboratories in Sydney, Melbourne, Brisbane and Papua New Guinea; the School of Population Health at the University of Melbourne; the Burnet Institute in Melbourne; the National Aboriginal Community Controlled Health Organisation; BakerIDI in Alice Springs; and the Menzies School of Health Research in Darwin.

This was another busy and productive year. In 2012 several new joint projects were developed with the Sydney Sexual Health Centre. Methodologies used by the program range from descriptive epidemiology with novel analytical techniques, molecular epidemiology, enhanced surveillance strategies, data linkage studies, social and behavioural research, test evaluations, detecting antimicrobial resistance, evaluating and improving health care delivery, legal and policy research, anthropology, and biomedical prevention trials.

In March, the program launched a report called *The Sex Industry in New South Wales*, commissioned by the NSW Ministry of Health. The report favourably evaluated the long-term impact of the decriminalisation of sex work and made recommendations to inform future policy development.

In conjunction with the Burnet Institute, the Sexual Health Program continues to steer the Australian Collaboration for Chlamydia Enhanced Sentinel Surveillance (ACCESS), which uses routine clinical data to complement routine notification data and evaluate clinical service strategies. Over 100 clinical sites participate in ACCESS, each providing a core set of routinely collected data in de-identified line-record format which are extracted on a six-monthly basis. The ACCESS network provided the first reliable means of interpreting trends in national rates of chlamydia diagnoses. Plans are well advanced to expand the range of STIs and risk behaviours captured by ACCESS. In addition, the program's national genital warts surveillance system documented a dramatic population-level reduction in warts as a result of the national HPV vaccination program.

The Sexual Health Program also continued its involvement in the Australian Chlamydia Control Effectiveness Pilot (ACCEPt), led by Associate Professor Jane Hocking at the University of Melbourne. ACCEPt is the first study to assess the population impact of annual chlamydia screening in primary care on the prevalence of chlamydia using a randomised controlled study design.

Continuing the program's commitment to innovative research aimed at improving testing for STIs, the chlamydia re-test trial (REACT), funded by the NHMRC STI Program Grant, uses a randomised controlled design to assess the effectiveness of coupling SMS reminders with home-based self-collected samples in improving the uptake of chlamydia re-testing. Regular testing and re-testing for HIV and other STIs in high risk populations is recognised as a key control strategy. NSW Health has funded the eTEST intervention which is designed to increase the frequency of HIV/STI screening in 'high risk' MSM through a novel multi-faceted intervention using decision support software coupled with other evidence-based strategies. This project involves 10-12 general practice clinics in Sydney and Melbourne that see a high case load of MSM.

Rebecca Guy leads the NHMRC-funded Test, Treat and Go (TTANGO) Project: a trial of a novel nucleic acid amplification point-of-care test for chlamydia and gonorrhoea (GeneXpert®). The trial uses a cross-over, cluster-randomised design in 12 remote Aboriginal communities in northern Queensland, Western Australia and South Australia. During 2012, the laboratory evaluation of the testing system was successfully completed and field evaluations began. The Sexual Health Program was also involved in the multi-centre (Sydney, Melbourne and Goroka) laboratory-based evaluation of six rapid point-of-care tests for syphilis.

The program continued to provide clinical and technical support to several large trials of sexual health care quality improvement in Aboriginal medical services, including the STRIVE Project (WA, NT, and Qld), the NHMRC Centre for Clinical Research Excellence in Aboriginal sexual health (NSW, SA, Qld, and Vic), and the SHIMMER Project (NSW).

The program had a strong presence at the IUSTI World STI & HIV Congress in Melbourne in October with 18 presentations. Program staff also accepted invitations to present their research in Brazil, Canada, Turkey, the UK and Chile.

THE SURVEILLANCE AND EVALUATION PROGRAM FOR PUBLIC HEALTH

The Surveillance and Evaluation Program for Public Health (SEPPH) monitors the pattern of transmission of HIV, viral hepatitis, specific sexually transmissible infections, transfusion transmissible infections, and trachoma in Australia. The program assesses past and expected epidemic trends, and evaluates the epidemiological impact and cost-effectiveness of public health intervention strategies through various trial designs and retrospective analyses. SEPPH also conducts efficiency studies of HIV programs and informs national strategic planning, including optimal resource allocation and financing with primary focus in Asia and Eastern Europe.

Blood-borne viral and sexually transmissible infections (STIs) surveillance activities are conducted in collaboration with the Australian Commonwealth Government Department of Health and Ageing, State and Territory health authorities and collaborating networks. Analyses and interpretation of recent trends in new diagnoses of HIV, viral hepatitis and STIs, and estimates of prevalence and incidence in key population subgroups are published in our Annual Surveillance Report. Publicly released datasets on new HIV and AIDS diagnoses are also available for download. SEPPH, is a collaborating unit of the Australian Institute of Health and Welfare. The program collaborates with the Australian Red Cross to conduct surveillance of transfusion transmissible infections among blood donors in Australia. In collaboration with the Office of Aboriginal and Torres Strait Islander Health of the Department of Health and Ageing and other Kirby Institute Programs, SEPPH coordinates national surveillance and reporting of trachoma among Aboriginal communities.

In 2012, SEPPH released a number of Surveillance Reports, including the sixteenth annual review of available surveillance data pertaining to the occurrence of 'HIV, viral hepatitis and sexually transmissible infections in Australia', and the sixth annual 'Blood-borne viral and sexually transmitted infections in Aboriginal and Torres Strait Islander people: Surveillance and Evaluation Report'. Surveillance activities and analyses of transfusion transmissible infections in Australia were once again conducted, which led to the second-annual 'Transfusion Transmissible Infections in Australia Surveillance Report'. Cross-program contributions resulted in advancement of the National Trachoma Surveillance and Reporting Unit at UNSW and the production of the second UNSW trachoma report 'Australian Trachoma Surveillance Report 2011', due for publication in 2013. Further cross-program collaboration resulted in the release of the National BBV and STI Surveillance and Monitoring Plan which will be followed by SEPPH in the production of an annual report for monitoring progress against the latest blood-borne viral and STI national strategies.

SEPPH advanced its international expertise, working in collaboration with the World Bank Group, to commence a project to contribute to the improvement of the effectiveness and efficiency of HIV prevention responses in Asia's concentrated HIV epidemic settings. Extensions of this work involve studies around evaluation, health economics, efficiency and financing for informing Ministries of Health and Ministries of Finance in many countries. SEPPH currently conducts analyses in: Malaysia, Myanmar, Nepal, Thailand, China, Philippines, Cambodia, Indonesia, Vietnam, Jamaica, Malawi, Nigeria, Swaziland, Zimbabwe, Ukraine, Moldova, Armenia, Belarus, Tajikistan, Estonia, Georgia, Kazakhstan, and Russia.

Associate Professor David Wilson, head of the Surveillance and Epidemiology Program for Public Health, has presided over a restructure and expansion of our surveillance work in the few short years since he joined the Kirby Institute. His program has extended its standing monitoring of HIV, viral hepatitis, and specific sexually transmissible infections to other surveillance activities as well as to the assessment of past and expected epidemic trends, and more recently to impact evaluation, cost-effectiveness and efficiency studies of HIV programs.

THE THERAPEUTIC AND VACCINE RESEARCH PROGRAM

The Therapeutic and Vaccine Research Program (TVRP) conducts a range of clinical trials designed to assess the effectiveness of new HIV therapies and therapeutic strategies. These studies provide data that have an impact on policy and clinical practice, in both resource-rich and resource-limited settings. The TVRP provides leadership through the program's role as an international co-ordinating centre for the INSIGHT network, a major international collaboration for the conduct of large clinical endpoint strategic trials in HIV disease which has more than 300 sites in 30 countries. In parallel, the TVRP co-ordinates the activities and operations of an international network in over 20 countries on seven continents in which investigator-initiated research is performed.

Investigator-initiated research

The SECOND-LINE study completed enrolment in September 2011 and 48 week follow-up concluded in September 2012. This clinical trial was designed to compare the safety and efficacy of ritonavir-boosted lopinavir (r/LPV) + 2-3N(t)RTI with r/LPV + raltegravir in participants virologically failing first-line therapy. Preliminary results were presented at CROI 2013. The experimental regimen was non-inferior to the standard of care regimen. Follow-up of the cohort with additional and ongoing analyses will further illuminate the care of people who have failed first line therapy.

The ENCORE1 study commenced recruitment in 2011, with all sites opening for recruitment in the period between August and December. A total of 636 patients were randomised in a period of approximately nine months. Results from the first 48 weeks of this study will be available in mid-2013.

The MARCH study continued to recruit during 2012 through a network of 63 clinical centres. The first patients were randomised in September 2011. Results of the QA/QC program have been accepted for publication and recruitment will be completed in August 2013.

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INSIGHT research

The START study has now recruited close to 4000 subjects with final participants to be recruited by December 2013 based on a re-estimation of sample size to 4600. This large study with seven nested substudies addresses the question of when to start antiretroviral therapy based on CD4+ cell count. The TVRP co-ordinates this trial at more than 40 centres in nine countries. The estimated completion date for the trial is 2016.

The FLU studies (002, 003 and 004) have continued to recruit patients with, initially, pandemic H5N1 swine variant influenza, but more recently with all seasonal influenza-like illnesses. The TVRP coordinates these studies in six countries that have recruited approximately 2000 subjects.

Professor Sean Emery is head of the Therapeutic and Vaccine Research Program. He has been at The Kirby Institute for 20 years and is a recognised expert in HIV therapeutic research and the design, conduct and reporting of clinical trials. He is a recognised leader in clinical trial research providing expert advice to UK NHS/MRC, US NIH, NSW Cancer Institute and NHMRC.

THE VIRAL HEPATITIS CLINICAL RESEARCH PROGRAM

HCV therapeutic development continued in 2012 with the first phase III interferon-free trials with new direct-acting antiviral (DAA) agents for the treatment of chronic hepatitis C infection commencing. The rapidly changing HCV therapeutic landscape should provide considerable opportunity for phase IV clinical trials over the next two-to-five years, particularly in specific sub-populations and indications not addressed in phase II/III development. The Viral Hepatitis Clinical Research Program, was established in 2003 and continues to demonstrate national and international leadership in HCV research, particularly in key affected communities such as people who inject drugs and HIV coinfected populations.

The program has three main areas. Clinical research including clinical trials forms the main part of the program's work. The second component is molecular virology and host genetic research utilising samples from HepBank, the program's viral hepatitis sample repository. The third component is epidemiological research through data linkage studies and mathematical modelling.

In addition to chronic HCV research, the program, also has interest in the natural history of newly acquired HCV and treatment of acute and chronic HCV, particularly in the setting of injecting drug use and a strong interest in HIV/ HBV coinfection. The program's laboratory research focuses on superinfection / mixed infection, protective immunity, host genetics, phylogenetics and transmission dynamics and the incidence and prevalence of viral mutations that impart resistance to the new therapies. The Viral Hepatitis Clinical Research Program liaises with all other programs within the Kirby Institute, as well as with hepatologists, infectious disease physicians and primary care networks nationwide. The ACTIVATE study, which is evaluating the safety and efficacy of individualised treatment with pegylated interferon and ribavirin, commenced recruitment through a newly established international network.

Several new projects commenced or were funded in 2012. VHRCP was awarded funding from Janssen to conduct DARE-C, a study evaluating the feasibility of response guided triple therapy of telaprevir, pegylated interferon 2b and ribavirin in recently acquired genotype 1 infection. The ATAHC Recall study, which aims to examine the long term outcomes of participants enrolled in the original Australian Trial in Acute Hepatitis C study (NIH funded 2004-2009), commenced at three Australian sites. The ETHOS study completed recruitment with a total of 440 subjects enrolled from nine opiate substitution clinics and primary care clinics in NSW. The ACTIVATE study, a clinical trial of response guided treatment for chronic hepatitis C genotype 2/3 infection in current injection drug users, commenced recruitment in Canada and Australia. The study will also enrol patients through sites in five European countries and 2012 was focussed on obtaining ethical and regulatory approval in these countries.

In 2012 Professor Greg Dore was elected to the NHMRC Council and was also awarded a five-year NHMRC Program Grant. Dr Gail Matthews was awarded a four-year NHMRC Career Development Fellowship.

Professor Greg Dore heads the Viral Hepatitis Clinical Research Program which investigates therapeutic strategies for people infected with hepatitis B or C and particularly those for acute and chronic hepatitis C among people who inject drugs. He has been at the Kirby Institute for more than 18 years.

THE VIRAL HEPATITIS EPIDEMIOLOGY AND PREVENTION PROGRAM

The Viral Hepatitis Epidemiology and Prevention Program (VHEPP) aims to conduct rigorous research that is ethical, innovative and makes a difference. The program is committed to working in partnership with affected communities in Australia and internationally to achieve key goals. Program objectives are to:

- · Conduct epidemiological, social and behavioural research examining viral hepatitis and other infections in vulnerable populations, including people who inject drugs (PWID) and female sex workers (FSW)
- Develop and trial interventions designed to prevent infectious diseases in vulnerable populations
- · Initiate and support surveillance activities including monitoring trends in anti-HIV and anti-HCV prevalence and risk behaviour among PWID
- \cdot Translate research outcomes into public health policy and practice
- · Build capacity for research, surveillance and harm reduction within Australia and the region through the provision of training and technical assistance.

Highlights of 2012 included completion of the first-ever trial of a brief intervention designed to increase clinical trial literacy and willingness to participate in future candidate hepatitis C vaccine trials among people PWID. Conducted as part of the NHMRC-funded program of HCV vaccine preparedness studies, early results indicate an improvement in clinical trial literacy, with a significant increase in the mean number of correct responses 24 weeks post-intervention. Other VHEPP projects completed in 2012 included the Young Women's Health Study, a collaboration between UCSF, the Kirby Institute, NCHADS and the Cambodian Women's Development Association; and a cluster randomised trial of non-pharmaceutical protection against influenza in Vietnam in collaboration with the School of Public Health and Community Medicine at UNSW.

In 2012 a new NIH subcontract for the Cambodia Integrated HIV and Drug Prevention Implementation Program. Using a randomised cluster trial, this study will examine the impact of conditional cash transfer and microfinance interventions on HIV risk and ATS use among FSWs in ten provinces in Cambodia. Other new projects included an NIH-funded collaboration with the British Columbia Centre for Excellence in HIV/AIDS to evaluate the impact of social, structural and environmental factors on HIV risk, incidence and treatment outcomes among PWID and FSW. Also in 2012, VHEPP NHMRC post-doctoral fellow Jo Kimber, and Lisa Maher received funding from the Centre for Research Excellence into Injecting Drug Use (CREIDU) to conduct a ten year mortality follow-up of the HCV cohort using linkage to the National Death Index to determine causes of death and mortality risk factors in this group. Recruitment and follow-up for the Hepatitis Incidence and Transmission Study - community (HITS-c) also continued during 2012 with more than 180 anti-HCV negative PWID enrolled and 25 incident cases observed to date (8.45/100 person years).

Among the 53 papers published (and in press) by VHEPP staff and students in 2012 were the first published report of the epidemiology of human papillomavirus infection among young FSWs in Cambodia in BMC Infectious Diseases, a paper by Anna Olsen examining the health beliefs and behaviours of women living with hepatitis C in the International Journal of Drug Policy, a report by Bethany White in the Australian and New Zealand Journal of Public Health on the epidemiology of hepatitis B virus in PWID, and a study by Ju Park examining factors influencing willingness to participate in candidate HCV vaccine trials among PWID in Drug and Alcohol Dependence. Also in 2012, Lisa Maher and Nick Walsh co-edited a special issue of Current Opinion in HIV and AIDS on injecting drug use and HIV, and Rachael Green (National Drug Research Institute cosupervision) was awarded a PhD for her thesis An ethnographic study of recreational drug use and identity management among a network of electronic dance music enthusiasts in Perth, Western Australia.

Professor Lisa Maher is head of the Viral Hepatitis Epidemiology and Prevention Program and an NHMRC Senior Research Fellow. She conducts ethnographic, epidemiological and clinical research with a focus on interventions designed to prevent infectious diseases in vulnerable populations, including people who inject drugs and female sex workers.

RESEARCH ACTIVITIES

ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH PROGRAM 2012 STUDIES

STRIVE

This study is a cluster randomised trial with an intervention of a sexual health quality improvement program (SHQIP) aimed at reaching best-practice targets in STI control. It is located in 68 remote communities, comprised of 23 clusters of communities, in the Northern Territory, Western Australia and Far North Queensland. Baseline prevalence data for chlamydia, gonorrhoea and trichomonas has been collected from 64 of 68 health services that are participating in the trial and prevalence assessment reports have been fed back to health services. STRIVE coordinators have completed a baseline systems assessment for health services that were randomised to year one of the SHQIP and implemented sexual health action plans with goals set to improve sexual health service delivery. Coordinators have conducted three and six month visits of randomised health services with reports of STI testing activity derived from lab data presented to services.

Status: All participating sites will receive the intervention and the trial is currently in the second year of the activated arm. Year three sites are due to commence the intervention from May 2013 onwards. STRIVE field coordinators are conducting site visits to provide feedback on STRIVE best practice target activity prior to the intervention and since the sexual health quality improvement program commenced. Modifications have been made to patient information systems with the inclusion of STI templates, STI clinic reports are under development, tailored action plans have been developed and the first round of incentive payments have been sent to health services based on their progress towards best practice targets.

Personnel: John Kaldor, James Ward, Alice Rumbold, Rebecca Guy, Robyn McDermott, Lisa Maher, Basil Donovan, Linda Garton, Christopher Fairley, Bronwyn Silver, Janet Knox, Belinda Hengel, David Glance, Skye McGregor, Donna Ah Chee, John Boffa, Steven Skov, Debbie Taylor-Thomson Funding: NHMRC Project Grant

REACCH: Research Excellence in Aboriginal Community Controlled Health

REACCH is a collaborative project led by the Kirby Institute and NACCHO working with four Aboriginal Community Controlled Health Services in urban and regional areas. REACCH works with services to conduct community-driven clinical research with the potential to lead to improved health outcomes, foster training of clinical researchers working within Aboriginal Community Controlled Health Services and ensure effective translation of research outcomes into clinical practice. Status: A group quality improvement project is underway with six monthly reporting of STI and BBV testing and outcomes with CQI visits underway in several services. Service-led projects are under way or under development in three services and two Aboriginal researchers have been appointed with REACCH funding to lead these projects. Personnel: John Kaldor, James Ward, Dea Delaney Thiele, Sophie Couzos, David Scrimgeour, Jenny Hunt, Greg Dore, Basil Donovan, Mary Ellen Harrod, Mark Saunders, Sid Williams, Peter Waples-Crowe, Julie Mooney-

Funding: NHMRC Centre for Clinical Research Excellence (CCRE)

GOANNA

The first Australian study assessing knowledge, risk behaviours and health service access in relation to sexually transmissible infections and blood borne viruses of young Indigenous people. This is the first-ever Australian study describing levels of knowledge, risk practice and access to health services in relation to sexually transmissible infections (STIs) and blood borne viruses (BBVs) of young Aboriginal and Torres Strait Islander people aged 16 to 30 years. Status: Currently underway; 40 survey collections sites completed Personnel: James Ward, Heather Worth, Donna Ah Chee, John Kaldor, Smith A, Marion Pitts, Joanne Bryant Funding: Australian Research Council (ARC) Linkage Grant

Australian Chlamydia control effectiveness pilot (ACCEPt) study

Current national guidelines for general practitioners (GPs) recommend all sexually active people aged 15-29 years old receive annual testing for chlamydia. More than 80% of 15-29 year-olds attend a GP each year however less than 10% are being tested for chlamydia by their GP. ACCEPt involves a multifaceted intervention in the GP setting to maximise testing rates and annual testing in sexually active 16-29 year-olds to see if it can reduce the prevalence of chlamydia infections and associated complications such as pelvic inflammatory disease (PID). This is the first trial of this nature in Australia and is being led by the Centre for Women's Health, Gender and Society at the University of Melbourne in collaboration with a large consortium of experts including a number of researchers from the Kirby Institute. In addition, the Kirby Institute has been contracted to develop the

protocol for program evaluation, conduct mathematical modelling, and assist with implementation.

Status: 48 postcodes have been recruited. Personnel: Rebecca Guy, John Kaldor, Basil Donovan, David Regan, David Wilson, Matthew Law, Rebecca Lorch, Lisa Edward, James Ward, Belinda Ford Collaborators: Jane Hocking, Meredith Temple-Smith, Jenny Walker, Simone Poznanski, Alaina Vaisey, Dyani Lewis, Jane Gunn, Christopher Fairley, Nicola Low, Marian Pitts, Marion Saville, Dorota Gertig, Sepehr Tabrizi, Margaret Hellard Funding: Australian Government Department of Health and Ageing Chlamydia Pilot Program. Further funding from NHMRC Project grant from 2011. **Co-location:** Sexual Health Program, Public Heath Interventions Research Group, Biostatistics and Databases Program, Aboriginal and Torres Strait Islander Health Program

An Evaluation of Aboriginal Sexual and Reproductive Health and Viral Hepatitis Program in selected Aboriginal Community Controlled Health Services

This evaluation program seeks to examine changes in service delivery within selected Aboriginal Community Controlled Health Services (ACCHS) throughout NSW. Sexually transmissible infections (STIs) for Aboriginal youths aged 16-25 years of age and blood-borne viral (BBV) infections for patients aged 16-54 years will be monitored over time by examining the number of diagnostics tests conducted in relation to occasion of service, rate of positive test results and care and management of diagnosis (with particular regards to viral hepatitis). A further component of this program will be to examine demographic and behavioural correlates of sexual and reproductive health knowledge and risk behaviours. This evaluation aims to determine if a continuous quality improvement program can improve STI/ BBV testing and management practices in Aboriginal Community Controlled Health Services throughout NSW.

Status: Evaluation updates have been presented at several national conferences. Personnel: John Kaldor, Handan Wand, Rebecca Guy, Brigitte Gerstl, Amalie Dyda, Andrew Nakhla, Mary Ellen Harrod, Stephen Anthony, James Ward (Baker IDI), Douglas Boyle (Melbourne University)

Collaborating centres: Family Planning NSW; AH&MRC; Bulgarr Ngaru Aboriginal Community Controlled Health

Service; Biripi Aboriginal Corporation Medical Centre Taree; Coomealla Health Aboriginal Corporation; Coonamble Aboriginal Health Service; Griffith Aboriginal Medical Service; AMS Western Sydney; Hunter New England Health; National Centre in HIV and Social Research

Funding: NSW Health

SHIMMER: NSW Aboriginal Health Research Program

This project is trialling a sexual health and quality improvement program designed to improve STI/BBV testing and management at four Aboriginal Community Controlled Health Services in NSW. The project aims to increase STI/BBV testing, re-testing and follow-up. Another aim is to improve the clinical management and ongoing monitoring of patients diagnosed with chronic hepatitis B and hepatitis C. The overall aim of SHIMMER is to incorporate sustainable sexual health testing and management processes in each participating ACCHS, irrespective of staff turnover. Status: Since March 2012, SHIMMER researchers have been visiting the participating ACCHS and meeting with clinic staff who have been developing long term sustainable STI testing and management strategies for their ACCHS and communities. Overall, the proportion of 15-29 year-olds tested for chlamydia and gonorrhoea has increased. SHIMMER will be conducting a second audit in March 2013 to examine STI and hepatitis C management.

Increasing completeness of 'Aboriginality' in infectious diseases data through record linkage – a feasibility study

Personnel: James Ward, Basil Donovan,

Rebecca Guy, Simon Graham, Janet

Knox, Handan Wand, John Kaldor

Funding: NSW Health

The aim of this project is to link notifiable diseases database with other health data and provide availability and validity of epidemiological data on notifiable diseases in Aboriginal people in NSW, so that incidence and prevalence of these diseases can be more accurately estimated. The objective of this project is to link records from the Notifiable Diseases Database (NDD) with other routinely collected population health databases to prepare a de-identified 'snapshot' dataset, with improved completeness of Aboriginal status.

Status: Linkage complete; data analysis and interpretation underway Personnel: Jeremy McAnulty, James Ward, Amalie Dyda, Paula Spokes, Jenny Hunt, Mark Bartlett Funding: NSW Health

BIOSTATISTICS AND DATABASE PROGRAM 2012 STUDIES

The Australian HIV Observational Database (AHOD)

Observational cohort study of patients with HIV. Demographic, clinical and treatment data are aggregated twice each vear via electronic data transfer. Status: The study commenced in December 1999 and currently has 26 active sites contributing data twice yearly on a total of >3500 enrolled patients. Personnel: Hamish McManus, Stephen Wright, Courtney Bendall, Kathy Petoumenos, Matthew Law **Collaborators:** Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia Funding: Foundation for AIDS Research (amfAR) via a US National Institutes of Health grant through the International Epidemiologic Databases to Evaluate AIDS collaboration; consortium of pharmaceutical companies.

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

This large, international, collaborative study is aimed at assessing the medium to long-term effects of antiviral treatment of people with HIV in terms of possible increased risk of cardiovascular events. **Status:** The study combines data from 11 cohorts, including more than 33,000 patients. Australia contributes 706 patients from the Australian HIV Observational Database.

Personnel: Hamish McManus, Stephen Wright, Kathy Petoumenos, Matthew Law Collaborators: Network of clinical sites (GPs, hospitals and sexual health clinics) throughout Australia; Copenhagen HIV Programme, Hvidovre University Hospital Funding: European Agency for the Evaluation of Medicinal Products (EMEA)

The Australian HIV Observational Database (AHOD) STI project

Sexual health clinics in AHOD will contribute data on sexually transmissibly

infections and treatment in patients recruited to AHOD.

Status: Protocol agreed with 11 sites involving around 900 patients. Protocol is under review by ethics committees. First data transfer and analysis in March

Personnel: Kathy Petoumenos, Hamish McManus, Stephen Wright, Courtney Bendall, Matthew Law

Collaborators: Network of 11 Australian sexual health clinics

Funding: National Health and Medical Research Council, NIH, EMEA and pharmaceutical consortium

The Australian HIV Observational **Database Temporary Residents** Access Study

An AHOD sub-study recruiting 180 HIV-positive legal temporary residents who are ineligible for Medicare and providing free antiretroviral for a maximum of four years. Recruitment to this study commenced November 2011. Antiretrovirals are provided by all seven pharmaceutical companies with licensed anti-HIV drugs in Australia.

Status: Ongoing

Personnel: Hamish McManus, Stephen Wright, Courtney Bendall, Kathy

Petoumenos

Collaborators: National Association of people living with HIV/AIDS (NAPWA)

Mathematical modelling of human papillomavirus transmission

This research involves the design, implementation and analysis of mathematical models for assessing the health-economic impact of Human papillomavirus (HPV) vaccination, screening and testing policies in Australia. Status: A general HPV modelling framework has been completed allowing for the transmission of multiple HPV types to be modelled. The model has been used to estimate the long-term impact of the current female-only vaccination programme, and a theoretical male + female vaccination programme, on the incidence of genital warts due to HPV types 6 and 11 as well as the incidence of infection due to HPV types 6, 11, 16, and 18. The results of this work were reported in a Technical Report and formed part of a submission to the Pharmaceutical Benefits Advisory Committee for males to be included in the National HPV Immunisation Programme. The model is being further developed to incorporate progression to HPV-related disease (e.g.,

cervical intraepithelial neoplasia and cervical cancer). New methodology has been developed to facilitate the calibration of the model in a Bayesian framework. Individual-based models have been developed to investigate the potential impact of HPV vaccination on non-vaccine types and to assess the implications of changes in HPV ecology for surveillance. Personnel: David Regan, Matthew Law, Andrew Grulich, John Kaldor, Igor Korostil, Edward Waters

Collaborators: CSL Limited, Victorian Cytology Service Incorporated, University of Melbourne, La Trobe University Funding: Australian Research Council, CSL Limited, Victorian Cytology Service Incorporated

Mathematical modelling of bacterial STIs in Australian sub-populations

This research involves the design, implementation and analysis of mathematical models for assessing the health economic impact of public health interventions for the control and prevention of chlamydia, gonorrhoea, syphilis and trichomaniasis in different populations in Australia. The models will address the STIs that are of most importance in heterosexual, MSM, and indigenous populations, respectively. Status: A range of compartmental and individual-based models have been developed to evaluate a wide range of screening and intervention strategies for the control and prevention of bacterial STIs in remote individual communities and to assess the potential importance of community mobility in sustaining high prevalence of STIs in these communities. A model of gonorrhoea transmission, incorporating infection at different anatomical sites, is in development to assess the potential impact of moving from culture to NAAT as the primary diagnostic test.

Personnel: David Regan, David Wilson, Ben Hui, Matthew Law, Rebecca Guy, Basil Donovan, John Kaldor Collaborators: University of Melbourne, La Trobe University, Deakin University Funding: National Health and Medical Research Council

TREAT Asia HIV Observational Database (TAHOD)

Observational cohort study of patients with HIV at 19 sites throughout the Asia-Pacific region. Demographic, clinical and treatment data are aggregated twice each year via electronic data transfer.

Status: At the data transfer in March 2011, baseline and retrospective data from some 5000 patients from 19 sites were aggregated. It is expected that follow-up will continue for at least a further three years.

Personnel: Jialun Zhou, Awachana Jiamsakul, Matthew Law, David Cooper Collaborators: Network of 19 clinical sites at countries throughout the Asia-Pacific region

Funding: American Foundation for AIDS Research (amfAR) via a US National Institutes of Health grant through the International Epidemiologic Databases **Evaluating AIDS collaboration**

TREAT Asia Studies Evaluating Resistance (TASER)

There are two studies: First, a surveillance study (TASER-S) examining rates of transmitted HIV-resistance in newly diagnosed HIV-infected subjects not previously treated with antiretroviral drugs. Second, a monitoring study (TASER-M) assessing rates of developing HIV-resistance in patients starting antiretroviral treatments.

Status: Approximately 2000 naive and experienced patients had been recruited to TASER-M. Enrolment and follow up have ceased. The TASER-M cohort will be terminated in December 2011 with some of the patients being transferred into TAHOD for future follow-up. TASER-S: Approximately 480 patients

have been recruited from five sites. Recruitment has ceased for this study. Personnel: Awachana Jiamsakul, Jialun Zhou, Matthew Law

Collaborators: Network of 12 sites in South East Asia

Funding: American Foundation for AIDS Research (amfAR) via a grant from the government of the Netherlands

TREAT Asia Paediatric HIV Observational Database (TApHOD)

TREAT Asia Paediatric HIV Observational Database (TApHOD) is a collaborative cohort of HIV-infected children in the Asia-Pacific region. The study participants are recruited from TREAT Asia clinical sites. Demographic, clinical and treatment data are aggregated twice each year via electronic data transfer. Currently, 18 sites in six countries have agreed to participate and transferred their data to the Kirby Institute. Status: Up to March 2011, 4045 children were recruited into TApHOD. Of these, 3277 (81%) children have received

antiretroviral treatment. There have been 345 (8.5%) deaths, 490 (12.1%) lost to follow-up, and 416 (10.3%) transfers to other clinics.

Personnel: Azar Kariminia, Matthew Law

Collaborators: Network of 18 sites initially throughout the Asia-Pacific region Funding: TApHOD is funded by The Foundation for AIDS Research (amfAR), the Austrian AIDS Life Association, and the US National Institute of Child Health and Human Development (NICHD).

HIV EPIDEMIOLOGY AND PREVENTION PROGRAM 2012 STUDIES

HIV vaccine preparedness cohort study (Health in Men study)

The HIM study was conducted as a HIV vaccine preparedness study, to describe HIV and STI incidence and associated risk behaviours, and attitudes towards HIV prevention technologies, in a community-based sample of HIV negative homosexual men. Men were interviewed twice yearly about a wider range of HIV and STI risk behaviours, and about their attitudes towards HIV prevention. They were tested annually for HIV, syphilis, gonorrhoea and chlamydia, and consent was collected for later testing of stored specimens. By 2011, stored samples from consenting participants had been tested for antibodies to hepatitis C, herpes simplex types 1 and 2, Helicobacter pylori and human papillomavirus. In a substudy, around 300 men also underwent an anal pap smear. Those with an abnormality on pap smear also underwent a high resolution anoscopy. Chlamydia positive tests underwent further testing to examine whether lymphogranuloma venereum was present in this population.

Status: By the end of the study 1427 men had been followed for over 5000 personyears.

Personnel: Andrew Grulich, Garrett Prestage, Jeff Jin, Mary Poynten, David Templeton, Brian Acraman, Patrick McGrath, Jack Bradley, Harry Smith, Leon Botes, Daniel O'Neill, Paul Kelly, Kim Scholey, Lara Cassar, Hédimo Santana, Matthew Hua, Joanne Holden, Suzanne Kippax, Limin Mao, John Imrie Collaborating centres: National Centre in HIV Social Research; Royal Women's Hospital, Melbourne; Sexually Transmitted Infections Research Centre, University of Sydney

Funding: NHMRC; NSW Health

The Opposites Attract study

A four-year cohort study to examine the effect of HIV treatment and HIV viral load on the rate of HIV transmission in 240 HIV serodiscordant gay couples. **Status:** The study started recruitment in early 2012.

Personnel: Andrew Grulich (PI), Garrett Prestage, Iryna Zablotska, Jeff Jin, Ben Bavinton, Lara Cassar, David Cooper, Anthony Kelleher, David Wilson, Kersten Koelsch, Christopher Fairley, Kathy Triffitt, Sean Emery, Kate Merlin, Jennifer Hoy, Darren Russell, Ban Kiem Tee, Nick Doong, David Baker, Robert McFarlane, David Orth, Mark Bloch, Richard Moore, William Donohue, Norm Roth, David Templeton, Anna McNultv. Emanuel Vlahakis, Mark Kelly. Collaborators: The Alfred Hospital, Cairns Sexual Health Service, Centre Clinic, Dr Doong's Surgery, East Sydney Doctors, Gladstone Road Medical Centre, Holdsworth House Medical Practice, Melbourne Sexual Health Centre, Northside Clinic, O'Brien Street General Practice, Prahran Market Clinic, Royal Prince Alfred Hospital, St Vincent's Hospital Immunology B Ambulatory Clinic, Sydney Sexual Health Centre, Taylor Square Private Clinic, Sexual Health and HIV Service Clinic 2

Funding: NHMRC Project grant

Modelling interventions to prevent HIV infection and their acceptability among gay men in NSW

This study uses mathematical modelling to estimate the likely impact of a range of interventions designed to reduce rates of HIV infection among gay men, and uses both quantitative and qualitative research methods to assess how acceptable such interventions would be to the target population. The study recruited 600 gay men to answer specific questions about their attitudes toward a range of possible interventions through an online survey and were then invited to participate in five focus groups in Sydney. Data from mathematical models were considered alongside the findings from the acceptability study.

Status: Data collection completed; data analysis and reporting is ongoing Personnel: Garrett Prestage, Jack Bradley, Ian Down, David Wilson, Richard Gray

Collaborators: Australian Research Centre in Sex Health and Society Funding: NSW Health

Risk factors for HIV seroconversion (The Seroconversion Study)

A study of risk factors for HIV infection among people recently diagnosed with HIV infection. The findings from this study inform HIV organisations and state health departments about the contexts of risk behaviours and motivations for these behaviours. The study also considers current gaps in policy and program development and implementation, including in the research base, by interviewing individuals who have recently been diagnosed with HIV about the factors they believe led to their HIV seroconversion and their experiences since receiving their diagnosis.

Status: By January 2013, 484 individuals who had recently seroconverted had participated in the survey and 92 had been interviewed. The study continues to recruit participants

Personnel: Garrett Prestage, Ian Down, Jack Bradley, Andrew Grulich, Jeanne Ellard, Kathy Triffitt, Graham Brown Collaborators: National Centre in HIV Social Research; Australian Research Centre in Sex, Health and Society; Curtin University; State AIDS Councils, State PLWHA organisations, and State Health Departments.

Funding: Queensland Health; Victorian Department of Health; NSW Health Department; Western Australian Health Department; South Australian Department of Health; Tasmanian Department of Health; Health Department of the ACT

PEP users in Sydney, NSW: pilot cohort

A cohort of PEP users at St. Vincent's Hospital, Sydney, with quantitative behavioural data collection at enrolment when men request PEP, at the completion of PEP course and six months after completing the PEP course. The aims were to assess ability to enrol and maintain a cohort of PEP users and to compare sexual practices of participants before, during and after their PEP course. As a pilot study, this cohort prepared and tested the methodology of recruitment and data collection in a pilot cohort of NPEP users.

Status: Enrolment complete.
Personnel: Iryna Zablotska, John
McAllister

Collaborators: St Vincent's Hospital PEP clinic

Funding: Kirby Institute

The PASH (Pleasure and Sexual Health) Study: understandings of risk among gay men

A study of beliefs and attitudes about risks and consequences of HIV infection in Australian gay men. Data collection is completed: In total, 4125 men were referred to the survey, of whom 2306 provided sufficiently complete survey questionnaires for inclusion in analysis. 40 men were interviewed in depth. The aims of the PASH Study were to iInterview gay men about their current beliefs and understandings of HIV, and the risk of HIV transmission, and the relations between these and pleasure; inform HIV organisations and state health departments about the contexts of risk behaviours and motivations for these behaviours; and consider current gaps in policy and program development and implementation, including in the research base..

Status: In the five months of recruitment, 2306 online responses were collected, while 40 men were interviewed.

Personnel: Pól Dominic McCann, Garrett Prestage, Ian Down, Jack Bradley, Michael Hurley, Graham Brown

Collaborating centre: Australian

Research Centre in Sex, Health and Society, La Trobe University

Funding: State health departments.

Sexually adventurous men's study (SAMS)

A study to document and record the work of the Sexually Adventurous Men's Projects of the Victorian AIDS Council and PLWHA Victoria, and to investigate the beliefs and behaviours among gay men in sexually adventurous networks in Melbourne.

Status: Processes and record-keeping documentation have been established, and data collection is ongoing. Interview schedules have been developed.

Personnel: Garrett Prestage.
Collaborators: Australian Research
Centre in Sex Health and Society;
Victorian AIDS Council; PLWHA Victoria.
Funding: Victorian Health Department

Defining risk and mechanisms of permucosal transmission of acute HCV infection within high-risk populations (RAMPT-C Studu)

Hepatitis C (HCV)-related liver disease has emerged as a major contributor to morbidity and mortality among people with HIV. Recently, epidemics of acute HCV among HIV-infected men who have sex with men (MSM) have been reported in UK, Europe, USA and Australia. All of these cohorts report permucosal, including high-risk sexual, rather than parenteral, usually injecting drug use (IDU), risk associated with HCV transmission. This study of HCV transmission and its risk factors among homosexual men recruited HIV-positive gay men recently diagnosed with hepatitis C to answer specific questions about their knowledge of hepatitis C and their beliefs about its transmission.

Status: Data collection will continue with an overseas component (London). Australian data collection was completed in December 2011.

Personnel: Garrett Prestage, Ian Down, Jack Bradley, Mark Danta, Gail Matthews, Tanya Applegate, Margaret Hellard, Joseph Sasadeusz

Funding: NHMRC

Monogamy: meanings and practices among gay men

This is a study of gay men's attitudes toward and beliefs about monogamy, and how that affects the kinds of relationships they form. Gay men are being interviewed in depth about the concept of monogamy and their own relationships.

Status: Data collection is complete.
Personnel: Garrett Prestage
Collaborators: Australian Research
Centre in Sex Health and Society

Funding: NHMRC

Periodic surveys of HIV risk behaviour (The Gay Community Periodic Surveys)

A repeated cross-sectional survey conducted annually in each participating state of sexual risk behaviour, HIV and STI testing, and illicit drug use among gay men in Australia. In 2011, more than 9000 behavioural questionnaires surveys were completed in Sydney, Melbourne, Adelaide, Perth, Canberra and Brisbane, as well as in certain regional areas of Queensland.

Status: Ongoing annual surveillance, with about 8000-9000 men participating each year.

Personnel: Garrett Prestage, Iryna Zablotska, Andrew Grulich, Martin Holt, John de Wit, Limin Mao

Collaborators: National Centre in HIV Social Research; State AIDS Councils; State PLWHA organisations; State Health Departments

Funding: State and Territory Health Departments

Predictors of PEP awareness and use in Australian Gay Community (Australian Gay Community Periodic Surveus)

A quantitative study of trends in PEP awareness and use among gay men in Australia. In 2011, all behavioural questionnaires completed by the participants in Sydney, Melbourne, and Brisbane Gay Community Periodic Surveys were analysed in parallel with the analyses of data from the PEP clinic in St. Vincent's hospital. Analyses of PEP use were published in the *Journal of Acquired Immune Deficiency Syndromes*. **Status:** The team is conducting data analyses of PEP awareness and will be working on the preparation of the report in 2013.

Personnel: Iryna Zablotska, John McAllister

Collaborators: National Centre in HIV Social Research; State AIDS Councils; State PLWHA organisations; State Health Departments

Funding: State and Territory Health Departments

Social norms regarding HIV/STI risk and risk reduction behaviours among men who have sex with men in Australia (CONNECT study)

HIV/STI risk reduction is more likely to occur if community norms regarding risk reduction are supportive and are shared in the community. There is a lack of research on the social norms regarding HIV/STI related behaviours among MSM. The CONNECT Study investigated norms and acceptability of risk reduction strategies in Australian gay communities. This cross-sectional quantitative study used respondent-driven sampling to recruit homosexual men in Sydney, Melbourne and Perth to investigate norms regarding sexual practices across different social/sexual networks. **Status:** Recruitment was completed in 2012. The research team is currently conducting data analyses for publication. Personnel: Iryna Zablotska, Garrett Prestage, Michelle McKechnie, Ben Bavinton, Matthew O'Dwyer, John De Wit, Graham Brown, Bruce Maycock, Alden Klovdahl, Christopher Fairley, Jeffery Grierson.

Collaborators: Curtin University, Aids Council of New South Wales (ACON), Positive Life NSW, Australian Federation

of AIDS Organisations (AFAO), New South Wales Department of Health, Victorian AIDS Council (VAC), People Living with HIV/AIDS (PLWHA), Western Australian AIDS Council (WAAC) and Western Australia Department of Health. Funding: NHMRC

Mapping gay community networks in Sydney, NSW

No formal research has been undertaken to map the various groups within Sydney's gay community, or to locate them geographically and culturally, and to describe their characteristics, interconnections and the best ways of accessing them. This mixed-method cross-sectional study involved interviews of opinion leaders representing different networks and organisations of gay men in Sydney to describe the structure and functioning of the Sydney gay community. The protocol and data collection instrument were developed. Data collection has commenced and 130 gay community groups and networks have been interviewed by the end of 2011. Status: 200 groups have been identified and 183 interviews conducted..

Personnel: Iryna Zablotska, Garrett Prestage, Michelle McKechnie, Matt O'Dwyer

Collaborating centres: The Australian Research Centre in Sex Health and Society at La Trobe University and the gay community organisations and partners (particularly, the AIDS Council of NSW and Positive Life NSW).

Funding: NSW Health

TAXI KAB Study

Knowledge Attitudes, and Beliefs (KAB) of gay men in Australia when they Think About eXposure to Infection (TAXI) to HIV. This project describes understandings of HIV risk by gay men in the context of knowledge, attitude and behaviour. The study aims to describe patterns of belief about HIV transmission and relative risk; assess the attitudes these men have developed; and describe the behaviour of these men in those contexts. The study aims to explore the knowledge, attitudes and beliefs around HIV among gay and bisexual men in a single research project that uses quantitative methods. This study would: 1. Measure current attitudes, knowledge levels, and beliefs about HIV among gay men; and 2. Explore these beliefs about relative risk, both in terms of their understandings of the relative risk of transmission and

the relative priority this understanding takes with respect to other aspects of understanding and knowledge which may change or be influenced over time by prevailing healthcare policy, educational efforts, or personal and anecdotal experiences. The responses will provide data that can be analysed to identify key patterns regarding beliefs and attitudes toward HIV, and which will lend itself to close analysis.

Status: Recruitment completed, preliminary analysis completed, report underway and expected to be published in March 2013.

Personnel: Garrett Prestage, Andrew Grulich, Jack Bradley, Martin Holt, Mary Poynten, Ben Bavinton, Kathy Triffit, Graham Brown, Phillip Keen, Geoff Honnor, Colin Batrouney, Dean Murphy, Lance Schema.

Collaborating centres: NCHSR, PositiveLife NSW, La Trobe University, NAPWA, ACON, AFAO Funding: NHMRC

The SPANC study (Study of the prevention of anal cancer)

Gay men are at greatly increased risk of human papillomavirus (HPV)-related anal cancer. This study tracks the precursors of anal cancer in a cohort of HIV negative and HIV positive gay men. This cohort study examines the prevalence, incidence and risk factors for progression of human papillomavirus infection and anal cancer precursors in HIV positive and HIV negative homosexual men aged 35 and older. **Status:** By the end of 2011, 190 participants were recruited. Initial analyses were reported on safety and adverse effects of anal cancer screening were presented.

Personnel: Andrew Grulich, Jeff Jin, David Templeton, Garrett Prestage Andrew Grulich, Richard Hillman, Jeff Jin, Mary Poynten, David Templeton, Brian Acraman, Patrick McGrath, Matthew O'Dwyer, Dorothy Machalek, Garrett Prestage, Winnie Tong, Kate Thompson, Suzanne Garland, Christopher Fairley, Jennifer Roberts, Annabelle Farnsworth, Adele Richards, Sepehr Tabrizi, Alyssa Cornwall, Andrew Carr, Kirsten McAffery, Kirsten Howard. Collaborating centres: St Vincent's Hospital Immunology B Ambulatory Clinic; Sexually Transmitted Infections Research Centre, University of Sydney; School of Public Health, University of Sydney; Douglas Hanly Moir Pathology; Royal Women's Hospital, Melbourne. Funding: NHMRC Program Grant

International pooled analysis of immune risk factors for lymphoma

A pooled analysis of case-control studies

of immune risk factors for lymphoma. All twelve member studies sent data on a pooled total of 12,982 cases and 16,441 controls, and results on auto-immune disease as a risk factor for non-Hodgkin lymphoma (NHL) were reported. **Status:** Analyses on infectious conditions and NHL risk were reported. Personnel: Andrew Grulich Collaborators: UNSW Cancer Research Centre; University of Southern California; German Cancer Research Centre; Feinberg School of Medicine, Northwest University; Centre for Study and Prevention of Cancer: Aviano Cancer Centre; Catalan Institute of Oncology; University of California, San Francisco; David Geffen School of Medicine, University of California, Los Angeles;

Funding: Leukaemia Foundation of Australia

Yale University

University of York; British Columbia

Cancer Registry; School of Medicine,

Serological studies of HPV in gay Australian men

A sero-epidemiological study of the prevalence, incidence and predictors of infection with a number of different HPV types.

Status: In 2011, over 5000 serological samples from the Health in Men study were analysed for antibodies to 10 HPV types at the German Cancer Research Centre (DKFZ) in Heidelberg, Germany. Analyses of the data were completed. Two papers have been published. Personnel: Mary Poynten, Andrew Grulich, Jeff Jin, Dave Templeton, Garrett Prestage, Tim Waterboer, Michael Pawlita, Christopher Fairley, Basil Donovan, Suzanne Garland Collaborators: German Cancer Research Centre (DKFZ), Heidelberg, Germany Funding: STI Program Grant, NHMRC Post-doctoral Training Scholarship (M. Poynten)

IMMUNOVIROLOGY AND PATHOGENESIS PROGRAM 2012 STUDIES

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

SPARTAC (short pulse antiretroviral treatment at seroconversion) looks at the effect on CD4 T-cells of three interventions at primary HIV infection, either treating with antiretroviral therapy for 12 or 48 weeks or not treating at all until CD4 declines to <350 cells. Enrolment ceased in June 2007, by which time 37 patients had been screened, and 31 patients continue to be followed up. Status: Study completed, primary manuscript accepted for publication in NEJM

Personnel: Anthony Kelleher, Pat Grey Collaborators: Jonathon Weber, Sarah Fidler, Robert Finlayson, Mark Bloch, Robert McFarlane, Cassy Workman, Nick Doong, David Cooper, Mark Kelly, Norman Roth, Dr BK Tee, Richard Moore, Philip Cunningham, Kate McGhie, Julie Yeung

Funding: Wellcome Trust

Laboratory surveillance of incident HIV infection

Laboratory markers are used to determine incident from established HIV infection to monitor the trends in newly acquired infections, providing an important sentinel surveillance tool. BED ELISAs, and analysis of other routine laboratory markers used in the diagnosis of HIV infection, are used in monitoring new infections.

Status: All newly identified cases of HIV infection at the NSW State Reference Laboratory for HIV at St Vincent's Hospital were analysed on BED assays. Protocols were further developed towards a goal of deriving viral sequence for RT protease and integrase genes from dried blood spots. This would allow sophisticated molecular epidemiology to be performed even in resource-poor settings.

Personnel: Anthony Kelleher Collaborators: Philip Cunningham, St Vincent's Hospital, Sydney; Sara Evans, Celine Yang, Kazuo Suzuki, Jane Cornwall

Funding: NSW Health Department

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

A systematic mechanism to follow-up the PHAEDRA and Core01 cohorts in Sydney and Melbourne with acute and early HIV-1 infection.

Status: Good follow-up of patients already enrolled and some patients rolled over from SPARTAC. Database

and repository provided basis for several publications and ongoing and new collaborations

Personnel: Pat Grey, Ansari Shaik, David Cooper, Anthony Kelleher.

Collaborators: Robert Finlayson, Mark Bloch, Cassy Workman, Robert McFarlane, Dr B.K. Tee, Norman Roth, Phillip Cunningham, John Zaunders, Tim Read, John Murray (School of Mathematics)

Funding: NHMRC Program Grant

Australian Long-Term Non-progressor Study

The Australian long-term non-progressor cohort study was established in 1994 and is ongoing. Studies focussing on identifying the reason this rare group of people with prolonged HIV infection remain healthy, with virtually no damage to their immune system, are extremely important for understanding the pathogenesis of HIV and for developing new antiretroviral therapy and preventative vaccines.

Status: Of the 163 participants recruited to this cohort 42 individuals (sustained non-progressors) are still treatment-naïve. Four new patients were recruited in 2012. Provided basis for a several publications.

Personnel: Anthony Kelleher, Pat Grey, Ansari Shaik, John Kaldor, David Cooper Collaborators: Long-Term Non-progressor Study Group, including clinical sites in Sydney, Port Kembla, Canberra, Brisbane and Melbourne; Kat Marks, St Vincent's Hospital, Sydney; Stephen Kent and Ivan Stratov, University of Melbourne. International collaboration includes Elite Controller Collaborative Project and the International AIDS Vaccine Initiative (IAVI).

Funding: NHMRC

Specimen receipt and processing for clinical trials and natural history studies

The laboratory provides a service to other Kirby Institute programs encompassing the separation of blood components including but not limited to; cryopreservation of serum, plasma and PBMC, archiving and on shipping of samples. The service also includes database management of the storage of these samples. Staff also have experience with the implementation of assays which are not offered by local diagnostic laboratories. This service contributes to

the overall smooth running of clinical trials and natural history studies.

Status: Ongoing

Personnel: Anthony Kelleher Collaborators: Kate Merlin, Julie Yeung, Maria Piperias, Bertha Fsadni (St Vincent's Hospital, Sydney) Funding: Project-specific grants Co-located: Viral Hepatitis Clinical Research Program and Immunovirology

and Pathogenesis Program

RESTORE

An observational study to explore reconstitution of immunity in patients with advanced HIV-1-infection commencing combination antiretroviral therapy

Target: 50 patients recruited and in follow-up

follow-up
Status: week 48 follow up completed
Sites: one site in Thailand
Personnel: Denise Hsu, Sarah Pett, Sean
Emery, Anthony Kelleher,
Collaborators: Jintanat Ananworanich,
Sasiwimol Ubolyam, Anchalee
Avihingsanon, Kiat Ruxrungtham,
Praphan Phanuphak, HIV-NAT Bangkok
Funding: NHMRC, UNSW

Dynamic trafficking of HIV spread

HIV as a cell-free viral entity is vulnerable to many attacks by the innate and acquired immune system. To get around these often hostile conditions, HIV predominately spreads from one cell to the next when they are intimately contacting each other in a structure referred to as a synapse. Whilst the main objective for virus to move across a synapse is evasion, it may also be seen as a form of synchronised infection. For instance, once an infected cell makes contact with a future HIV target, the virus actively promotes release of many virions towards this neighbouring target. This effectively overwhelms the new cell with virus, making it difficult for natural defences and also antiretroviral drugs to stop and/or control. This project represents a study only currently capable in a few laboratories worldwide, as it has taken years to develop appropriate HIV constructs that could be used to visualise in primary infected cells. The major aim of this project is to track live infectious HIV moving from cell to cell and delineate key cellular pathways the virus corrupts in this process. **Status:** For the first time, we have

Status: For the first time, we have identified HIV using long acting-based structures to co-ordinate spread to new targets. The virus does so by embedding

in the tips of long finger-like projections called filopodia. In doing so, the virus has hijacked a probing structure that is otherwise used by cells of the immune system to initiate communication of the immune response.

Personnel: Stuart Turville, Anupriya Aggarwal, Tina Iemma, Ivy Shih **Collaborators**: Thomas Hope, Timothy Newsome

Funding: NHMRC

Novel inhibitors of HIV entry

The site where HIV fuses to the cellular membrane has remained one of the most controversial areas in HIV biology. As HIV can fuse with cellular membranes in a pH independent manner, it is already assumed that the virus can directly fuse with the plasma membrane. However, recent studies knocking down both Dynamin and Clathrin proteins, has highlighted HIV may favour entry via endosomal membranes. Through a collaborative venture with Professor Philip Robinson at the Children's Medical Research Institute, we are currently testing a portfolio of Dynamin and Clathrin specific set of compounds and their impact on HIV entry.

Status: We have developed an imaging platform of uniquely labelled virions, to map the entry, fusion and uncoating of the virus under normal conditions and in the presence of inhibitors. In conjunction with high throughput assays, we have identified a novel block to HIV entry using Dynamin and Clathrin specific compounds, but not at the level of viral fusion as expected. Rather, the block is at the time of reverse transcription, with little to no block at the time of entry/fusion.

Personnel: Stuart Turville, Tina Iemma, Anupriya Aggarwal

Collaborators: Philip Robinson
Funding: Australian Centre for HIV and
Hepatitis Virology Research (ACH2)
Location: Immunovirology and
Pathogenesis Program

Lentiviral vectors and gene therapy

The quest for a HIV cure is top on the list of objectives worldwide in the fight against this disease and therapy by lentiviral vectors is one means to attack the virus potentially at multiple levels. One of the key limitations to the use of gene therapy is the natural resistance of immune cells to this procedure. Thus understanding why cells of the immune

system are resistant to gene therapy, will help in increasing the efficacy of this type of treatment.

Status: Using lentiviral vectors that can package the related monkey virus protein VPX, we and others have been able to introduce genes into highly resistant cells (macrophages and dendritic cells) at efficiencies of greater than 60%. Presently, we are targeting resting primary CD4 T cells, with the aim of raising gene transduction to similar levels. In doing so we wish later to create cells of the immune system that are resistant to future HIV infection. Personnel: Stuart Turville, Sam

Personnel: Stuart Turville, Sam McAllery, Anupriya Aggarwal, Tina Iemma

Collaborators: Nathaniel R. Landau **Funding**: NHMRC

Assays of T-cell function, proliferation and cytotoxicity, and identification of antigen-specific T-cells

A range of flow cytometric assays for assessing CD4+ and CD8+ T-cell function are worked up in the laboratory. The measures of antigen-specific T-cells include T-cell proliferation, activation and cytokine secretion. Such assays are important for understanding HIV pathogenesis and in responses to vaccines, and therefore are included in the protocols of clinical trials and natural history studies carried out by the Kirby Institute. Assays were performed as part the PINT trial of therapy with the integrase inhibitor, Raltegravir and the Restore and PrIRIS studies in Bangkok and Sydney respectively. Other studies were conducted as part of the PHIIDO observational study of primary HIV infection. These assays were validated in the context of two competed clinical studies assessing latent TB infection in Bangkok and Sydney; in a clinical study of CMV re-activation and Adenovirus infection following paediatric bone marrow transplantation, and in following immune responses with gluten induced flares of Coeliac disease. Assays were also conducted to elucidate the generation of CD4+ T-cell responses during primary vaccinia vaccination.

Status: Continued analysis of samples from PHAEDRA and the long-term non-progressor cohorts, TB studies completed, studies of CMV disease completed in 2011 and coeliac study commenced.

Personnel: Susanna Ip, Laura Cook, Mee-Ling Munier, Michelle Bailey, Yin Xu, Chansavath Phetsouphanh, Celine Yan, Anthony Kelleher, Denise Hsu Collaborators: John Zaunders,
Mahila Namasivayam, Tony Walls,
John Ziegler, Nabila Seddiki, Stephen
Kent, Bob Anderson, Jason Tye-Din,
Jintanat Ananworanich, Sasiwimol
Ubolyam, Anchalee Avihingsanon, Kiat
Ruxrungtham, Praphan Phanuphak
Funding: NHMRC, St Vincent's Hospital,
Coeliac Foundation
Co-located: Viral Hepatitis Clinical
Research Program and Immunovirology
and Pathogenesis Program

RNA inducing viral latency

This project is related to siRNA gene silencing for HIV-1 and SIV infection. siRNAs targeting viral promoter DNA region induce transcriptional gene silencing (TGS) of viral genes in infected cells. The study has been extended to two major objectives: delivery system of siRNA and mechanism of gene silencing. To develop and evaluate delivery systems including lentiviral and nonviral systems for use in a humanised mouse HIV-1 infection model; and to define the pathways by which dsRNAs targeting the promoter regions of HIV-1 and SIV. Silencing constructs applicable for use in HIV-1 infection have been development. These constructs have been incorporated into a lentiviral delivery system, which will be assessed in vitro. Epigenetic changes induced by siRNAs targeting HIV-LTR will also be defined. We also investigated the subcellular localisation of Argonaute proteins (Ago) during the TGS process and recently reported the presence of Ago1 in the nucleus and Ago2 in the nuclear membrane as demonstrated by confocal microscope using tagged Ago 1/ Ago2 and fluorescently labelled siRNA. We also demonstrated colocalisation between Ago1 or Ago2 and F-actin and are currently following up of this novel finding to potentially link transport of the molecules from the cytoplasm into the nucleus where they would then act on the HIV-1 promoter to initiate gene silencing.

Status: successful completion of in vivo proof of principle experiments using SCID-Hu mouse model of HIV-1 infection with Japanese collaborators

Personnel: Anthony Kelleher, Chantelle

Hood, Sanjay Swaminathan **Collaborators**: Kazuo Suzuki, Takaomi Ishida, Makoto Ymamagisi, Toshiki

Watanebe

Funding: NHMRC

Co-located: Viral Hepatitis Clinical Research Program and Immunovirology and Pathogenesis Program

HIV drug resistance and viral tropism

This project involves the development of expertise in the application of a number of methods of detecting antiretroviral drug resistance through genotypic testing of HIV isolates. The program has three major projects: evaluation and conducting commercially available genotype testing for protease, reverse transcriptase regions; development of a new, cheap in-house genotyping method from blood dry-spots as a starting material; and development of assays for the determination of CCR5 tropism of patient's HIV isolates. More than 700 HIV-1 resistance genotypes have been performed based on the commercial based resistant assays. Validation of new in-house genotyping method is close to completion.. The CCR5 tropism assay for RNA has been transferred to the NSW State reference laboratory at St Vincent's and is being used for routine care. The validation of the DNA version of this assay is complete and has been used for routine patient care since January 2012.

Status: In routine use

Personnel: Anthony Kelleher, Celine Yan, Kerstin Koelsch, Yong Pan

Collaborators: Kazuo Suzuki, Kat Marks, Nick Rismanto Philip Cunningham, Leon

McNally, Alexander Carrera

Funding: NSW Health Department, ViiV Co-located: Viral Hepatitis Clinical Research Program and Immunovirology

and Pathogenesis Program

PINT

A study of the effects of the integrase inhibitor, raltegravir, on viral reservoirs in those treated at primary HIV-infection compared to those treated during chronic infection.

Status: Two publications in 2012; further modelling of viral turnover in T-cell subsets commenced; extension phase analysis commenced.

Personnel: Anthony Kelleher, Linda Gelgor, Pat Grey, Kersten Koelsch, Christophe Boesecke, Sean Emery, Wendy Lee, Janaki Amin, David Cooper. Collaborators: Robert Finlayson, Mark Bloch, Robert McFarlane, John Zaunders, Kat Marks, Kate McGhie, Julie Yeung, John Murray

Funding: Merck & Co Inc. **Co-location:** Therapeutic and Vaccine Research Program and Immunovirology and Pathogenesis

In vivo visualisation of epithelial surfaces by confocal endomicroscopy

This project intends to combine the development of laser scanning endomicroscopy with antibody reagents and fluorophores as tools for detection of disease markers in the gastrointestinal tract. This will provide us with tools to visualise biological processes in the real time and enable instant diagnosis for diseases such as inflammatory bowel

Status: Preliminary studies in exvivo tissue have been conducted. Standardised protocols were established for the in vivo assessment of mucosal barrier function by confocal endomicroscopy. Fluorescent labelling of ex vivo tissue has been optimised and a mouse model has been established for intravital imaging of the mucosal lining of the small intestine.

Personnel: Tri Phan. Mehreen Arshi. Mark Danta, Anthony Kelleher Collaborators: Daniel Christ, Peter

Funding: ARC Linkage Grant

Characterisation of infection of follicular T helper cells during pathogenic SIV infection and HIV-1 Infection

The aim of this project is to understand the fate and role of T follicular helper cells, a subset of memory CD4+ T cells which helps B cells to make high affinity, class-switched antibodies and to develop memory, during pathogenic SIV infection or HIV infection. Macaque T_{FH} cells were phenotypically characterised from lymphoid tissues and sorted into pure population for SIV DNA quantification. Result shows that T_{FH} cells were infected with SIV at similar levels as other memory CD4+ T cells, and despite infection, they accumulated during the chronic stage. Current focus is on the mechanisms for viral entry and $T_{\text{\tiny FH}}$ cell accumulation. Collaboration was also set up with a French group lead by Professor Brigette Autran. T_{FH} cells and other CD4+ T cell subsets were sorted in Paris and shipped to Sydney for confirmation of T_{FH} cell infection with HIV in humans. Mechanism work will also be performed on T_{FH} cells from healthy donors. Status: Characterisation of infection of

 $T_{_{\mathrm{FH}}}$ cells in pathogenic SIV infection in pigtail macaques has completed with one publication in 2013. T_{FH} cell infection with HIV-1 has been confirmed. We are now sequencing envelope gp120 from

different subsets, which will provide hints on coreceptor usage. Ethics approval has obtained to collect tonsilar tissues from healthy donors by Dr. Richard Harvey. Cells will be isolated for real-time phenotyping and functional assays, and stored for later studies. Personnel: Yin Xu, Chris Weatherall, Michelle Bailey, Kazuo Suzuki, John Zaunders, Anthony Kelleher. Collaborators: Rob de Rose, Rob Center, Stephen Kent, Brigette Autran, Richard Harvev.

Funding: NHMRC Program Grant

Primary HIV Infection Data Observational (PHIIDO)

This is a study of untreated individuals. designed to recruit and follow up a cohort of people with documented acute and early HIV infection, not going onto antiretroviral therapy, although patients may initiate antiretroviral therapy at any stage in consultation with their treating clinicians in accordance with current standard of care guidelines. There is also an aim to provide the clinical and laboratory framework to characterise immunological responses/viral events that occur early in the course of HIV infection in untreated subjects with a focus on factors that determine natural viral control. Subjects are adults identified with acute or early HIV infection, who do not intend to go on treatment at present. Analysis of factors associated with disease progression will be undertaken on an annual basis including, CD4 decline to <350 cells/mm, plasma levels of HIV-1 RNA, serial CD4/CD8 counts, meeting the criteria for initiation of ARV therapy, progression to AIDS or death. Status: Study commenced in May 2009;

16 patients screened Personnel: Pat Grey Collaborating centres: St Vincent's Hospital, AIDS Research Initiative, East

Medical Practice, Taylor Square Private Clinic and Albion St Clinic

Sydney Doctors, Holdsworth House

Role of miRNA in disease progression

miRNAs are a relatively recently described mechanism of regulating and fine-tuning mRNA and protein production. Their role in determining outcomes of HIV infection is poorly understood. This study is designed to identify new targets for therapeutic intervention and to determine profiles of miRNAs in groups of patients with disparate clinical outcome

Status: Ongoing

Personnel: Sanjay Swaminathan,

Chansavath Phetsouphan, Yin Xu, Laura Cook, Daniel Murray, Chantelle Hood, Nabila Seddiki, Kazuo Suzuki, John Zaunders

Collaborating centres: Long-Term Nonprogressor Study Group; Faculté Créteil Henri Mondor, Créteil France; University of Canberra; St Vincent's Hospital, Sydney; Garvan Institute Funding: NHMRC

Role of ADCC in disease progression

Antibody dependent cytotoxicity is a mechanism by which natural killer cells kill infected cells. Its role in control of HIV-infection and in preventing HIV infection post vaccination is unclear. It is mediated by certain isotypes of IgG. This study will define quantity and quality of ADCC responses in various patient groups and look for correlations with control. Studies are being undertaken with collaborators in Melbourne and Perth to determine correlates of progression and unique epitopes. Status: Samples on all LTNP and untreated patients at primary infection with varying rates of progression have been transferred to Melbourne and Perth for conduct of assays. Manuscript reporting results in LTNPs and rapid progressors has been submitted for publication.

Personnel: Anthony Kelleher, Pat Grey, Ansari Shaik, David Cooper, Kat Marks. Collaborating centres: Long-Term Non-progressor Study Group, including clinical sites in Sydney, Port Kembla, Canberra, Brisbane and Melbourne; St Vincent's Hospital, Sydney; Department of Immunology and Infectious Diseases, Melbourne University; Department of Immunology, Royal Perth Hospital.

Immuno-phenotyping of T-cell subsets

Many of Kirby Institute's clinical trial and natural history protocols involve immunological sub-studies. The laboratory supports these sub-studies as a semi-routine service. Performance of intensive assays has been undertaken as part of the PINT and CORAL studies, including analysis of stem cells. Several novel assays have been developed with new insights into pathogenesis.

Status: The CORAL study was completed

Personnel: Mee-Ling Munier, Michelle Bailey, Chansavath Phetsouphanh, Yin Xu, Anthony Kelleher, Denise Hsu, Laura Cook, Will Hey-Cunningham, Kersten Koelsch, John Murray, John Zaunders.

Collaborating centre: St Vincent's Hospital, Sydney

Funding: Project-specific grants

Immunopathogenesis of immune reconstitution disease

Studies of the immunopathogenesis of immune reconstitution disease (IRD) based on the samples studied ex vivo from patients suffering this disease. This study is exploring the causes of this dysregulation, with particular focus on the role of T regulatory cells. Studies commenced in 2006 and were formalised to recruit all patient-commencing CART late in the disease with a natural history study called PrIRIS. Analysis of assays performed real time elucidating the phenotype (eight flow cytometry panels) at intracellular cytokine secretion and at antigen-specific regulatory and effector T-cells.

Status: Data analysis is ongoing and cryopreserved samples are being used for immunopathogenesis studies. Personnel: Anthony Kelleher, Chansavath Phetsouphanh, Denise Hsu, Mee-Ling Munier, David van Bockel, Sarah Pett, Nabila Seddiki

Collaborating centres: St Vincent's Hospital, Sydney; Faculté Créteil Henri Mondor, Créteil

Funding: NHMRC

IUSTICE HEALTH RESEARCH PROGRAM 2012 STUDIES

National Prison Entrants' Bloodborne Virus Survey (NPEBBVS) 2010

The NPEBBVS is conducted triennially and involves screening a consecutive national sample of prisoners entering the correctional system in Australia. The survey screens for HIV, hepatitis B, hepatitis C, chlamydia, gonorrhoea, and syphilis. A short behavioural risk factor questionnaire collects information on demographic characteristics, drug use, injecting practices, tattooing, tobacco smoking, and sexual health.

Status: Completed latest iteration in 2010; 2013 version being planned.

Personnel: Tony Butler Project steering committee: Tony Butler (Kirby Institute), Michael Levy (ACT Corrections Health); Devon Indig (Justice Health NSW); Kiah McGregor, Simon Stafford, and Robyn Hopkins (NT Correctional Services); Alun Richards and Stacy Kambouris (Queensland Health); Peter Frost and Karen Harlin

(SA Prison Health Service); Chris Wake and Deborah Siddall (Tasmania Correctional Primary Health Services); Fiona MacFarlane and Michele Gardner (Justice Health Victoria); and Holly Beasley (WA Corrective Services). **Collaborating centres:** ACT Corrections Health; Justice Health NSW; NT Correctional Services; Queensland Health; SA Prison Health Service; Tasmania Correctional Primary Health Services; Justice Health Victoria; WA Corrective Services.

Funding: State and Territories governments contributions.

REINVEST: Reducing impulsive behaviour in repeat violent offenders using a Selective Serotonin Reuptake Inhibitor (the REINVEST study)

Serotonergic dysfunction in the brain has been linked to impulsivity and impulsive behaviour has been linked to offending behaviour, particularly violent offending. This randomised control trial examines whether treatment with a class of antidepressant medication know as a selective serotonin reuptake inhibitor (SSRI) is effective in reducing impulsivity, and hence offending behaviour, in repeat-violent offenders in New South Wales.

Status: planning underway Personnel: Tony Butler, Lee Knight; Peter Schofield (Hunter New England Health), David Greenberg (Justice Health NSW), Don Weatherburn (NSW Bureau of Crime Statistics and Research), Kay Wilhelm (St Vincent's Hospital), Vaughan Carr (Schizophrenia Research Institute), Catherine D'Este (Newcastle University), Phil Mitchell (University of New South Wales), Alison Jones (University of Wollongong); Tony Keech (Sydney University), Val Gebski (University of Sydney); Rodney Scott (University of Newcastle); Jocelyn Jones (National Drug Research Institute), Luke Grant (Corrective Services NSW), Carolynn Dixon (Justice Health NSW), Alison Churchill (CRC Justice Support), Steven Allnutt (Justice Health NSW), Andrew Ellis (Justice Health NSW) **Collaborating centres:** Corrective Services NSW; Justice Health NSW; Hunter New England Health; UNSW Psychiatry; Schizophrenia Research Institute; Newcastle University; NHMRC Clinical Trials Centre; Bureau of Crime Statistics and Research; University of Wollongong.

Funding: NHMRC Partnership Grant; NSW Health Department Funding.

HePaTO: Hepatitis C, Prison, and Treatment Opportunities

Few prisoners report receiving treatment for hepatitis C in prison. The aims of HePaTO are to identify cultural and systemic barriers to providing treatment for Indigenous and non-Indigenous prisoners during incarceration in Australia, to estimate the potential number of prisoners who could be treated for chronic hepatitis C in prisons in Australia, and to evaluate the potential economic impact of treating chronic hepatitis C in prison. Status: Qualitative interview completed. Modelling component underway Personnel: Tony Butler, Lorraine Yap; Susan Carruthers (National Drug Research Institute, Curtin University): Wendy Cheng (Royal Perth Hospital); Sandra Thompson (Combined Universities Centre for Rural Health, University of Western Australia); Jocelyn Jones (National Drug Research Institute, Curtin University) Funding: NHMRC Project Grant

Rates of reported past TBI within

Does traumatic brain injury (TBI) lead to offending behaviour?

offender and prisoner populations are extraordinarily high and it has been suggested that TBI may be responsible for up to half of all crimes leading to incarceration. Our study is designed to rigorously examine this question using high quality linked data, adopting a whole of life-time approach. Should a relationship between TBI and subsequent offending be established, this will open up the possibility of developing effective interventions to prevent this trajectory. Status: Analysis underway Personnel: Tony Butler, Basil Donovan, Lorraine Yap, Juliet Richters (SPHCM); Luke Grant (Corrective Services NSW); Alun Richards (Queensland Health) Collaborating centres: Justice Health NSW; Corrective Services NSW; Queensland Health; National Centre in **HIV Social Research**

Funding: NHMRC Project Grant

Broome to Berrima: building capacity Australia wide in Indigenous offender health research

Australia has one of the highest Indigenous incarceration rates in the OECD which impacts profoundly on indigenous communities. With offender populations known to endure a greater health burden compared with the general community, there is a need to develop knowledge in this area, particularly in relation to Indigenous incarceration. This project sees indigenous and non-Indigenous academics from Western Australia, the ACT, New South Wales and Victoria develop offender health research capacity within a team of indigenous and non-Indigenous investigators. Investigators work on collaborative projects in the areas of mental health, substance use, blood-borne viruses. impact of incarceration on indigenous communities, and models of care for indigenous offenders.

Status: Ongoing.

Personnel: Tony Butler, John Kaldor, Kay Wilhelm, Michael Doyle,. Megan Williams, Paul Simpson, Lise Lafferty Collaborating centres: National Centre for Indigenous Studies (Australian National University); National Drug and Alcohol Research Institute (Curtin University); Winnunga Nimmityjah Aboriginal Health Service (ACT) Other investigators: Michael Levy, Mick Dodson, Fadwa Al-Yaman, Dennis Gray, Steve Allsop, Jocelyn Jones, Jill Guthrie, Nerelle Poroch, Dina Saulo Funding: NHMRC

Strengthening China's response to HIV, TB and HIV/TB co-infection in labour camps (*lao jiao suo*) in a southwestern China region

The aim of the study is to describe the health status of detainees in re-educationthrough-labour-camp and identify through self-reported questionnaires their level of HIV and TB knowledge, risk behaviours, and health management of men and women in labour camp settings. Personnel: Lorraine Yap, Tony Butler, Zunyou Wu (China National Center in AIDS and STD Control and Prevention), Liu Wei (Guangxi CDC), Chen Yi (Guangxi CDC); Lei Zhang, Joanne Reekie Collaborating centres: China National Center in AIDS and STD Control and Prevention, Guangxi Provincial Centre for Disease Control (Department of AIDS Control and Prevention), Re-education-Through-Labour Administration in the region

Funding: AusAID Development Research Award

Alcohol and other drug interventions in Australian prisons for Indigenous men

73% of Indigenous people entering prison had used alcohol at levels harmful

to their health in the 12 months prior to their imprisonment. Alcohol has also been implicated as a major contributing factor to the high levels of Indigenous imprisonment, with Indigenous Australians only comprising about 2.5% of the general population but around 20% of the prison population nationally. This project investigated what alcohol and other drug rehabilitative programs exist in Australian prisons for Indigenous men. This research explored gaps in services provision and it is hoped that further work will look at how these gaps can be addressed.

Status: Complete.

Personnel: Michael Doyle, Colleen Fishers, Sherry Saggers, Tony Butler **Collaborating centres:** The University of Western Australia's School of Population Health, National Drug Research Institute (Curtin University)

Funding: This project was funded as part of the NHMRC capacity building grant

Reducing Australia's Aboriginal prisoner population through 'Justice Reinvestment': assessing the public's views on imprisonment versus non-imprisonment alternatives for offenders using Citizens' Juries

Justice Reinvestment has been gaining attention among Indigenous, health and offender advocates and is touted as a possible solution to Indigenous overrepresentation in Australia's criminal justice system. This project seeks to determine, through 'Citizens' Juries', the opinions and views of a critically informed public towards alternatives to incarceration. It also examines whether policy makers are influenced by the opinions and views of the Citizens' Juries. Status: Ongoing.

Personnel: Tony Butler, Paul Simpson, Michael Doyle, Jill Guthrie, Jocelyn Jones Collaborating centres: National Centre for Indigenous Studies (Australian National University); National Drug and Alcohol Research Institute (Curtin University) Project Funding: Lowitja Institute

PUBLIC HEALTH INTERVENTIONS RESEARCH GROUP 2012 STUDIES

Young Women's Reproductive Health Studu

This is a nationally representative survey of young women designed to obtain population-based information on human

papillomavirus vaccination coverage, prevalence of genital warts and genital chlamydia and other issues pertinent to young women's reproductive health such as pregnancy and contraception.

Status: Recruitment underway and analysis underway.

Personnel: Bette Liu, John Kaldor, Basil Donovan, Julia Brotherton, Marion Saville Collaborating centres: Victorian Cytology Service; National HPV Vaccination Register

Funding: NHMRC Program Grant, Victorian Cytology Service

Notifiable Diseases and Reproductive Health

This project uses data linkage in NSW to examine the effects of commonly notified diseases including sexually transmitted infections and blood borne viruses on reproductive health outcomes in women. **Status:** Recruitment completed and analysis underway.

Personnel: Bette Liu, Louisa Jorm, Christine Roberts, John Kaldor, Rebecca Guy, Basil Donovan, Joanne Reekie Collaborating centres: University of Western Sydney; Kolling Institute University of Sydney

Funding: NHMRC Post-doctoral fellowship; NHMRC Program Grant **Co-located:** Public Health Interventions Research Group and Sexual Health Program

Identifying predisposing factors for, and the consequences of, common and emerging infectious diseases

This project will involve using the 45 and Up Prospective cohort study and data linkage to examine what factors may predispose adults to certain infections and what the longer term consequences of infections are on health outcomes and health service utilisation.

Status: Analyses underway.

Personnel: Bette Liu, John Kaldor, Emily

Banks

 $\textbf{Collaborators:} \ \textbf{Sax Institute;} \ \textbf{Australian}$

National University

Funding: Ramaciotti Foundation

A bibliometric analysis of research capacity building in HIV in low-income countries

Many international health research programs aspire to the twin goals of acquiring new scientific knowledge and the building of research capacity in the institutions and workforce of developing country partners. While there is no standard approach to measuring research capacity, bibliometrics has been used in a number of developing country settings. We aimed to assess the change in research capacity over time, through a ten year analysis of trends in authorship positions and predictors of authorship. Status: analysis underway Personnel: Skye McGregor, John Kaldor,

Personnel: Skye McGregor, John Kaldor, Klara Henderson

Funding: Nil

Predictors of research involvement for developing country UNSW Public Health research graduates

Research in Masters and Doctoral degrees are pathways to understanding methods and the role of research. As a consequence of limited graduate education opportunities in developing countries, students in these countries tend to complete studies overseas. The question is whether these students go on to have careers in research, and contribute to the research capacity of their countries. Our aim is to describe the characteristics of UNSW public health research graduates, to measure their research output and to analyse predictors of research involvement.

Status: Ongoing

Personnel: Skye McGregor, John Kaldor, Klara Henderson, Joanne Travaglia Collaborating centre: School of Public Health and Community Medicine

Funding: Nil

Field Research Training Program, HIV Consortium for Partnerships in Asia and the Pacific

The Field Research Training Programme (FRTP) aims to build clinical and epidemiological HIV research capacity in Cambodia and Indonesia through training of researchers in the following areas: longitudinal research design, conduct and analysis; engagement with government and affected communities as research partners; research funding submissions; and the dissemination of research findings to inform policy. The content and structure of the FRTP are flexible and tailored to suit trainees, their institutions and country needs. The FRTP was established as part of the AusAIDfunded HIV Consortium for Partnerships in Asia and the Pacific.

Status: Ongoing

Personnel: Louise Causer, John Kaldor, Bradley Mathers, Skye McGregor, Janaki Amin, Kathy Petoumenos Collaborating centres: National Centre for HIV/AIDS, Dermatology and STD (NCHADS), Phnom Penh, Cambodia; School of Public Health, Udayana University (UU), Bali, Indonesia; Faculty of Medicine, Universitas Gadjah Mada, (UGM), Yogyakarta, Indonesia Funding: AusAID

Scables - Factors associated with scables in a highly endemic population

Scabies is a major cause of morbidity in many developing countries, leading to economic disadvantage and reduced quality of life. This project addresses the problem of scabies control in high prevalence countries, through the investigation of the efficacy of two alternative mass drug administration (MDA) regimens in Fiji compared to the current standard of care, which centres on treatment of asymptomatic cases and their direct contacts. This study has three main objectives: to characterise the participants in a Fiji community survey of scabies; to identify environmental and demographic risk factors for scabies in Fiji; and to provide information on possible preventative measures for scabies. Status: currently recruiting Personnel: John Kaldor, Lucia Romani,

Personnel: John Kaldor, Lucia Romani, Handan Wand, Andrew Steer, Margot Whitfield, Ross Andrews, Hla Hla Thein, Josefa Koroivueta, Lisi Tikoduadua, Timothy Furlong, Apisolome Nakolinivalu, Eric Rafai, Meciusela Tuicakau

Collaborating centres: Murdoch Children's Research Institute, Menzies School of Health Research, Fiji Ministry of Health, St Vincent's Hospital Funding: NHMRC Project Grant

Women's and men's experiences of preventing mother-to-child transmission (PMTCT) in Papua New Guinea: a gendered socio-cultural analysis of barriers and facilitators for program engagement

PNG is experiencing an expanding heterosexual HIV epidemic, placing an increasing number of newborns at risk of acquiring infection. This research seeks to understand the gendered sociocultural aspects influencing the uptake and outcomes of PMTCT programs from the perspectives of antenatal women, their partners, and health care workers. It seeks to: undertake an assessment of PMTCT programs; examine knowledge,

attitudes and decision-making processes regarding PMTCT; test enablers of return for safe delivery and post-natal care; examine experiences of consent, counselling and confidentiality; determine gender-specific barriers/facilitators to accessing PMTCT programs; and develop recommendations for improved PMTCT programs.

Status: 168 interviews were conducted with women, men and key informants. $Seventy-eight\ HIV-positive\ women\ took$ part in in-depth interviews (IDIs). Of these, twenty-four were interviewed three times, sixteen twice and thirtyeight once. Twelve HIV-negative women underwent one IDI. Eighteen men whose wives had undergone HIV testing were interviewed. Of these, one was interviewed three times, nine twice and seven once. Twenty-eight Key Informant Interviews (KIIs) were also conducted. Personnel: John Kaldor, Heather Worth, Angela Kelly, Martha Kupul, Lisa Vallely, Ruthy Neo, Voletta Fiya, Grace Karawiga, Glen Mola

Collaborating centres: PNG Institute of Medical Research; University of Papua New Guinea; Port Moresby General Hospital; UNICEF PNG; International HIV Research Group, UNSW Funding: AusAID Australian Development Research Award

MCAIS: Male Circumcision Acceptability & Impact Study, PNG

This four-year multi-disciplinary community-based research program is investigating the potential of male circumcision for HIV prevention in Papua New Guinea and has four principal components: ethnographic research; mathematical modelling; health systems research; and longitudinal clinical cohort studies. The study is being carried out among a combination of general and at-risk population cohorts at multiple sites in PNG. A sub-study to investigate the notional acceptability of a vaginal microbicide surrogate for HIV prevention among women and men attending a sexual health clinic in Port Moresby was completed in 2010. MCAIS jointly organised a national policy forum on male circumcision for HIV prevention in PNG, which was held in Port Moresby in November 2011 with the purpose of translating research evidence into public health policy and practice. The forum made three key recommendations: (1) the formation of a joint NDoH/NACS Policy Committee on Male Circumcision; (2) the establishment of an integrated harm reduction program; and (3) that

future policy on wide scale roll-out of MC for HIV prevention in PNG be informed by a combination of (a) data from MC intervention pilot programs and (b) formative research on the potential protective effect of other forms of penile cutting. The MCAIS group has been asked to take a lead role in these future research activities and will be leading these new activities from 2013 onwards. **Status**: Complete.

Personnel: Andrew Vallely, John Kaldor, John Murray, David Wilson, Richard Gray, Peter Siba, Angela Kelly, Claire Ryan, Martha Kupul, Herick Aeno, Voletta Fiya, James Neo, Richard Naketrumb, Greg Law, Petronia Kaima, Zure Kombati, Joyce Sauk, Joyce Allan, Pamela Toliman, Liza Fitzgerald, Peter Hill, Anna Tynan, John Millan.

Collaborators: PNG Institute of Medical Research; Mt Hagen General Hospital, PNG; HOPE Worldwide, PNG; University of Queensland, Australia; The Burnet Institute, Melbourne.

Funding: AusAID Australian Development Research Award (ADRA)

Qualitative longitudinal study to investigate constructions of masculinity, sexuality and agency among male youth in Papua New Guinea (NACS Masculinities Study, PNG)

This two-year multi-disciplinary community-based research program will investigate the role that individual, community and cultural constructs of masculinity, male sexuality and sexual agency have in determining sexual behaviour among young men in PNG, and specifically, their role in promoting behaviours known to increase the risk of HIV and STIs among men and women. The study will be conducted in Eastern and Western Highlands Provinces, PNG where 50 to 60 in-school and out-of school male youth aged 16-17 years will be recruited into a qualitative longitudinal research study and followed up every three months for up to 18 months. This research addresses a clear gap in current knowledge about masculinities and male sexuality in the context of the HIV epidemic in PNG. It will provide information vital to evidence-based public health policy development. The study is also expected to directly inform the implementation of new national programs designed specifically to address male sexual and reproductive health

Status: Qualitative longitudinal study among male youth in rural Eastern

Highlands Province commenced February 2012 and is on-going. Photovoice activity conducted in December 2012 is expected to lead to an interactive photographic exhibition in-country and in Australia in 2013.

Personnel: Andrew Vallely, John Kaldor, Angela Kelly, Lee Wilson, Lisa Fitzgerald, Peter Siba, Maxine Whittaker, Agnes Mek, Herick Aeno, John Millan, Joyce Sauk, Richard Naketrumb, Zure Kombati. Collaborators: PNG Institute of Medical Research, University of Queensland. Funding: National AIDS Council Secretariat, Papua New Guinea (NACS)

The epidemiology of sexually transmitted infections, including human papillomavirus, among pregnant women attending antenatal clinics at four sites in Papua New Guinea (STIs in Pregnancy Study, PNG)

An estimated 1500 women die every year in PNG due to cervical cancer. Despite this disease burden, no large-scale surveys have been conducted to establish the prevalence of HPV among general or atrisk populations of women. This study will investigate the epidemiology of sexually transmitted infections, including human papillomavirus (HPV), HIV and herpes simplex type-2 (HSV-2) among 1000 women attending antenatal clinics in four provinces in PNG. It will provide the first general population level estimates of HPV type prevalence and is expected to inform future policy on HPV vaccination and cervical cancer prevention in PNG. Status: Ethical clearance and clinical site preparation completed December 2011; study recruitment started February 2012. At the end of 2012, 227 study participants had been recruited at two sites. Personnel: Andrew Vallely, Claire Ryan, John Kaldor, Handan Wand, Peter Siba, Greg Law, Petronia Kaima, Zure Kombati, Joyce Sauk, Sandra Yamuwe, Lisa Vallely, Glen Mola, Nola N'drewei, Sepehr Tabrizi Collaborators: PNG Institute of Medical Research; National Department of Health, PNG; The Burnet Institute, Melbourne; Royal Women's Hospital, Melbourne.

Funding: PNGIMR ICRAS Program / AusAID PNG

Human papillomavirus infection among women attending sexual health clinics in Mt Hagen, Goroka and Port Moresby, Papua New Guinea (HPV Study PNG)

This study will investigate the epidemiology of human papillomavirus (HPV) and other sexually transmitted infections among women attending sexual health clinics in three provinces in PNG. It will provide the first estimates of HPV type prevalence among women at increased risk of HIV/STI acquisition in PNG and is expected to inform future policy on cervical cancer screening and prevention. Status: Currently recruiting. Personnel: Andrew Vallely, Claire Ryan, John Kaldor, Handan Wand, Peter Siba, Greg Law, Petronia Kaima, Zure Kombati, Joyce Sauk, Sandra Yamuwe, Glen Mol, Nola N'derewei, Sepehr Tabrizi **Collaborators:** PNG Institute of Medical Research; National Department of Health, PNG; HOPE Worldwide, PNG; Mt Hagen General Hospital: Save the Children in PNG; The Burnet Institute, Melbourne; Royal Women's Hospital, Melbourne

Cervical cancer screening using visual inspection with acetic acid (VIA) and its relationship to cervical cytology and high-risk human papillomavirus (HR-HPV) infection among women attending Well Woman Clinics in Papua New Guinea (VIA Study PNG)

Funding: AusAID PNG

This study will investigate: the prevalence of VIA-detectable cervical abnormalities; cervical intraepithelial dysplasia; high-risk human papillomavirus (HR-HPV) infection; and the behavioural and biological determinants associated with risk, among women attending Well Woman clinics in Eastern and Western Highlands Provinces, PNG. The study will determine the acceptability and operational feasibility of VIA plus cryotherapy ('test and treat') as an intervention for cervical cancer screening and treatment among urban and rural populations in PNG, and is being conducted in order to inform future national policy on cervical cancer screening.

Status: Currently recruiting.
Personnel: Andrew Vallely, Claire
Ryan, John Kaldor, Glen Mola, Antonia
Kumbia, Benny Kombuk, Handan Wand,
Lisa Vallely, Angela Kelly, Joanne Goyen,
Phillip Baird, Greg Law, Peter Siba
Collaborating centres: PNG Institute of
Medical Research, National Department
of Health, PNG, Mt Hagen General
Hospital, Goroka General Hospital,
MeriPath PNG; The Burnet Institute,
Melbourne

Funding: AusAID PNG

Meanings and beliefs of cervical cancer, its causation, prevention and treatment in Papua New Guinea

Cervical cancer is the most common cancer among women in PNG and a leading cause of premature death. Despite this disease burden, no research to date has been conducted to investigate traditional and contemporary socio-cultural contexts, meanings and understandings of cervical cancer causation, prevention and treatment in PNG. This mixed-method qualitative study will investigate socio-cultural contexts of cervical cancer in Papua New Guinea in order to inform future national prevention and care strategies, including HPV vaccination and cervical screening programs.

Status: Study conducted in Unggai Bena District, August-October 2012 with remaining sites to be completed by July 2013.

Personnel: Andrew Vallely, John Kaldor, Angela Kelly, Voletta Fiya, Priscilla Ofi, Herick Aeno, Glen Mola, Antonia Kumbia, Benny Kombuk, Alex Golpak, Lisa Vallely, Jane Jones, David Wood, Peter Siba.

Collaborators: PNG Institute of Medical Research, National Department of Health, PNG, Mt Hagen General Hospital, Goroka General Hospital, Kimbe Hospital Funding: AusAID PNG

HIV prevalence, predictors of infection, and effective interventions for female sex workers in Vietnam

Recent increases in prevalence among key risk populations in Vietnam, particularly FSW, have prompted the government and HIV donor community to launch new initiatives, but in a period of donor funding decline for HIV programs in Vietnam. Evidence-based planning is critically needed at this transitory stage of HIV prevention programming. This research helps fill the epidemiologic data gap on FSW, investigates barriers and incentives for FSW enrolment and retention in longitudinal studies, and evaluates the effectiveness of new interventions in reducing HIV risks among FSW. This is a combination of cross-sectional, prospective cohort and ethnographic studies characterising the HIV epidemic among female sex workers (FSW) in Vietnam and evaluating HIV interventions for FSW in Ho Chi Minh City. Status: ongoing

Personnel: Linh-Vi Le, John Kaldor, Lisa Maher, Keith Sabin

Collaborating centres: World Health Organization, UNAIDS, CDC Vietnam

Funding: U.S. President's Emergency Plan for AIDS Relief

A survey and follow-up study to assess research capacity building of developing country attendees of the 2012 International Microbicides Conference (M2012)

It is commonly accepted that attendance at international research conferences facilitates exposure to new research ideas, methodologies, and researchers. For developing country attendees, it could reasonably be assumed that this would contribute to the development of research capacity of individuals. Surveys of research attendees are common, but largely relate to the assessment of quality of the conference. A web based survey distributed to developing country attendees of M2012. Data is collected on education, current research involvement, and research activity in the twelve months following M2012.

Status: Ethics approval was granted in March 2012, the first survey was distributed in May 2012, the first follow up in October 2013, with the final survey to be distributed in April 2013

Personnel: Skye McGregor, John Kaldor, Klara Henderson

Funding: n/a

Mobile men with money: the role of mining development on sexual health risks among landowners

A qualitative study to examine the role of mining development on sexual health risks among landowners, their sexual partners and others affected by resource extraction development, in order to improve the health outcomes of Papua New Guineans. This study will examine the impact of development, mobility, and income remittance on sexual health risk and vulnerability for Papua New Guineans, particularly landowners and their sexual partners in the selected LNG project affected areas, and identify strategies and points of entry for sexual health impact mitigation.

Status: Currently recruiting Personnel: Andrew Vallely, Angela Kelly, Roselyn Siki, Richard Naketrumb, Priscilla Ofi, Michael Moses, Heather Worth, Richard Eves

Collaborating centres: PNG Institute of Medical Research; International HIV Research Group, University of New South Wales, Sydney; Australian National University, Canberra

Funding: PNGIMR ICRAS Program

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HIV, tuberculosis, sexually transmitted infections and blood borne viruses in prison populations in Papua New Guinea

A longitudinal clinical cohort study to investigate the prevalence and risk factors associated with HIV, tuberculosis, sexually transmitted infections and blood borne viruses in prison populations in Papua New Guinea. This study will estimate the prevalence of HIV, tuberculosis (TB), sexually transmitted infections (STIs), and blood borne viruses (BBVs) among new prisoners on admission to Bomana Prison, National Capital District, Papua New Guinea; and determine the behavioural and sociocultural factors associated with risk of infection.

Status: Currently recruiting
Personnel: Andrew Vallely, Bradley
Mathers, Tony Butler, John Kaldor
Collaborating centres: PNG Institute of
Medical Research; National Department
of Health, Waigani; Department of
Correctional Services, Boroko; The
Burnet Institute, Melbourne; University
of Western Australia, Perth
Funding: PNGIMR ICRAS Program

Drugs and HIV risk in prisons in PNG

An assessment of HIV risk in relation to alcohol and other drugs (particularly injecting) and HIV risk in prisons and access to prevention, treatment and care. This study investigated the risks for HIV associated with illegal drugs, particularly injecting drugs and in closed settings, HIV risk and access to HIV prevention, treatment and care.

Status: Currently recruiting **Personnel:** Bradley Mathers, Andrew Vallely, Angela Kelly, Thomas Kawage **Collaborating centres:** PNG Institute of Medical Research

Funding: UNAIDS/UNODC

Gonococcal resistance in Papua New Guinea

The prevalence and mechanisms of gonococcal resistance to antimicrobial compounds in Papua New Guinea. Gonorrhoea is a sexually transmitted infection (STI) caused by the bacteria Neisseria gonorrhoeae (Ng). Gonorrhoea is an important public health issue for PNG, as reported infection rates are high (131 per 100,000), and infection can result in a range of pathologies including urethritis in men, endocervicitis,

infertility and pelvic inflammatory disease in women, eye infection in neonates, and has been reported to potentiate the transmission of HIV. Standard treatment for gonorrhoea in PNG is amoxicillin-clayunate, however Ng strains that are resistant to this and other antibiotics are becoming increasingly prevalent in the Asia-Pacific region, raising concern that resistant strains may also be circulating in PNG. Status: currently recruiting Personnel: Andrew Vallely, Johanna Wapling, Mition Yohannes, Pamela Toliman, Sylvia Soso, Matthew David, Claire Ryan, Andrew Greenhill, Zure Kombati, Greg Law, David Whiley Collaborating centres: PNG Institute of Medical Research; Mt Hagen General Hospital: National Department of Health. Waigani; Burnet Institute, Melbourne; Monash University, Melbourne; University of Queensland, Brisbane Funding: PNGIMR ICRAS Program

Genital infections in Papua New Guinea

To determining the contribution of bacterial vaginosis and Candida albicans to vaginal discharge syndrome and vulval irritation in women attending a sexual health clinic in Goroka, Papua New Guinea. The aim of this study is to determine the contribution of bacterial vaginosis and C. albicans to vaginal discharge syndrome and vulva irritation in PNG women attending a sexual health clinic in Goroka.

Status: Ethical approvals obtained July 2012; specialist training for study PI completed in Melbourne, September 2012; participant enrolment to start April 2013.

Personnel: Andrew Vallely, Nola N'Drewei, Claire Ryan, Johanna Wapling, Alson Akege'e, Catriona Bradshaw Collaborating centres: PNG Institute of Medical Research; Michael Alpers Clinic, Goroka Provincial Hospital; Burnet Institute, Melbourne; Melbourne Sexual Health Centre, Melbourne Funding: PNGIMR ICRAS Program

Immuno-Histological correlates of protection from HIV transmission by male circumcision and other forms of penile cutting

This study will test the hypothesis that alternative forms of penile cutting may be protective against HIV infection among men in Papua New Guinea and investigate immuno-histological

correlates of protection it will be conducted as part of a male circumcision intervention being provided on-campus to students enrolled at Pacific Adventist University in Port Moresby.

Status: Currently recruiting
Personnel: Andrew Vallely, John
Kaldor, Stuart Turville, John McBride,
Mangalasiri Jayathunge, Tom Hope,
Minh Dinh, David MacLaren, Peter Siba,
Claire Ryan, Paul Horwood, Rachael
Tommbe

Collaborating centres: PNG Institute of Medical Research; National Department of Health, Waigani; Pacific Adventist University, Port Moresby; James Cook University, Cairns; The Burnet Institute, Melbourne; Feinberg School of Medicine, Northwestern University, Chicago Funding: National AIDS Council, PNG

The protective effect of dorsal longitudinal slit of the foreskin against HIV acquisition in men in Papua New Guinea

This prospective study will investigate the protective effect of dorsal longitudinal slit of the foreskin against HIV acquisition in men in Papua New Guinea. Male circumcision (MC) has been shown in large-scale clinical trials in Africa to have a protective efficacy of around 60% in preventing HIV acquisition in heterosexual men, confirming earlier observational and ecological studies, and resulting in a recommendation by WHO/ UNAIDS in 2007 that MC be considered an essential component of comprehensive HIV prevention in high prevalence settings. Dorsal longitudinal slit of the foreskin ('dorsal slit') appears to be the most common form of contemporary penile cutting in PNG and was reported by 47% of men in a large cross-sectional survey conducted in four provinces in 2010-11. Personnel: Andrew Vallely, John Kaldor, Handan Wand, David MacLaren, Rachael Tommbe, Angela Kelly, Claire Ryan, John McBride, Peter Siba, Lalen Simeon, Clement Manineng, Kel Browne, Petronia Kaima, Zure Kombati, Greg Law, John Millan, Peter Hill

Collaborating centres: PNG Institute of Medical Research; National Department of Health, Waigani; Pacific Adventist University, Port Moresby; Divine World University, Madang; James Cook University, Cairns; The Burnet Institute, Melbourne; University of Queensland, Brisbane

Funding: National AIDS Council, PNG

An investigation of health workers understanding of syphilis testing in PNG

Knowledge, attitudes and practices (KAP) survey among health workers in government, non-government and faith-based health care facilities in 10 provinces in PNG. Informants completed short interview based questionnaire to assess their understanding of syphilis testing, diagnosis and treatment. Information also captured on the level of training health workers received regarding the performance of syphilis rapid tests and the interpretation of results. The PNG Safe Motherhood/ Obstetrics Group has approved the use of a TPHA syphilis rapid test in rural antenatal clinics (ANCs). Informal interviews indicate that health care workers (HCWs) have not been trained in the use of TPHA rapid tests, that there are differences in how much blood is used, and how long before results are being read.

Status: Ethical approval obtain January 2012. Interviews with over 50 health workers conducted in 11 provinces April – November 2012

Personnel: Andrew Vallely, Claire Ryan, Tawarot Kurumop, Justin Pulford, Jimmy Elliot, Greg Law

Collaborating centres: PNG Institute of Medical Research; Burnet Institute, Melbourne; National Department of Health, PNG

Funding: PNGIMR ICRAS Program

Women's experiences of pregnancy and childbirth in Upper Bena, Unggai Bena District, Eastern Highlands Province, Papua New Guinea.

PNG has one of the highest maternal mortality ratios (MMR) in the world. This study will investigate the epidemiology of sexually transmitted infections, including human papillomavirus (HPV), HIV and herpes simplex type-2 (HSV-2) among 1000 women attending antenatal clinics in four provinces in PNG. It will provide the first general population level estimates of HPV type prevalence and is expected to inform future policy on HPV vaccination and cervical cancer prevention in PNG.

Status: Key informant interviews (KIIs) and recruitment of women into a longitudinal cohort started Jan 2012. Collection of health facility data relating to maternal health activities, follow-up interviews for women in the longitudinal cohort, and KIIs completed in May 2012.

Personnel: Andrew Vallely, Lisa Vallely, Primrose Homiehombo, Julie Liviko, Angela Kelly, Voletta Fiya, Andrew Whittaker, Caroline Homer Collaborating centres: PNG Institute of Medical Research; Eastern Highlands Provincial Department of Health, PNG; University of Queensland, Brisbane; University of Technology, Sydney Funding: PNGIMR ICRAS Program

STIs among pregnant women in Papua New Guinea

The epidemiology of sexually transmitted infections, including human papillomavirus (HPV), among pregnant women attending antenatal clinics at four sites in Papua New Guinea, Papua New Guinea (PNG) has one of the highest rates of cervical cancer in the world with an estimated age-standardised incidence of 23.7/100,000 compared to 5.0/100,000 in Australia and New Zealand, Cervical cancer is the most common cancer among women in PNG and a leading cause of premature death. An estimated 1500 women die every year in PNG due to cervical cancer. Despite this disease burden, no large-scale surveys have been conducted to establish the prevalence of human papillomavirus (HPV) among general or at-risk populations of women. Status: currently recruiting

Personnel: Andrew Vallely, John Kaldor, Handan Wand, Claire Ryan, Lisa Vallely, Suparat Phuanukoonon, Peter Siba, Glen Mola, Greg Law, John Millan, Glennis

Rai, Sepehr Tabrizi

Collaborating centres: PNG Institute of Medical Research; National Department of Health, PNG; The Burnet Institute, Melbourne; Royal Women's Hospital, Melbourne

Funding: Papua New Guinea Partnership in Health Program (PNG PiHP)

SEXUAL HEALTH PROGRAM STUDIES 2012

Australian Chlamydia control effectiveness pilot (ACCEPt) study

Current national guidelines for general practitioners (GPs) recommend all sexually active people aged 15–29 years old receive annual testing for chlamydia. More than 80% of 15–29-year-olds attend a GP each year less however less than 10% are being tested for chlamydia by their GP. ACCEPt involves a multifaceted intervention in the GP setting to maximise testing rates and annual testing

in sexually active 16–29- year-olds to see if it can reduce the prevalence of chlamydia infections and its associated complications such as PID. This is the first trial of this nature in Australia and is being led by the Centre for Women's Health, Gender and Society at University of Melbourne in collaboration with a large consortium of experts including a number of researchers from the Kirby Institute. In addition, the Kirby Institute has been contracted to develop the protocol for program evaluation, conduct mathematical modelling, and assist with implementation.

Status: 52 Postcodes recruited and randomised. Intervention is underway. Personnel: Rebecca Guy, John Kaldor, Basil Donovan, David Regan, David Wilson, Matthew Law, Rebecca Lorch, Lisa Edward, James Ward, Belinda Ford Collaborators: Jane Hocking, Meredith Temple-Smith, Jenny Walker, Simone Poznanski, Alaina Vaisey, Dyani Lewis, Jane Gunn, Christopher Fairley, Nicola Low, Marian Pitts, Marion Saville, Dorota Gertig, Sepehr Tabrizi, Margaret Hellard Funding: Australian Government Department of Health and Ageing Chlamydia Pilot Program. Further funding from NHMRC Project grant from 2011. Co-location: Sexual Health Program, Public Heath Interventions Research Group, Biostatistics and Databases Program, Aboriginal and Torres Strait Islander Health Program

Australian Collaboration on Chlamydia Enhanced Sentinel Surveillance (ACCESS)

Chlamydia is the most commonly notified infection in Australia and is an important cause of pelvic inflammatory disease, ectopic pregnancy and tubal infertility in women. Chlamydia notifications have been increasing for over a decade. However, the basis of the increase is not well understood. The ACCESS program determines chlamydia testing and positivity rates in priority populations nationally also maintains an ongoing surveillance system. Populations of interest include young heterosexuals, men who have sex with men, sex workers, pregnant women, and Indigenous people. The program involves national collaborative networks of selected services including sexual health clinics, antenatal clinics, Aboriginal Community Controlled Health Services, family planning clinics, general practices and laboratories.

Status: A number of peer-reviewed reports published.

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Personnel: Basil Donovan, Rebecca Guy, Hammad Ali, John Kaldor, Andrew Grulich, James Ward, Handan Wand, David Wilson

Collaborators: Margaret Hellard, Caroline Van Gemert, Mark Stoove, Isabel Bergeri, Jane Goller, Fabian Kong, Anna Bowring, Elizabeth Sullivan, Zhuoyang Li, Wayne Dimech, Marcus Chen, Christopher Fairley, Catherine O'Connor, Bridget Dickson, Lewis Marshall, Tony Merritt, Jane Hocking, Marie Pirotta, Phyllis Lau Douglas Boyle, Helena Britt, Clare Heal, Tom Brett, Caroline Harvey, Robyn Wardle, Kathy McNamee, Lynne Jordan, Anne Stephens, Christine Read, Deborah Bateson, Deborah Wright, Mick Adams, Mark Saunders, Sophie Couzos, Jenny Hunt, Peter Waples-Crowe, David Scrimgeour, Sid Williams, Ana Herceg, Liz Moore, Michael Beckmann, Julie MacPhail, Marian Currie, Zena Robinson, Trent Miller, Megan Halliday, Paul Goldwater Funding: Funding is currently being sought from States and Territories' Health Departments and from the Department of Health and Ageing. Co-location: Sexual Health Program, Public Heath Interventions Research Group, Surveillance and Evaluation Program for Public Health, Biostatistics and Databases Program

Chlamydia incidence and re-infection study (CIRIS): a longitudinal cohort study of young Australian women

Chlamydia incidence and re-infection rates have never been studied in Australian women. We aimed to determine the incidence of chlamydia in a cohort of young women who initially screen negative, along with determining the re-infection rate of women who initially screen positive, in order to inform future population screening programs. This study involved the establishment of a cohort of young women attending a range of primary health care services who agreed to complete questionnaires and return selfcollected vaginal swabs for testing. This study is lead by the Centre for Women's Health and Society at University of Melbourne.

Further funding was obtained from the National Health and Medical Research Council extending this project to investigate the incidence of Bacterial Vaginosis (BV) and Mycoplasma genitalium within this cohort of women. **Status** Final report published in PLoS one in 2012.

Personnel: Basil Donovan, John Kaldor

Collaborators: Jane Hocking, Jenny Walker, Christopher Fairley, Marcus Chen, Jane Gunn, Marie Pirotta, Veerakathy Harindra, Lyle Gurrin L, Kathy McNamee, Hudson Birden (University of Sydney); Frank Bowden, Sepehr Tabrizi, Suzanne Garland Funding: Australian Government Department of Health and Ageing Chlamydia Pilot Program; NHMRC Co-location: Sexual Health Program and Public Heath Interventions Research Group

Chlamydia re-test review

Repeat infection with *chlamydia trachomatis* following treatment is common and increases the risk of sequelae. Despite clinical guidelines recommending re-screening within three months of treatment, re-screening rates remains low. We undertook a systematic review to identify studies which compared rates of re-screening for repeat chlamydial infection between patients receiving and not receiving an intervention.

in Sexually Transmitted Infections
Personnel: Rebecca Guy, Hammad Al,
Basil Donovan, John Kaldor
Collaborators: Jane Hocking (University
of Melbourne); Low Nicola (University
of Bern, Switzerland); Bauer Heidi
(California Department of Public Health);
Jenny Walker (University of Melbourne)
Jeffrey Klausner (University of California).
Funding: Nil

Status: Review accepted for publication

Location: Sexual Health Program

Chlamydia testing and management practices in Australian family planning clinics

Chlamydia is the most common reportable infection in Australia with over 80,000 cases reported in 2011. Chlamydia infection is associated with adverse health outcomes including pelvic inflammatory disease (PID), ectopic pregnancy, and tubal infertility. Chlamydia testing, contact tracing and retesting practices of clinicians are important foundations for early detection and prevention of chlamydia infections. The aims of this study are: to assess chlamydia testing, partner notification and retesting practices of clinicians at family planning clinics in Australia; to determine enablers and barriers to chlamydia testing, contact tracing and retesting; and to identify opportunities for training and support of clinicians and future interventions for chlamydia prevention. This study was conducted at Family Planning Clinics in all states and territories of Australia and involved an online survey of clinicians' chlamydia testing and management practices. Following the survey, focus groups among family planning clinics' clinicians will be conducted to determine enablers and barriers to the testing and management of patients for chlamydia. **Status:** The study survey closed at the end of June, 2012 with an overall response rate of 79%. All of the focus groups (11 in total) have been completed. Preliminary data has been fed back to Family Planning Australia and individual clinic feedback is being put together.

Personnel: Joanne Micallef, Rebecca Guy, Larissa Lewis

Collaborators: Deborah Bateson (Family Planning New South Wales); Caroline Harvey (Family Planning Queensland); Julie Mooney-Somers (University of Sydney); Caroline Van Gemert (Burnet Institute)

Co-location: Sexual Health Program and Public Health Interventions Research Group

Cost analysis of rapid HIV testing in sexual health clinics

This analysis will assess the costs of both conventional and rapid HIV testing in terms of test kits and laboratory equipment, staff time and other ancillary costs to allow a direct comparison. A decision tree analysis will be used to assess the possible impact of provision of conventional HIV results by telephone and avoiding a second clinic visit through rapid HIV testing on the costs of HIV testing for MSM. The study is designed to assess whether rapid HIV testing can be shown to be cost saving compared to conventional serology testing.

Status: Ongoing. **Personnel:** Damian Conway,

Rebecca Guy

Funding: NHMRC program grant Co-location: Sexual Health Program and Biostatistics, HIV Epidemiology and Prevention Program, Surveillance and Evaluation Program for Public Health

Evaluation of sexual health services for men who have sex with men in Perth

Review of sexual health services for gay, bisexual and other men who have sex with men (MSM).

The Western Australian AIDS Council (WAAC) provides a peer (or community) based sexual health services for gay, bisexual, and other (MSM) clients at

two sites. This model is a relatively new approach to HIV/STI service delivery among MSM in Western Australia. This study will describe the approach and compare it with two other service delivery models (general practice and sexual health clinic). It will describe the clinic (funding, staffing, location), the MSM clients attending (numbers, demographics, testing patterns, reasons for attending) and the clients perceptions of the services. Multiple data collections will take place.

Status: Data collection for patient survey complete with 373 participants. HIV and STI lab testing data pending. Report in preparation with manuscript for journal submission to follow during 2013.

Personnel: Damian Conway, Rebecca Guy, Denton Callander
Collaborators: Martin Holt, Lewis

Marshall, Trish Langdon, Michael Atkinson, Jenny McCloskey, Ric Chaney Funding: NHMRC Program grant Location: Sexual Health Program

Genital Warts Surveillance Network

A national program of human papilloma virus (HPV) vaccination of Australian teenage girls and young women requires systems that can provide long-term surveillance for trends in HPV-related diseases. Genital warts can only be prevented by quadrivalent vaccine that also covers HPV types 6 and 11. We established a network for enhanced sentinel surveillance of genital warts in eight larger sexual health clinics across Australia.

Status: Two further reports submitted for publication.

Personnel: Basil Donovan, Rebecca
Guy, Hammad Ali, David Regan,
Andrew Grulich, Handan Wand
Collaborator: Christopher Fairley
Funding: CSL Biotherapies Ltd
Co-location: Sexual Health Program,
Biostatistics and Databases Program and
HIV Epidemiology and Prevention Program

eTEST An initiative to enhance STI Testing in gay men

Regular testing of sexually active gay men is required to prevent ongoing transmission of STIs. This project assesses whether a multi-faceted intervention which involves software designed to encourage clinicians to test through passive prompts, SMS recall messaging, audit tools, education and incentives for testing can increase testing rates in general practice. eTEST will take place in Sydney among 10-15 GP clinics with the aim of increasing HIV/STI testing to at least two times per year in high-risk gay men, four times per year in HIV positive men, and re-testing after a chlamydia and gonorrhoea infection. These aims are in accordance with the testing guidelines for men who have sex with men.

Status: Recruitment for eTEST finished. with interventions designed for eight clinics in NSW and one in VIC: The collection of testing and positivity surveillance data was organised for each site and audit reports were presented to several clinics; Ongoing support to participating clinics and regular data reporting will continue into 2013 Personnel: Rebecca Guv. Denton Callander, Larissa Lewis, Handan Wand, John Kaldor, Basil Donovan Collaborators: Chris Bourne (Sydney Sexual Health Centre); Vijay Ramanathan (Central Sydney GP Network); Jane Hocking (University of Melbourne); Mark Stoove (Burnet Institute); John de Wit, (National Centre in HIV Social Research); Cathy Pell, (Taylor Square Private Clinic); Liza Doyle, (Australasian Society for HIV Medicine); Geoff Honnor (ACON); Barry Edwards (NSW Health); Sonny Williams (Positive Life)

Funding: NSW Ministry of Health Co-location: Sexual Health Program, Biostatistics and Databases Program and Public Heath Interventions Research Group

A longitudinal study of bacterial vaginosis and Mycoplasma genitalium in young Australian women

Little is known about the epidemiology and natural history of bacterial vaginosis (BV) and nothing is known about *M genitalium* (MG) infection in Australian women. We seek to determine the prevalence, incidence and persistence of BV and MG in a general population of Australian women using the cohort established by the CIRIS study. This study is lead by the Centre for Women's Health and Society at University of Melbourne. **Status:** Two reports have been published in PLoS one and Clinical Infectious Diseases

Personnel: Basil Donovan Collaborators: Jane Hocking, Jenny Walker, Christopher Fairley, Marcus Chen, Catriona Bradshaw, Jane Gunn, Marie Pirotta, Veerakathy Harindra, Lyle Gurrin L, Kathy McNamee (University of Melbourne); Sepehr Tabrizi, Suzanne Garland (Royal Women's and Royal Children's Hospitals, Melbourne) Funding: NHMRC Project Grant Co-location: Sexual Health Program

Rapid HIV testing in men who have sex with men in sexual health clinics in Sydney

This is the first study to use rapid HIV tests in a clinical setting in NSW. The study will be undertaken at four public sexual health clinics in Sydney: Sydney Sexual Health Centre, Albion Street Centre, Clinic 16 Royal North Shore Hospital and Parramatta Sexual Health Clinic. The rapid HIV test used in the study is the Alere Determine HIV 1&2 Antigen/Antibody Combo assay which gives a result in 21 minutes. Men who have sex with men and who attend the study sites for HIV screening will be offered rapid HIV testing. Participants will undergo usual care in relation to sexually transmissible infection screening and conventional HIV serology testing. The participants' rapid HIV test results will be provided during their visit, and if the result is reactive they will be referred to the counsellor for support. The evaluation will assess acceptability of the rapid HIV testing process among clients and clinic staff, barriers to HIV testing, the impact of rapid HIV testing on client flow, the performance of the rapid test compared to conventional laboratory HIV serology, and the cost of rapid HIV testing in a sexual health clinic settings, compared with standard of care.

Status: Ethics and site-specific approvals and staff training completed. Staff were trained in rapid HIV testing as part of a formal training workshop conducted in partnership with the National Serology Reference Laboratory and the St Vincent's Centre for Applied Medical Research. By the end of 2012, 1672 men had 1981 rapid tests performed at the four clinic sites. Initially funded through NHMRC STI program grant, NSW Health awarded funding for expansion of the study to more sites around NSW. There were 1111 participants in the patient acceptability survey and 68 participants in the staff acceptability survey. Three manuscripts are in preparation for journal submission in 2013.

Personnel: Damian Conway, Rebecca Guy, Andrew Grulich

Collaborators: Martin Holt, Philip Cunningham, Don Smith, Phillip Keen, Stephen Davies, Deborah Couldwell,

Anna McNulty **Funding:** NHMRC

Location: Sexual Health Program

REACT: Chlamydia re-test trial

Chlamydia re-infection is common in women and men. Chlamydia re-infections increase the risk of chlamydia-related sequelae such as pelvic inflammatory disease (PID) and infertility, when compared to initial infection, and in men who have sex with men (MSM) has been associated with an increased HIV seroconversion risk. Clinical guidelines in Australia recommend that all people treated for chlamydia undergo a repeat test three months after initial treatment. This randomised controlled trial will assess the effectiveness of a SMS reminder and home-based self-collected samples (home group) to increase the proportion of patients re-tested after a chlamydia infection, compared to an SMS reminder and clinic testing (clinic group). Approximately 600 patients diagnosed with chlamydia across two sexual health clinics will be randomised to the home group or the clinic group.

Status: Recruitment completed in September 2012. Follow-up to continue until February 2013

Personnel: Kirsty Smith, Rebecca Guy, Handan Wand, Basil Donovan, John Kaldor

Collaborators: Christopher Fairley, Marcus Chen, Catriona Bradshaw, Karen Worthington, Jane Hocking, Anna McNulty, Phillip Read, Simon Wright, Samantha Morgan, Sepehr Tabrizi, Suzanne Garland, Bill Rawlinson, Marion Saville, Gary Rickard

Funding: NHMRC STI Program Grant **Co-location:** Sexual Health Program, Public Heath Interventions Research Group and Biostatistics and Databases Program

Report on the sex industry in New South Wales

This is a state-specific report of the sex industry in New South Wales that was commissioned by the NSW Ministry of Health.

Status: Final report launch February 2012.

Personnel: Basil Donovan, Chris Harcourt, John Kaldor, Handan Wand, Lucy Watchirs Smith

Collaborators: Sandra Egger (Faculty of Law, UNSW); Sepehr Tabrizi (Royal Women's and Royal Children's Hospitals, Melbourne); Christopher Fairley (Melbourne Sexual Health Centre/ University of Melbourne)

Funding: NSW Health

Location: Sexual Health Program

Syphilis testing in HIV positive men: a multi-site review

Clinical guidelines recommend three-monthly syphilis testing in HIV-positive men who have sex with men (MSM) as part of quarterly routine HIV management checks. However, not all men are having quarterly HIV management checks, particularly if they have been clinically stable for a number of years. This study aims to assess the syphilis testing frequency in HIV positive men against the frequency of HIV management checks at seven clinical sites in Melbourne and Sydney, Australia. Status: Final report published in Sexually Transmitted Diseases.

Personnel: Rebecca Guy, Handan Wand Collaborators: Andrew Carr, John McAllister, Karl Hesse (St Vincent's Hospital, Sydney); Marcus Chen, Christopher Fairley (Melbourne Sexual Health Centre/University of Melbourne); Anna McNulty, Chris Bourne (Sydney Sexual Health Centre); David Baker (East Sydney Doctors); Norm Roth (Prahran Market Clinic); BK Tee (The Centre Clinic); Jenny Hoy, Kerry Watson (The Alfred Hospital); Mark Stoove, Carol El-Hayek (Burnet Institute)

Co-location: Sexual Health Program and Biostatistics and Databases Program

Test, Treat ANd GO, the TTANGO Trial: a randomised trial of rapid point-of-care tests for chlamydia and gonorrhoea infections in remote Aboriginal communities

Many remote and isolated communities in Australia continue to experience higher rates of chlamydia and gonorrhoea despite focused efforts at STI prevention and control. In order to interrupt disease transmission and reduce the risk of complications, early diagnosis and treatment is important. However in many remote communities, there are long delays between clinical testing and the provision of treatment, due to both distance from laboratories and difficulties in recalling patients when results arrive. This study will be the first to trial the addition of pointof-care testing to standard diagnostic procedures with aims of improving the interval time to treatment and decreasing rates of persistent chlamydia and gonorrhoea infections (many of which are due to re-infection). The randomised controlled study will take place in remote communities in Queensland and Western Australia. The study will utilise the

GeneXpert, a new point-of-care diagnostic device based on molecular detection of infections. The GeneXpert performs on par with routine laboratory based tests and has the potential to revolutionise point-of-care testing for chlamydia and gonorrhoea, previously reliant on poor performing lateral flow devices.

Status: Ethical approval obtained in QLD and WA;

Sites identified, with signing of participation agreements underway; Operational group active and meeting fortnightly; Reference group established with first meeting held.

Personnel: Rebecca Guy, James Ward, Basil Donovan, John Kaldor, David Wilson, David Regan, Handan Wand, Louise Causer.

Collaborators: Lisa Natoli, David
Anderson, Belinda Hengel, David Whiley,
Sepehr Tabrizi (Royal Women's Hospital);
Christopher Fairley, Mark Shephard, Lisa
Bastian, Sharon Clews, Jarran Heywood
Funding: NHMRC project grant
Co-located: Sexual Health Program,
Aboriginal and Torres Strait Islander
Health Program, Public Health
Interventions Research Group, Biostatistics
and Databases Program and Surveillance
and Evaluation Program for Public Health

Uptake and outcomes of chlamydia or gonorrhoea testing programs in nonclinical settings: a systematic review and meta-analysis

Primary care clinics play an important role in the prevention and management of sexually transmissible infections (STIs). A large proportion of young people attend primary care clinics each year for one reason or another and most chlamydial infections are diagnosed in this setting. However, despite the central role of primary care in chlamydia management, the proportion of sexually active young people attending these clinics who are offered screening at the time of their visit is suboptimal in many developed countries. This systematic review aims to examine the participation rate and outcomes of chlamydia and/ or gonorrhoea testing programs among young people outside of clinical services. Status: Final report published in BMC public health.

Personnel: Rebecca Guy, Muhammad Shahid Jamil, Hammad Ali, Basil Donovan, John Kaldor.

Collaborators: Jane Hocking (University of Melbourne); Heidi Bauer (Program Development and Evaluation, STD Control Branch, California Department of Public Health); Jennifer Walker

(Melbourne Sexual Health Centre/ University of Melbourne)

Funding: Nil

Co-location: Sexual Health Program and Biostatistics, Public Heath Interventions Research Group and Biostatistics and Databases Program

COLLABORATIVE PROJECTS WITH SYDNEY SEXUAL HEALTH CENTRE

Do SMS reminders improve retesting rates after chlamydia infection in heterosexuals?

Chlamydia re-infection is common in women and men. By 12 months, reinfection rates have been reported to be as high as 22% in a chlamydia reinfection prospective cohort of young women in Australia 2008-2009. In light of the high re-infection rates, clinical guidelines in Australia recommend that any people diagnosed with chlamydia should be re-tested in three months to detect chlamydia re-infections. Despite this, a recent analysis of heterosexuals attending 19 sexual health clinics found that the proportion of patients with chlamydia infection who were re-tested in one-to-four months was 11.9% in heterosexual males and 17.8% in heterosexual females. In late 2008, Sydney Sexual Health Centre implemented a SMS reminder system to improve the frequency of the re-testing within three months of a chlamydia infection. We evaluated the impact of the SMS reminder system on chlamydia re-testing within three months of initial infection in heterosexuals attending Sydney Sexual Health Clinic. A controlled observational study design was used.

Status: Manuscript published. The project informed the design of a randomised controlled trial of home collection combined with SMS reminders (REACT).

Personnel: Rebecca Guy, Handan Wand Collaborators: Phillip Read, Aurelie Kenigsberg, Vickie Knight, Anna McNulty (Sydney Sexual health Centre)

Co-location: Sexual Health Program and Biostatistics and Databases Program

Do SMS reminders improve STI testing frequency in men who have sex with men (MSM)?

In late 2008, Sydney Sexual health Centre implemented a reminder system to improve re-testing rates for HIV and sexually transmissible infections (STIs) in men who have sex with men (MSM); three-to-six monthly SMS reminders were recommended for high-risk MSM. We evaluated the impact of the SMS reminder system on HIV/STI testing retesting rates in MSM attending Sydney Sexual Health Clinic. A controlled observational study design was used. The evaluation demonstrated re-testing was 4.4 times more likely (95% CI 3.5 to 5.5) in the SMS group than the comparison group.

Status: Final report published in *Sexually Transmitted Infections*

Personnel: Rebecca Guy, Handan Wand Collaborations: Chris Bourne, Vickie Knight, Heng Lu, Anna McNulty (Sydney Sexual health Centre)

Funding: Nil

Co-location: Sexual Health Program and Biostatistics and Databases Program

The use of SMS reminders to increase completion of Hepatitis A and B vaccination courses in a Sudneu sexual health clinic

Hepatitis B virus (HBV) is a major public health problem worldwide. Prevention is widely acknowledged to be the most effective approach to the problem. A vaccine has been available since 1982, and the standard immunisation schedule consists of three injections, at zero, one and six months. There are also Hepatitis A/B combinations vaccinations which follow the same schedule. Noncompliance with vaccination schedules undermines the potential benefits of immunisation. Despite this, the completion rates among sexual health clinic attendees have been reported to be suboptimal in many clinics. In 2008, Sydney Sexual health Centre implemented a SMS reminder system to improve compliance with HBV vaccine schedule. The purpose of this study was to evaluate whether a reminder of the next vaccine dose sent by (SMS to the vaccinee's mobile phone increases compliance with hepatitis B vaccination schedule. A secondary objective was to identify differences in completion between patient sub-groups eligible for HBV vaccination.

Status: Analysis complete.

Personnel: Handan Wand, Rebecca Guy,

Amalie Dyda, Ruth McIver

Collaborators: Phillip Read, Vickie Knight, Anna McNulty (Sydney Sexual health Centre)

Funding: Nil

Co-location: Sexual Health Program and Biostatistics and Databases Program

New Xpress STI screening clinic improves patient journey and clinic capacity at a large sexual health clinic

In December 2010 a new 'express' testing service (Xpress) was implemented alongside routine clinics at a large sexual health clinic. Xpress involved a computer assisted self interview (CASI), self-collected samples, and enrolled nurse staffing. The evaluation demonstrated the Xpress clinic improved the patient journey in regards to waiting times and length of stay at the clinic, and even though the Xpress clinics was not fully utilised, more patients were seen overall in the clinic with minimal additional costs.

Status: Manuscript published in Sex Transm Dis.

Personnel: Handan Wand, Rebecca Guy, Basil Donovan

Collaborators: Phillip Read, Vickie Knight, Heng Lu, Anna McNulty (Sydney Sexual Health Centre); Nathan Ryder, (Sexual Health and Blood Borne Virus Unit, Department of Health and Families, NT) Funding: Nil

Co-location: Sexual Health Program and Biostatistics and Databases Program

Seasonal trends in STI diagnoses: an investigation

Local, state-wide and national notification data for STIs appears to show consistent variation at specific times during the year. The aim of the study is to identify seasonal trends in STI diagnoses, and to correlate this to trends in sexual behaviour, alcohol and drug use. Data from the Sydney Sexual Health Centre database will be used for this analysis. **Status:** Analysis complete. Manuscript being prepared.

Project members: Handan Wand, Basil Donovan, Rebecca Guy

Collaborators: Phillip Read, Aurelie Kenigsberg, Vickie Knight, Anna McNulty (Sydney Sexual Health Centre)

Funding: Nil

Co-location: Sexual Health Program and Biostatistics and Databases Program

Culturally and linguistically diverse MSM at SSHC: diagnostic and behavioural trends

People of culturally and linguistically diverse backgrounds (CALD) and men who have sex with men (MSM) are recognised as potential priority populations in the 6th National HIV Strategy. The Sydney Sexual Health

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Centre (SSHC) sees a range of MSM from different CALD backgrounds, particularly Asian. Differences may exist in both STI risk behaviour, testing patterns and prevalence of HIV and sexually transmissible infections (STIs) between CALD and non-CALD MSM, and the information can inform health promotion programs. The analysis demonstrated the annual proportion of MSM who were born in Asia increased over time, and compared to non-Asian MSM, Asian MSM were more likely to be younger, less likely to report sexual risk behaviour and ever injected drugs, less likely to have presented with genital symptoms, less likely to report a previous HIV testing, and more likely to be diagnosed with chlamydia.

Status: The analysis is completed and was presented at ASHM conference 2011; manuscript is in preparation.

Personnel: Rebecca Guy, Handan Wand, Basil Donovan

Collaborators: Chris Bourne (NSW Health); Phillip Read (Sydney Sexual Health Centre)

Funding: Nil

Co-location: Sexual Health Program and Biostatistics and Databases Program

Unprotected oral sex and sex workers at Sydney Sexual Health Centre

Unprotected fellatio at work may represent a risk for STI acquisition in the oropharynx, and subsequent onwards transmission. This study seeks to identify the determinants of unprotected fellatio, and where possible correlate this to the presence of gonorrhoea in the oropharynx. Sex workers attending Sydney Sexual Health Centre were asked about their use of condoms for fellatio at work, and swabs were taken for gonorrhoea testing.

Status: Final report published in STI in 2012

Personnel: Basil Donovan, Rebecca Guy, Handan Wand

Collaborators: Phillip Read, Anna McNulty (Sydney Sexual Health Centre) **Co-location:** Sexual Health Program and Biostatistics and Databases Program

SURVEILLANCE AND EVALUATION PROGRAM FOR PUBLIC HEALTH 2012 STUDIES

Modelling and Health Economic Evaluation of HIV Epidemics and Prevention Programs in Australia

This project carries out rigorous evaluations of public health programs to

understand drivers of epidemic trends, project future epidemic trajectories, and assess the potential impact of public health strategies. It also extends impact evaluations to assess what the investments in programs have brought, at what cost, and whether the past or future return on investment warrants shifts in funding. In addition to broad quantitative evaluation aims, national and jurisdiction-specific mathematical models of HIV transmission are developed to represent clinical care and access, relevant biological factors, heterogeneity of sexual behaviour and epidemiology. The models are used to understand past epidemic trends and to simulate the expected population incidence and prevalence of HIV in disease and clinical burdens according to a number of future scenarios of specific programmatic and/or policy changes. HIV clinical service supply is also monitored through surveys sent to hospital departments, sexual health services and general practices with expertise in HIV management Australiawide. This project is ongoing to address current policy, program and research questions nationally, sub-nationally and inform global HIV prevention discussions. The results from this project provide insight into reasons for observed surveillance trends and a stronger evidence-base for designing effective HIV policies and programs locally and abroad.

Status: Ongoing

Personnel: David Wilson, Richard Gray, Alex Hoare, Ann McDonald, James Jansson, Kylie-Ann Mallitt, Kathy Petoumenos

Collaborators: Levinia Crooks (Australasian Society for HIV Medicine (ASHM)); Jo Watson (National Association of People Living with HIV/AIDS (NAPWA)); NSW Health; Australian Research Centre in Sex Health and Society, La Trobe University, Melbourne

Funding: Department of Health and Ageing (DoHA); NSW Health; Australian Research Council (ARC); National Association of People Living with HIV/ AIDS (NAPWA); National Health and Medical Research Council (NHMRC).

Modelling & Health Economic Evaluation of Hepatitis Epidemics & Prevention Programs in Australia

This project aims to conduct estimates and projections of hepatitis B and hepatitis C epidemics in Australia including incidence of infection, morbidities and mortality and estimate the current burden of disease. The project also aims to evaluate the epidemiological and economic impact of prevention and treatment strategies for reducing the burden of viral hepatitis. **Status:** Ongoing

Personnel: David Wilson, Rosie Thein, Lisa Maher, Greg Dore, Tony Butler, Shamin Kinathil

Collaborator: Murray Krahn, Ahmed Bayoumi (University of Toronto); Chris Bauch (University of Guelph); Marina Klein (Canadian Institutes of Health Research)

Funding: National Health and Medical Research Council (NHMRC); Canadian Institutes of Health Research

Co-location: Surveillance and Evaluation Program for Public Health; Viral Hepatitis Epidemiology and Prevention Program; Viral Hepatitis Clinical Research Program; Public Health Interventions Research Group; Justice Health Research Program.

Modelling and Health Economic Evaluation of STI Epidemics & Prevention Programs in Australia

Surveillance systems to monitor the extent, characteristics, and trends of transmission and burden of disease of STIs in Australia may not reflect the true epidemics due to dependencies on testing rates among populations at higher risk or other biases in healthcareseeking subpopulations. This project develops and applies tools to adjust routinely collected surveillance data to provide better estimates of the prevalence and incidence of new STI infections and morbidities. This project also evaluates the past impact of programs and the potential future epidemiological and economic impact of new strategies. The methods used involve a combination of data synthesis, literature review, new epidemiological and statistical analyses from existing data sources, and mathematical modelling. Mathematical models which describe the transmission of STIs are powerful tools that can facilitate our understanding of the transmission dynamics and the epidemiology of an STI in a population. Importantly, this can also help to identify the most effective interventions for lowering STI prevalence in a population. The output from these models can link with economic models to examine issues of allocative and technical efficiency (whether to invest and if so, how). In view of the marked increases in STIs and the National STI Strategy, there is an immediate need for tools to help explore

the potential of, and inform the design of interventions aimed at reducing STIs. The findings from this project will inform the development of public health policy on the most effective and cost-effective strategies for reducing the incidence of STIs and their sequellae in Australian populations.

Status: Ongoing

Personnel: David Wilson, Richard Gray, Gordana Popovic, Matthew Law, John Kaldor, Andrew Grulich, Basil Donovan, David Regan, David Philp, Ben Hui. Collaborators: Jane Hocking (University of Melbourne); Anthony Smith (La Trobe University); Rob Carter (Deakin University); Queensland University of Technology; Papua New Guinea Institute of Medical Research; James Ward (The Baker IDI Institute)

Funding: National Health and Medical Research Council (NHMRC)

Co-location: Surveillance and Evaluation Program for Public Health; Biostatistics and Databases Program; Public Health Interventions Research Group; Sexual Health Program; Aboriginal and Torres Strait Islander Health Program; HIV Epidemiology and Prevention Program.

Evaluation & Cost Effectiveness of HIV Prevention in Asia

In Asia, HIV epidemics are concentrated, driven by the prevalence of risky practices such as injecting drug use (IDU) and unprotected sex among men who have sex with men (MSM), and sex workers and their sexual contacts. Drawing from data and experiences from countries in East Asia and Pacific, Europe and central Asia and the South Asia Region, this study contributes to the improvement of the effectiveness and efficiency of HIV prevention responses in Asia's concentrated HIV epidemic settings. HIV/AIDS effectiveness evaluation and cost-effectiveness studies have become important analytical tools to understand what HIV investments have bought, whether the interventions averted new infections and AIDS deaths, and at what cost. They can support decision-making and prioritisation of intervention strategies and target groups within the HIV/AIDS response with its overall goals of minimising the burden of disease and maximising health outcomes.

This project involves the conduct of numerous large-scale empirical evaluation trials across multiple countries in Asia and Eastern Europe, a large national technical efficiency study, and a series of modelling and economic based post-hoc evaluation, projection, cost-effectiveness, return on investment and allocative efficiency studies.

Status: Ongoing

Personnel: David Wilson, Klara Henderson, Lei Zhang, Richard Gray, Cliff Kerr, Karina Razali, Rosie Thein, Alexander Hoare, Josephine Reyes, Eric Chow, Quang Pham, Corrine Iu, Dam Anh Tran, Kelly-Jean Heymer, Amy Kwon, Karen Schneider, Andrew Craig, Megan Tapia.

Collaborators: World Bank Global HIV/AIDS Program; National Center for AIDS Prevention and Control; Nantong University; Tsinghua University: University of Indonesia: Indonesia National AIDS Commission; Indonesian Ministry of Health; University of Malaya; Malaysian Ministry of Health; Malaysian AIDS Council: Malaysia National Anti-Drug Agency; Royal Malaysian Police; Malaysian Prison Department; National Epidemiology Center, Department of Health, Philippines; World Health Organization; HIV-NAT (HIV-Netherlands-Australia-Thailand) Research Collaboration; Thai Ministry of Health; Viet Nam Administration of HIV/ AIDS Control; UNAIDS; Pasteur Institute; National Drug and Alcohol Research Centre, UNSW; School of Public Health and Community Medicine, UNSW; HART Consulting; Yale University; Philippines National AIDS Council; AIDS Projects Management Group; Hanoi School of Public Health; Mai Hoa Do Consulting; China National Centre for AIDS/ STD Control and Prevention; USAID; Alliance Ukraine; Department for International Development; Family Health International (FHI) Funding: The World Bank Group; Department for International Development (DFID)

National Surveillance of BBV&STIs

The Surveillance and Evaluation Program for public health monitors the pattern of transmission of HIV, viral hepatitis and specific sexually transmissible infections in Australia, in collaboration with the Australian Government Department of Health and Ageing, State and Territory health authorities and collaborating networks. The program coordinates national surveillance for HIV, managing the national HIV/AIDS

registries, and develops new initiatives in surveillance, such as monitoring incident HIV infection through the use of specialised laboratory tests, and carries out quality control studies of surveillance data. The surveillance reports: HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report; Bloodborne viral and sexually transmitted infections in Aboriginal and Torres Strait Islander people: Surveillance and Evaluation Report, the Australian HIV Surveillance Report: and the National Blood-borne virus and Sexually Transmissible Infections Surveillance and Monitoring Report, are compiled annually as part of this surveillance project. The program also provides the secretariat supporting the activities of the National Blood Borne Virus and Sexually Transmissible Infections Surveillance Committee and other ad hoc sub-committees established to develop new data sources and standardised procedures for data collection across State and Territory health jurisdictions in Australia, to support this project. The Surveillance and Evaluation Program for Public Health at the Kirby Institute is a research associate of the Australian Institute of Health and Welfare. In addition to the production of the abovenamed reports, activities conducted within this project, in 2012 included:

- Monitoring perinatal exposure to HIV
- Monitoring long-term outcomes of chronic hepatitis B and C
- Monitoring long-term outcome of newly acquired HIV infection
- Monitoring HIV transmission through specialised tests for incident HIV infection
- Monitoring HIV prevalence and incidence through sexual health clinics
- Monitoring HIV antibody prevalence among prison entrants in Australia
- Monitoring cases of newly diagnosed viral hepatitis
- Monitoring diagnoses of newly acquired HIV infection
- Monitoring cases of newly diagnosed HIV infection
- Monitoring cases of AIDS
- Australian HIV Surveillance Report
- Merging National HIV and AIDS registries
- Community-based behavioural and epidemiological surveillance among culturally and linguistically diverse populations

Status: Ongoing

Personnel: Ann McDonald, Melanie Middleton, David Wilson, Elizabeth Mlambo, Megan Tapia, Rebecca Guy, Jenny Iverson, Mihaela Ivan, Hammad Ali, Stephen Wright, James Jansson,

Basil Donovan, John Kaldor, Tony Butler, David Cooper, Gregory Dore, Sean Emery, Andrew Grulich, Lisa Maher, Joanne Micallef, Kathy Petoumenos, Garrett Prestage

Collaborators: State and Territory
health authorities; Australian
Government Department of Health
and Ageing; State and Territory
Departments of Corrections; Australian
Paediatric Surveillance Unit; Australian
Institute of Health and Welfare; NSW
State Reference Laboratory for HIV;
Australia and New Zealand Liver
Transplant Register; networks involved
in surveillance for HIV, viral hepatitis and
sexually transmissible infections, James
Ward (The Baker IDI Institute)
Funding: Commonwealth Department of

National Surveillance of Trachoma

Health and Ageing

This project is contained within the responsibility of the National Trachoma Surveillance and Reporting Unit (NTSRU) which is based at the Kirby Institute. The NTSRU is responsible for trachoma data collation, analysis and reporting related to the ongoing evaluation of trachoma control strategies in Australia. The unit was particularly established due to recent action by the Commonwealth Department of Health and Ageing in response to trachoma levels. Australia is the only developed country where trachoma is still endemic. It occurs primarily in remote and very remote Aboriginal communities in the NT, SA and WA. The Australian Government, in accordance with GET 2020 initiative and the Closing the Gap initiative, through the Improving Eye and Ear Health Services for Indigenous Australians for Better Education and Employment Outcomes measure, committed \$16 million over a four-year period towards eliminating trachoma in Australia. The funding is to be used for improving and expanding screening and control activities, as well as establishing a strong framework for monitoring and evaluation.

Status: The second annual *National Trachoma Surveillance Report*, edited by the NTSRU, was produced in 2012, due for release in 2013.

Personnel: Carleigh Cowling, John Kaldor, David Wilson, Bette Liu, Gordana Popovic, Andrew Shattock

Collaborators: Office for Aboriginal and Torres Strait Islander Health (OATSIH), Department of Health and Ageing; Aboriginal Community Controlled Health Services in the NT, WA and SA; Aboriginal Medical Services Alliance of the Northern Territory; Aboriginal Health Council of South Australia; Country Health South Australia; Department of Health, Western Australia; The University of Melbourne; Western Australia Country Health Service; National Trachoma Reference Group; James Ward (The Baker IDI Institute); Tom Snelling (Sydney Children's Hospital)

Funding: Commonwealth Department of Health and Ageing (DoHA)

Co-location: Surveillance and Evaluation Program for Public Health; Public Health Interventions Research Group; Aboriginal and Torres Strait Islander People Program

National Surveillance of Transfusiontransmissible Infections

This project collects and analyses national donation testing data on Australian blood donors. It is designed to be a core evidence resource to inform further revision and evaluation of donor selection guidelines and donation testing algorithms in Australia. In addition, a large blood donor survey has been conducted and calculations of risk of infections in the blood supply to provide important evidence for decisions around exclusion criteria of donors to ensure continued maintenance of a safe blood supply. Surveillance activities and analyses of transfusion transmissible infections in Australia were once again conducted in 2012 which led to the second-annual 'Transfusion transmissible infections in Australia Surveillance Report', being published in December of that year. Status: The second annual report on Australian blood donors' surveillance was published in December 2012. Personnel: Tarana Lucky, David Wilson, Ann McDonald, Handan Wand, Collaborators: Clive Seed, Sue Ismay, Stephen Wroth, June Lee, Anthony Keller, Claire Styles, Hung-Sing Yang Funding: Australian Red Cross Blood Service, Australian Research Council (ARC), Commonwealth Department of Health and Ageing

Modelling Cellular & Intercellular Dynamics of Chlamydia Infections

Chlamydia trachomatis is the most commonly notified sexually transmitted disease in Australia, and in women even asymptomatic infections can cause infertility. Chlamydial infections are not restricted to humans: Chlamydia pecorum infects koalas, and is considered to be an important driver behind

declining koala population levels. This study aims to discover the essential correlates of chlamydial infection of the human reproductive tract, to determine the most effective vaccination strategy against Chlamydia in koalas given the practical and financial restrains on vaccine distribution, and to gain qualitative and quantitative insight into the innate immune response to Chlamydia infection. In 2012, this project contributed a book chapter titled 'Biomathematical Modeling of Chlamydia Infection and Disease' to the American Society for Microbiology publication 'Intracellular Pathogens I: Chlamydiales' (Tan and Bavoil) and neared completion of an evaluation of koala vaccination strategies. Data collation is also near completion for assessing correlates of infection of the human reproductive tract.

Status: Ongoing

Personnel: David Wilson, Andrew Craig Collaborators: Patrik Bavoil, Jacques Ravel, Anthony Maurelli, Garry Myers (University of Maryland, Baltimore); Peter Timms, Ken Beagley (Queensland University of Technology); Roger Rank (Arkansas Children's Hospital Research Institute)

Funding: National Institutes of Health (NIH); Australian Research Council (ARC)

THERAPEUTIC AND VACCINE RESEARCH PROGRAM 2012 STUDIES

PHIDISA la

A prospective epidemiological cohort study of HIV and risk-related coinfections in the South African National Defence Force (SANDF). Status: Recruitment opened January 2004. Sites: Six military medical sites in Republic of South Africa

Enrolled/target: 8,439/unlimited Personnel: Sean Emery

Funding: US National Institutes of Health; US Department of Defense; South African National Defence Force

ENCORE1

Encore1 (NCT01011413) is an ongoing investigator-initiated, international, multicentre, randomised, double blind, placebo-controlled, 96 week non-inferiority trial to determine whether a dose reduction of the antiretroviral drug (ARV) efavirenz (EFV) provides safe and effective viral suppression as part of initial combination antiretroviral therapy

(cART) compared with the currently licensed EFV dose. EFV, a non-nucleoside reverse transcriptase inhibitor, is recommended in current treatment guidelines and used globally in first-line antiretroviral regimens. Worldwide it is estimated that 7.4 million people receive cART. Positive outcomes for reduced dose EFV in Encore1 will change treatment guidelines, with particular relevance to developing countries where HIV is most prevalent and resources more scarce. In these settings, publicly funded roll-out programs could save money by reducing dosages of key ARVs.

Status: The study is fully recruited at 38 sites in Argentina, Australia, Chile, Germany, Hong Kong, Israel, Malaysia, Mexico, Nigeria, Singapore, South Africa, Thailand and the United Kingdom. The scheduled week 48 primary endpoint analysis will take place in May 2013.

Target: 630
Personnel: Rebekah Puls, Dianne
Carey, Enmoore Lin, Carlo Dazo, Anna
Donaldson, Janaki Amin, Kate Merlin,
Julie Yeung, Bertha Fsadni, Ansari Shaik
Funding: Bill & Melinda Gates Foundation

ENCORE1 CNS Sub-study

A randomised, double-blind, placebocontrolled clinical trial to determine the safety and efficacy of reduced dose efavirenz (400mg qd) versus standard dose efavirenz (600mg qd) as part of combination therapy in treatment naive individuals with HIV infection: EFV central nervous system exposure sub-study. Status: Recruitment is underway. Sites: Five sites in four countries Target: Approximately 40 Personnel: Rebekah Puls, Enmoore Lin, Jessica Taylor, Carlo Dazo, Janaki Amin Funding: UNSW

ENCORE1 Intensive Pharmacokinetics Sub-study

A randomised, double-blind, placebocontrolled clinical trial to determine the safety and efficacy of reduced dose efavirenz (400mg qd) versus standard dose efavirenz (600mg qd) as part of combination therapy in treatment naive individuals with HIV infection: intensive 24 hour pharmacokinetic analysis. Status: Recruitment is underway. Sites: Four sites in four countries Target: approximately 40

Personnel: Rebekah Puls, Dianne Carey, Enmoore Lin, Jessica Taylor, Carlo Dazo, Janaki Amin

Funding: UNSW

ENCORE1 Neurocognitive Sub-study

This randomised, double-blind, placebocontrolled clinical trial will compare the neurocognitve (NC) function of standard (600 mg) versus reduced (400 mg) dose efavirenz (EFV) to determine its safety and efficacy as part of combination therapy in treatment naive individuals with HIV infection. Seven clinical sites are participating in the sub-study; one in each of Thailand, South Africa, Mexico. Malaysia and two sites in Argentina. Eligible participants will complete a computerised battery of NC tests, the Cogstate[™] tests at weeks 0,4,24 and 48. Data from the sub-study will be combined with plasma sampling data from the main study to examine the association between week 4 plasma EFV levels and change from baseline NC function to week 4 and 24.

Status: recruitment underway **Sites:** 17 sites in 11 countries

Target: 126

Personnel: Amanda Clarke, Rebekah Puls, Anna Donaldson, Stephen Kerr

Funding: UNSW

SECONDLINE

A randomised open-label study comparing the safety and efficacy of ritonavir boosted lopinavir and 2-3N(t)RTI backbone versus ritonavir boosted lopinavir and raltegravir in participants virologically failing first-line NNRTI/2N(t)RTI therapy.

Status: Closed to enrolment

Sites: 40

Target: 558 recruited

Personnel: Mark Boyd, Alli Humphries, Natalie Espinosa, Nisha Seneviratne, Maria Arriaga, Rosemary Robson **Funding:** UNSW, Merck, Abbott, amfAR

SECONDLINE Dried Blood Spot sub-study

To test concordance between dried blood spots to assess viral load and genotypes as compared to centrally tested stored samples.

Status: Closed to enrolment

Sites: 40 Target: 150

Personnel: Mark Boyd, Alli Humphries,

Natalie Espinosa

Funding: UNSW, Merck, Abbott, amfAR

SECONDLINE Body Composition sub-study

To determine the difference in mean limb fat changes and BMD changes at the

proximal femur as measured by DXA scan between the two study arms in a sub-set

of the SECOND-LINE cohort. **Status:** Closed to enrolment.

Sites: 40 Target: 212

Personnel: Mark Boyd, Alli Humphries, Nisha Seneviratne, Paddy Mallon, Jennifer Hoy, Waldo Belloso, Samuel

Ferret

Funding: UNSW, Merck, Abbott, amfAR

Strategic Timing of Antiretroviral Therapy (START)

An open-label randomised multicentre trial to examine the safety and efficacy of commencing combination antiretroviral therapy at a CD4+ cell count of > 500 cells/mm³ versus commencing at a CD4+ cell count of <350 cells/ mm³. This initiative includes several substantial substudies (see below for details) designed to determine the effects of treatment with ART on neurological manifestations of HIV disease, cardiovascular complications, bone mineral metabolism, chronic obstructive pulmonary disease, liver fibrosis progression and abbreviated forms of informed consent documentation. Status: Recruitment underway Sites: 100 in the pilot phase with 17 sites co-ordinated by the Kirby Institute), expanding in the definitive phase with a further 30 sites co-ordinated by KI (in Argentina, Chile, Mexico, Israel, Thailand, Nigeria, India, Malaysia and Australia). Target: pilot phase enrolment 1200 patients with 220 from sites coordinated by the Kirby Institute; enrolment in the definitive phase will be 4000, with approximately 1000 from sites coordinated by the Kirby Institute Personnel: Cate Carey, Megan Evans, Simone Jacoby, Sally Hough (maternity leave), Joseph Levitt, Sean Emery, Lara

Cassar, Sarah Pett Funding: Division of AIDS (DAIDS), The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH); Australian National Health and Medical Research Council (NHMRC); Agence Nationale de Recherches sur le SIDA et les Hépatites Virales (ANRS, France); Bundesministerium für Bildung und Forschung (BMBF, Germany); NEAT - European AIDS Treatment Network; Department of Bioethics, The Clinical Center, NIH; Division of Clinical Research, NIAID, NIH; National Cancer Institute (NCI), NIH; National Heart, Lung, and Blood Institute (NHLBI), NIH; National Institute of Mental Health (NIMH),

NIH; National Institute of Neurological

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Disorders and Stroke (NINDS), NIH; National Institute for Arthritis and Multiple Sclerosis (NIAMS), NIH

Informed Consent Substudy: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

This substudy is evaluating understanding of study information and satisfaction with the consent process among research participants of the START protocol, after receiving information from one of two different types of consent form: a standard or a concise consent.

Status: Recruitment underway **Sites:** 75 in the pilot phase with 15 sites in the Sydney region: the definitive phase (from October 2010) with a further 19 sites in the Sydney Region. Target: n=2000.

Personnel: Cate Carey, Megan Evans, Simone Jacoby, Sally Hough (maternity leave), Joseph Levitt, Sean Emery, Lara Cassar, Sarah Pett Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT -European AIDS Treatment Network; Department of Bioethics, The Clinical Center, NIH

Location: Therapeutic and Vaccine Research Program

Genomics: A substudu of Strategic Timing of AntiRetroviral Treatment (START)

The purpose of this substudy is to obtain a whole blood sample from which DNA will be extracted to study validated (present and future) genetic variants that determine the risk of the various primary and secondary outcomes assessed in START. Status: Since April 2009, 1156/4000 enrolled, with 172 in the Sydney

region. **Sites:** As many of the START sites as possible to be involved; to date 125 sites are registered with 17 in the Sydney

Target: As many of the overall cohort of 4000 START patients as possible. Personnel: Cate Carey, Megan Evans, Simone Jacoby, Sally Hough (maternity

leave), Joseph Levitt, Sean Emery, Sarah

Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT -European AIDS Treatment Network; Division of Clinical Research, NIAID, NIH **Location:** Therapeutic and Vaccine Research Program

Neurology: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

The purpose of the substudy is to determine whether immediate initiation of antiretroviral therapy (ART) in ARTnaïve persons with a CD4+ count > 500 cells/mm³ is superior, with respect to neurocognitive function, compared to deferring ART initiation until CD4+ counts decline to 350 cells/mm³.

Status: Recruitment opened April 2009. To date 468/600 enrolled, with 158 in the Sydney region.

Sites: 30 in the pilot phase (11 in Sydney region) expanding to a total of 33 sites Target: n=600

Personnel: Cate Carey, Megan Evans, Simone Jacoby, Sally Hough (maternity leave), Joseph Levitt, Sean Emery, Sarah

Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT -European AIDS Treatment Network; NIMH, NIH; NINDS, NIH **Location:** Therapeutic and Vaccine

Research Program

Arterial Elasticity: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

The arterial elasticity substudy will determine if early initiation of ART is superior to deferred ART in increasing large artery elasticity (LAE) and small artery elasticity (SAE) (i.e., in reducing arterial stiffness) as measured by pulse wave tonometry.

Status: Recruitment open

Sites: 17 sites in the pilot phase (5 sites co-ordinated by KI), expanding to 21 sites, with one additional site co-ordinated by KI (in India), and six sites in Australia, Thailand and Argentina contributing patients utilising tonometers located at other sites in the same city.

Target: n=300

Personnel: Joseph Levitt, Cate Carey, Megan Evans, Simone Jacoby, Sally Hough (maternity leave), Sean Emery, Sarah Pett

Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT - European AIDS Treatment Network and NHLBI, NIH **Location:** Therapeutic and Vaccine

Research Program

Pulmonary Substudy: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

The pulmonary substudy will determine if early initiation of ART is superior to deferred ART in with regards to pulmonary function as assessed by annual spirometry and respiratory health questionnaire. Status: 263/1000 enrolled, with 38 co-

ordinated by KI.

Sites: 45 in the pilot phase with 7 sites in the Sydney region; a further 40 sites will be added for the definitive phase including another 17 sites co-ordinated by KI.

Target: n=1000

Personnel: Cate Carey, Megan Evans, Simone Jacoby, Sally Hough, Joseph Levitt, Sean Emery, Sarah Pett Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT -European AIDS Treatment Network and

NHLBI, NIH

Location: Therapeutic and Vaccine

Research Program

Bone Mineral Density: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

The bone mineral density substudy will determine if early initiation of ART is superior to deferred ART with regards to bone health as measured by annual bone mineral density.

Status: Recruitment opened March 2011. To date 13/400 enrolled, with 11 at sites co-ordinated by KI.

Sites: 44 with 18 sites co-ordinated by KI (includes pilot sites already open and definitive phase sites)

Target: n=400

Personnel: Simone Jacoby, Megan Evans, Sally Hough, Joseph Levitt, Sean Emery, Cate Carey, Lara Cassar, Sarah Pett Funding: DAIDS; NHMRC; ANRS, France; BMBF, Germany; NEAT -European AIDS Treatment Network and The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH. **Location:** Therapeutic and Vaccine

Research Program

Liver Fibrosis Progression: A substudy of Strategic Timing of AntiRetroviral Treatment (START)

The liver fibrosis progression (LFP) substudy will use fibroscan technology to examine the effect of HIV, hepatitis C virus (HCV) and ART on the rates of LFP among ART naive HIV-infected individuals with and without viral hepatitis with CD4+ counts above 500 cells/mm³.

Status: Protocol release September 2011, recruitment expected to commence towards the end 2011.

Sites: Approx. 40 with 13 sites in Sydney

region (includes pilot sites that are already open and definitive phase sites) Target: n=990 (900 HIV mono-infected and 90 HIV/HCV co-infected) Personnel: Cate Carey, Megan Evans, Simone Jacoby, Joseph Levitt, Sean Emery, Lara Cassar. Funding: No additional funding

FLU002

An International Observational Study to Characterize Adults with Influenza A-Pandemic H1N1 (H1N1v) INSIGHT H1N1v Outpatient Study (FLU 002). Note that version 3.0 broadens inclusion to include all influenza subtypes not just H1N1 and the protocol has been renamed An International Observational Study to Characterize Adults with Influenza.

Status: Ongoing, globally 2777

participants enrolled

Sites: 85 sites globally; in Sydney region: 23 sites (in Thailand, Argentina, Chile and Australia)

Target: 1895/5000; enrolment in Sydney region n=968

Personnel: Sarah Pett, Sean Emery, David Courtney-Rodgers, David Cooper, Dominic Dwyer, Richard Moore, Tuck Meng Soo, Norm Roth, Mark Bloch Funding: NIAID

FLU003

An International Observational Study to Characterize Adults Who Are Hospitalized with Complications of Influenza A – Pandemic H1N1 (H1N1v) INSIGHT H1N1v Hospitalization Study (FLU 003)). Note that version 2.0 broadens inclusion to include all influenza subtypes not just H1N1 and the protocol has been renamed An International Observational Study to Characterize Adults Who Are Hospitalized with Complications of Influenza

Status: Ongoing with 810 participants enrolled globally

Sites: 98 globally; 19 in Sydney region (in Thailand, Argentina, Chile, Hong Kong and Australia)

Target: 580/1600; total enrolment; enrolment in Sydney region n=116 Personnel: Sarah Pett, David Cooper, Dominic Dwyer, John McBride, Jenny Hoy, Julian Elliott

Funding: NIAID

FLU004

Status: globally 181 enrolled in FLU002 co-enrolled in FLU004; globally 36 enrolled in FLU003 co-enrolled in FLU004

Personnel: Sarah Pett, David Cooper, Dominic Dwyer, Richard Moore, Tuck Meng Soo, Norm Roth, Mark Bloch Funding: NIAID

LASA

A multicenter randomised study to compare the efficacy and safety of lower dose atazanavir/ritonavir (ATV/r 200/100 mg OD) versus standard dose (ATV/r 300/100 mg OD) in combination with 2NRTIs in well virology suppressed HIV-infected adults.

Status: 199/560

Sites: nine clinical centres in the Thai National Health Service network

Target: 560

Personnel: Sean Emery

Funding: Kirby Institute, HIVNAT, Thai

MARCH

A randomised, controlled trial to evaluate the efficacy and safety of maraviroc as a switch for either nucleoside analogue reverse transcriptase inhibitors (N(t)RTI) or boosted HIV protease inhibitors(r/ PI) in HIV infected patients with stable, well-controlled plasma HIV-RNA while taking their first N(t)RTI + r/PI regimen of combination antiretroviral therapy (cART) - The MARCH study.

Status: 400 patients screened and 158 randomised. Expected date of completion August 2015.

Sites: 70 clinical centres in the Kirby international network including Argentina, Australia, Brazil, Canada, Chile, France, Germany, Ireland, Israel, Japan, Mexico, Peru, Spain, UK.

Target: 560

Personnel: Sean Emery, Sarah Pett, Nisha Seneviratne, Elise, Tu, Hila Haskelberg, David Silk, Rose Robson, Kymme-Courtney-Vega

Funding: Pfizer/ViiV Healthcare

MARCH CNS substudy

A randomised, open-label study to evaluate the efficacy and safety of maraviroc (MVC) as a switch for either nucleoside or nucleotide analogue reverse transcriptase inhibitors (N(t)RTI) or boosted protease inhibitors (PI/r) in HIV-1 infected individuals with stable, well-controlled plasma HIV-RNA while taking their first N(t)RTI + PI/r regimen of combination antiretroviral therapy (cART). Impairment of neurocognitive (NC) function is a major concern in the

setting of Chronic HIV-1 infection and ways to minimise this are currently being pursued in many different settings. Maraviroc penetrates the CNS and as almost all virus in the brain is R5, the drug may have a potential role in the treatment and/or prevention of impairment of NC function. The randomised arms of MARCH offer an opportunity to explore, in a pilot study, the effects of MVC either partnered with PI/r or NRTI on the CNS.

Status: Currently recruiting.

Sites: 15 clinical centres in the Kirby Institute's international network. Sites located in Australia (n=7), Canada (n=1), France (n=1), Germany (n=2),

Israel (n=1), UK (n=3).

Target: 50

Personnel: Nisha Seneviratne, Sarah

Pett, Rose Robson **Funding:** Kirby Institute

MARCH resistance substudy

A study to explore the prevalence and evolution of HIV drug-resistance using cell associated HIV DNA: The MARCH Resistance Sub-study. Version 0.4, 12 September 2011

Status: Recruitment is underway.

Sites: All sites

Personnel: David Cooper, Sean Emery, Tony Kelleher, Sarah Pett, Elise Tu

Funding: Kirby Institute

MARCH – VE substudy

Maraviroc Switch vascular endothelium substudy: a randomised, open-label study to evaluate the efficacy and safety of maraviroc (MVC) as a switch for either nucleoside or nucleotide analogue reverse transcriptase inhibitors (N(t)RTI) or boosted protease inhibitors (PI/r) in HIV-1 infected individuals with stable, well-controlled plasma HIV-RNA while taking their first N(t)RTI + PI/r regimen of combination antiretroviral therapy (cART). To explore changes in VE as measured by pulse wave tonometry in the MARCH study. Status: Currently recruiting.

Sites: St. Vincent's Hospital and sites in Argentina, UK, Thailand and Germany, in a total 11 sites.

Target: 75

Personnel: Sarah Pett, Elise Tu, Janaki Amin

Funding: Kirby Institute

MARCH renal substudy

This substudy is a prospective, observational, open-label, randomised

study within the MARCH study exploring changes in protein (UPCR) and albumin (UACR) excretion through the kidneys between the randomised and standard of care (control) arm of MARCH. Secondary objectives are to evaluate the following aspects of renal function at baseline and changes within and between study groups:

Status: Recruiting. **Sites:** Site survey pending

Target: 150

Personnel: Sarah Pett, David Silk, Janaki Amin David Cooper, Mark Bloch, David Sowden, Mark Kelly, Dominic Dwyer

Funding: Kirby Institute

VIRAL HEPATITIS CLINICAL RESEARCH PROGRAM 2012 STUDIES

ATAHC Recall: Long-term outcomes following treatment of recently acquired hepatitis C virus infection

Hepatitis C virus (HCV) infection is a public health problem, however very little is known about the health of patients years following therapy, and whether HCV treatment at an early stage continues to be beneficial to people. The Australian Trial in Acute Hepatitis C (ATAHC) previously enrolled 163 subjects with recent (ie acute or early chronic) HCV infection between 2004 and 2008. Uptake of treatment was high, with 79% initiating therapy. Follow-up was maintained for up to two years post SVR with continued specimen and data collection, with seven reinfections observed during this time. The study closed in 2007 and the original subjects are now an average of 5.6 years from initial infection. The ATAHC study demonstrated the successful recruitment, engagement and early follow-up of one of the largest cohorts of individuals with AHC and established an extensive serum, plasma and PBMC storage banks of AHC worldwide. Longitudinal follow-up will allow for the first international, long-term assessment of clinical, social, behavioural, psychological and immunovirological outcomes following recently acquired HCV. Status: Ongoing.

Personnel: Gail Matthews, Greg Dore, Sofia Barlett, Amanda Erratt, Jason Grebely, Pip Marks, Francois Lamoury, Austin Butcher, Margaret Hellard, Joseph Doyle, David Shaw

Collaborating centres: St Vincent's Hospital, Sydney; The Alfred Hospital, Melbourne; Royal Adelaide Hospital, Adelaide

Funding: St Vincent's Hospital Research Foundation

DARE-C: Direct Acting Antiviral (DAA) based therapy for recently acquired hepatitis C

Future therapy for the treatment of individuals with chronic HCV will involve directly acting antiviral agents, with or without pegylated interferon (PEG-IFN)/ribavirin (RBV). In early chronic HCV infection (duration less than 18 months) treatment responses are generally very good and individuals often keen to be treated. The use of short course triple therapy including telaprevir (TVR) in this setting warrants evaluation. ATAHC II study is examining a broad strategy of individualisation of duration of PEG-IFN/RBV therapy based on early response in acute and early chronic HCV infection across all genotypes and HIV status. The sub-study DARE-C aims to evaluate individualisation of therapy duration using triple therapy (PEG-IFN/RBV/ TVR) in a subgroup of ATAHC II subjects with genotype 1 infection and early chronic HCV infection.

Status: Ethics and regulatory approval for St Vincent's Hospital are expected by the end of 2012 and the first patient visit is expected for January 2013.

Personnel: Austin Butcher, Gail Matthews, Sophie Quiene, Ineke Shaw, Greg Dore, Pip Marks, Barbara Yeung, Mahshid Tamaddoni

Collaborating centres: St Vincent's Hospital Sydney, The Alfred Hospital and Royal Adelaide Hospital.

Funding: Janssen

ACTIVATE – Response Guided Treatment for Patients with Chronic HCV Infection and Ongoing Injection Drug Use

This is a phase IV, open-label, multicentre, international trial of response guided treatment with directly observed pegylated interferon alfa 2b and self-administered ribavirin for patients with chronic HCV genotype 2 or 3 infection and ongoing injection drug use. The primary objective is to evaluate the proportion of patients with sustained virological response at 24 weeks post end of treatment (SVR24) following directly observed pegylated interferon alfa 2b and self-administered ribavirin for 12 weeks in participants with undetectable HCV RNA at week four of therapy, and for 24 weeks in participants with detectable HCV RNA at week four of therapy. The study will be conducted in Australia, Canada, United Kingdom,

Germany, Switzerland, France, Belgium, Norway and Finland.

Status: Open to recruitment at 13 sites in six countries. A further four sites to be opened in the first half of 2013.

Enrolled: 11 patients at 31 December 2012. The accrual target is 100 patients by 31 December 2013.

Personnel: Greg Dore, Pip Marks, John Morrison, Marianne Byrne

Collaborating centres: St Vincent's Hospital, NSW, Burnet Institute, Alfred Hospital. VIC

Royal Adelaide Hospital, SA, Hunter Pharmacotherapy, John Hunter Hospital, NSW, Nepean Hospital, NSW, Vancouver Infectious Diseases Centre, Canada; Centre Hospitalier de l'Universite de Montreal (CHUM), Canada; East Toronto Hepatitis C Program, Canada: ARUD. Poliklinik Zokl 1, Zurich, Switzerland; Zentrum fur Suchtmedizin, Basel, Switzerland; Koda Bern/Poliklinik fur Infektiologe, Switzerland; ZNA Stuivenberg and Free Clinic, Antwerp, Belgium; Ziekenhuis Oost Limburg and MSOC, Genk, Belgium; Leppavaarankatu 10 Espoo, Finland; Praxiszentrum Im Tal (PIT); Ludwig-Maximilians-Universitat Munich, Germany; CONCEPT Center for Addiction Treatment Munich, Germany; Oslo University Hospital, Norway; Barts and the London Queen Mary's School of Medicine and Dentistry, United Kingdom; Nottingham University Hospital, United Kingdom.

Funding: Merck Sharpe and Dohme

GP Pilot-Enhanced Treatment for Hepatitis C in Primary Care Settings

This is a prospective observational cohort study, aiming to evaluate the feasability, safety and efficacy of a primary care based model for the delivery of HCV services, including initiation of anti-viral therapy. Those subjects that commence treatment will be followed until 24 weeks post treatment (SVR). The cohort will be recruited through a network of primary care clinics undertaking HCV assessment, treatment and monitoring.

Status: All study sites open. Ongoing recruitment through five sites in New South Wales

Enrolled: 39 patients enrolled. **Personnel**: Greg Dore, Pip Marks, Amanda Erratt

Collaborating centres: Australasian Society for HIV Medicine (ASHM); National Centre in HIV Social Research (NCHSR); East Sydney Doctors, Darlinghurst; Clinic 96, Orange; Hunter Pharmacotherapy Services, Newcastle; The Byrne Surgery, Redfern; Cowra

Medical Associates, Cowra; Asquith Medical Centre, Asquith; Dr Doong's Surgery, Burwood.

Funding: Australasian Society for HIV Medicine (ASHM)

Morbidity in people with hepatitis B and C in New South Wales

Understanding hepatocellular carcinoma (HCC) in NSW. This was a population-based data linkage study. Notification records for cases of hepatitis B and/or hepatitis C in New South Wales were linked to their hospital, death, and HIV/AIDS records by The Centre for Health Record Linkage (CHeReL). Statistical methods to account for within patient clustering were employed

Status: Analyses on the epidemiology and natural history (including morbidity and mortality) of HCC and viral hepatitis are ongoing.

Personnel: Rosie Thein, Greg Dore, Jason Grebely, Maryam Alavi, Janaki Amin, Heather Gidding, Matthew Law Collaborating centres: Kate Ward (NSW Health)

Funding: The Cancer Council NSW

Australian Trial in Acute Hepatitis C (ATAHC II)

A prospective longitudinal study of natural history and treatment outcomes following response guided treatment of recent hepatitis C infection.

Status: All study sites have received ethics and research governance approval and all open to recruitment.

Enrollment target: 120 subjects
Personnel: Gail Matthews, Greg Dore,
Barbara Yeung, Pip Marks, Jason Grebely,
Tanya Applegate, Margaret Hellard (the
Burnet Institute and the Alfred Hospital),
David Shaw (Royal Adelaide Hospital),
Paul Haber (Royal Prince Alfred
Hospital), Andrew Lloyd (UNSW), Alex
Thompson (St. Vincent's Hospital, VIC),
David Iser (St. Vincent's Hospital and
the Alfred Hospital, VIC), Joe Sasadeusz
(Royal Melbourne Hospital), Silvana
Gaudieri (Royal Perth Hospital and
Murdoch University, WA)

Collaborating centres: St. Vincent's Hospital, Sydney, Royal Prince Alfred Hospital, Kirketon Road Centre and Nepean Hospital in NSW, The Alfred Hospital, Royal Melbourne Hospital and St. Vincent's Hospital, Melbourne in VIC, Royal Adelaide Hospital in SA and Princess Alexandra Hospital in QLD. Funding: US National Institutes of Health

Enhancing Treatment of Hepatitis C in Opiate Substitution Settings (FTHOS)

The Kirby Institute was awarded an NHMRC Partnership Grant (partner organisations listed below) to address the issue of HCV treatment in the opiate pharmacotherapy setting. Among patients with a history of injection drug use, the specific objectives of this study are to examine:

- Assessment and treatment of HCV in a prospective cohort study – the ETHOS Cohort.
- Patient and provider attitudes and barriers towards the provision of services for assessment and treatment of HCV infection.
- 3. Peer based support as a strategy for enhancing knowledge and uptake of treatment for HCV infection.
- 4. Cost effectiveness of providing assessment and treatment for HCV infection in the opiate pharmacotherapy setting.

Status: Closed to recruitment. There are currently 438 participants enrolled in the ETHOS Cohort and 77 on treatment. Follow-up of participants will continue until mid-2014

Target: 500

Personnel: Greg Dore, Jason Grebely, Pip Marks, Michelle Micallef Collaborating centres: National Centre in HIV Social Research (NCHSR); NSW Department of Health; Sydney Local Health District; Hepatitis C Council of NSW; NSW Users and AIDS Association (NUAA); Discipline of Addiction Medicine, The University of Sydney and Australian Injecting and Illicit Drug Users League (AIVL).

Funding: Australian Government Department of Health and Ageing and NSW Health Department.

Defining Risk and Mechanism of Permucosal Transmission for acute HCV Infection within high-risk populations (RAMPT-C Study)

The study aims to characterise permucosal transmission of HCV among HIV-positive and HIV-negative MSM, through clinical and molecular epidemiological analysis, with qualitative socio-behavioural and biological studies to explore the transmission mechanisms. The Study consists of three parts: Part I – Phylogenetics analysis, Part II – semen analysis, and Part III – Behavioural mechanism interview. An eligible

patient can participate in Part I only or all three parts.

Status: ongoing;

Personnel: Gail Matthews, Greg Dore, Pip Marks, Tanya Applegate, Amanda Erratt, Dan Bradshaw.

Collaborating centres: Macfarlane Burnet Institute for Medical Research and Public Health, VIC; St Vincent's Hospital, NSW.

Funding: National Health and Medical Research Council Project Grant and St. Vincent's Clinic Foundation Research Grant

The Healthy Liver Campaign

This study is to evaluate the impact of a Healthy Liver Campaign on HCV knowledge, assessment and treatment among people attending OST clinics. Among people attending OST clinics, the aims of the study are to assess knowledge of liver disease and associated factors; assess willingness and barriers to receiving assessment for liver disease and associated factors; evaluate the impact of a Healthy Liver Campaign on knowledge of liver disease, liver disease assessment and uptake of interventions; and develop guidelines for liver disease and FibroScan assessment in the OST setting.

Status: Ongoing.
Target: 480

(MREII) grant

Target: 480
Personnel: Greg Dore, Jason Grebely,
Pip Marks, Michelle Micallef
Collaborating centres: National Centre
in HIV Social Research (NCHSR);
Centre for Health Initiatives, University
of Wollongong; Australian Injecting
and Illicit Drug Users League (AIVL);
Hepatitis C Council of NSW and NSW
Users and AIDS Association (NUAA)
Funding: Schering Plough and
University of NSW Major Research
Equipment and Research Infrastructure

LABORATORY SERVICE AND SUPPORT

HepBank Clinical Sample Repository & Open Access Substudy database (LabKey)

Samples are stored in -80°C freezers (monitored by alarms 24/7) and Vapour Phase Tanks at St Vincent's Centre for Applied Medical Research, Lowy Packer Building in Darlinghurst. The repository stores serum, plasma, PBMC, DNA and semen samples collected during HREC VHCRP approved clinical trials, research

projects or clinic visits from patients with hepatitis B or C including those co-infected with HIV. Several processes determine the allocation of samples from Hepbank to be used for a laboratory research substudy project, including a review of sample criteria availability, protocol steering committee (PSC) approval of investigator driven concept sheets, HREC approval for all sites participating in the study and a Letter of Understanding (LOU) between the PSC and the research site. The sample repository is managed by HIVIRL, an Oracle database developed by Tony Kelleher's laboratory, which is interfaced with the LabKey database. The web-based LabKey database links existing clinical, sample repository and laboratory data-sets to allow comprehensive analysis of clinical trial results. This provides an invaluable group of samples to be used for Hep C related laboratory research.

Status: Samples from new VHCRP trials are being added to the repository. The Live Labkey site is now in official use with several central laboratories using the offsite repository function to enter specimen data for samples collected from VHCRP clinical trials. This enables real time analysis of patient sample data and improves efficiency in data collection for both the central laboratory and VHCRP.

Personnel: Austin Butcher, Sofia Bartlett, Ineke Shaw, Pip Marks, Trent Schafer, Brendan Jacka, Tanya Applegate, Ansari Shaik, Tony Kelleher Funding: NHMRC Program Grant and UNSW Major Equipment Research funding

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

ASSAY DEVELOPMENT

Assays of T-cell function, proliferation and cytotoxicity, and identification of antigen-specific T-cells

A range of flow cytometric assays for assessing CD4+ and CD8+ T-cell function are worked up in the laboratory. The measures of antigen-specific T-cells include T-cell proliferation, activation and cytokine secretion. Such assays are important for understanding HIV pathogenesis and in responses to vaccines, and therefore are included in the protocols of clinical trials and natural history studies carried out by the Kirby Institute. Assays were performed as part the PINT trial of therapy with the

integrase inhibitor, Raltegravir and the Restore and PrIRIS studies in Bangkok and Sydney respectively. Other studies were conducted as part of the PHIIDO observational study of primary HIV infection. These assays were validated in the context of two completed clinical studies assessing latent TB infection in Bangkok and Sydney; in a clinical study of CMV re-activation and Adenovirus infection following paediatric bone marrow transplantation, and in following immune responses with gluten induced flares of coeliac disease. Assays were also conducted to elucidate the generation of CD4+ T-cell responses during primary vaccinia vaccination.

Status: Continued analysis of samples from PHAEDRA and the long-term non-progressor cohorts, TB studies completed, Studies of CMV disease to be completed in 2011 and coeliac study commenced.

Personnel: Susanna Ip, Laura Cook,
Mee-Ling Munier, Michelle Bailey, Yin
Xu, Chansavath Phetsouphanh, Celine
Yan, Anthony Kelleher, Denise Hsu
Collaborating centres: John Zaunders,
Mahila Namasivayam, Tony Walls,
John Ziegler, Nabila Seddiki, Stephen
Kent, Bob Anderson, Jason Tye-Din,
Jintanat Ananworanich, Sasiwimol
Ubolyam, Anchalee Avihingsanon, Kiat
Ruxrungtham, Praphan Phanuphak
Funding: NHMRC, St Vincent's Hospital,
Coeliac Foundation

Co-located: Viral Hepatitis Clinical Research Program and Immunovirology and Pathogenesis Program

Development of research tools to assess host and viral genetic variations

To develop affordable assays to support host genetic and viral phylogenetic studies. **Status:** Ongoing.

Personnel: Francois Lamoury, Brendan Jacka, Sofia Bartlett, Tanya Applegate Collaborating centres: Philip Cunningham, Alex Carrera Funding: NHMRC Program Grant Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

Development of new therapeutic modalities

HIV drug resistance and viral tropism This project involves the development of expertise in the application of a number of methods of detecting antiretroviral drug resistance through genotypic testing of HIV isolates. There are three major projects: evaluation and conducting commercially available genotype testing for protease, reverse transcriptase regions; development of a new, cheap in-house genotyping method from blood dry-spots as a starting material,; and developing assays for the determination of CCR5 tropism of patient's HIV isolates. More than 700 HIV-1 resistance genotypes have been performed based on the commercial based resistant assays. Validation of new in-house genotyping method is close to is close to completion.. The CCR5 tropism assay for RNA has been transferred to the NSW State reference laboratory at St Vincent's and is being used for routine care. Status: The validation of the DNA version of this assay is complete and is being used for routine patient care from

Personnel: Anthony Kelleher, Celine Yan, Kerstin Koelsch, Yong Pan Collaborators: Kazuo Suzuki, Kat Marks, Nick Rismanto, Philip Cunningham, Leon McNally, Alexander Carrera Funding: NSW Health Department, ViiV Co-located: Viral Hepatitis Clinical Research Program and Immunovirology and Pathogenesis Program

RNA inducing viral latency

January 2012.

This project is related to siRNA gene silencing for HIV-1 and SIV infection. siRNAs targeting viral promoter DNA region induce transcriptional gene silencing (TGS) of viral genes in infected cells. The study has been extended to two major objectives: To develop and evaluate delivery systems including lentiviral and non-viral systems for use in a humanised mouse HIV-1 infection model; and to define the pathways by which dsRNAs targeting the promoter regions of HIV-1 and SIV. Silencing constructs applicable for use in HIV-1 infection have been development. These constructs have been incorporated into a lentiviral delivery system, which will be assessed *in vitro*. Epigenetic changes induced by siRNAs targeting HIV-LTR will also be defined. We also investigated the subcellular localisation of Argonaute proteins (Ago) during the TGS process and recently reported the presence of Ago1 in the nucleus and Ago2 in the nuclear membrane as demonstrated by confocal microscope using tagged Ago1/ Ago2 and fluorescently labelled siRNA. We also demonstrated colocalisation between Ago1 or Ago2 and F-actin and are currently following up of this novel finding to potentially link transport of the

molecules from the cytoplasm into the nucleus where they would then act on the HIV-1 promoter to initiate gene silencing.

Status: Ongoing

Personnel: Anthony Kelleher, Chantelle

Hood, Sanjay Swaminathan

Collaborators: Kazuo Suzuki, Takaomi Ishida, Makoto Yamagisi, Toshiki Watanebe

Funding: NHMRC

Co-located: Viral Hepatitis Clinical Research Program and Immunovirology

and Pathogenesis Program

TRANSLATIONAL RESEARCH: **HOST**

In-vivo hepatitis C virus adaptation to host in recently acquired HCV (ATAHC)

To characterise HCV adaptation to HLArestricted immune response and examine the influence of HLA alleles on HCV sequence evolution and escape mutations. Status: Ongoing

Personnel: Greg Dore, Gail Matthews Collaborating centres: Simon Malal and Silvana Gaudieri (CCiBS, Perth) and Andrew Lloyd (UNSW)

Funding: National Institute of Health Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

IP10, IL28B serum protein levels and T-cell responses in recently acquired **HCV (ATAHC)**

Analysing serum IP-10 and IL28B protein levels (by ELISA) as a marker of spontaneous and treatment-induced clearance during early HCV infection.

Status: Ongoing

Personnel: Jason Grebely, Tanya Applegate, Greg Dore, Gail Matthews Collaborating centres: Jordan Feld (Toronto University, Canada), Andrew Lloyd (UNSW), Jacqueline Flynn and Rosemary Ffrench (Burnet Institute, Victoria)

Funding: National Institute of Health, NHMRC Program Grant

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

Investigation of the association between ITPA polymorphism, ontreatment anemia and treatment outcome in the CHARIOT cohort

This study is designed to evaluate the association between the ITPA polymorphisms rs1127354 and rs7270101, and on-treatment anaemia, RBV dose reduction and rate of SVR in the CHARIOT cohort.

Status: Ongoing

Personnel: Greg Dore, Gail Matthews, Pip Marks, Sofia Bartlett.

Collaborating centres: Alex Thompson (St Vincent's Hospital, Melbourne) and **CHARIOT PSC**

Funding: St Vincent's Hospital Sydney, Roche Products Pty Ltd

Co-located: Viral Hepatitis Clinical Research

Program (laboratory program) and Immunovirology and Pathogenesis Program

A study of the relationship between vitamin status and the severitu of liver disease and outcomes of the treatment with Pegulated interferon alfal 2A plus Ribavirin in Hepatitis C Genotype 1 infected patients

This study is designed to evaluate serum vitamin d levels and the relationship between vitamin d and histologic disease severity in hcv genotype 1 patients with biopsy proven CHC from the CHARIOT study.

Status: Ongoing

Personnel: Greg Dore, Pip Marks, Sofia

Bartlett.

Collaborating centres: Stuart Roberts,

Matthew Kitson.

Funding: The Alfred Hospital, Melbourne, Roche Products Pty Ltd **Co-located**: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

Role of host genetics in chronic HCV combination treatment response

To identify a combination of baseline covariates, serum protein markers and host genetic markers to develop a treatment algorithm to predict the response rate of each patient considering treatment for CHC.

Status: Ongoing

Personnel: Greg Dore, Pip Marks, Sofia

Bartlett, Tanya Applegate.

Collaborating centres: Jacob George,

Stuart Roberts.

Funding: Roche Products Pty Ltd **Co-located**: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

TRANSLATIONAL RESEARCH: VIRAL

RADAR: Resistance Against Directly Acting Antivirals in Australian Trial in Acute Hepatitis C, (ATAHC)

Identification of the prevalence of preexisting resistance mutations within the ATAHC cohort in treatment naïve patients, to Polymerase and Protease Inhibitors using Deep Sequencing analysis.

Status: Ongoing

Personnel: Gail Matthews, Tanya

Applegate, Greg Dore

Collaborating centres: Silvana Gaudieri

Funding: NHMRC Project Grant,

NHMRC Program grant

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

Characterisation of reinfection/mixed HCV infection in recently acquired **HCV (ATAHC)**

Analysis of the prevalence and impact of HCV reinfection and mixed infection using novel real time PCR (MNAzyme) technology, direct sequencing and genotype specific PCR.

Status: Ongoing

Personnel: Brendan Jacka, Tanya Applegate, Jason Grebely, Greg Dore,

Gail Matthews

Collaborating centres: Sean Pham & Peter White (UNSW, Sydney), Alison Todd & Elisa Mokany (SpeeDx Pty Ltd,

Funding: National Institute of Health, NHMRC Program Grant, Australian

Postgraduate Award

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

TRANSMISSION RESEARCH

ITHACA: Investigating Transmission Dynamics of HCV Among injecting drug users in Canada and Australia

Status: The goal of this project is to evaluate HCV transmission dynamics among people who inject drugs (PWID). First, we are interested in how HCV is transmitted from older to younger PWID and whether public health initiatives have led to a reduction in transmission. Second, we are interested

in understanding how frequently reinfection and mixed infections with HCV occur and what characteristics are associated with reinfection/mixed infections. We plan to conduct this study within well-established cohorts of PWID in Vancouver, the Vancouver Injecting Drug Users Study (VIDUS) and the Atrisk Youth Study (ARYS). Ethics approval is expected from the UBC Providence Health Care Ethics Committee in Canada during 2012. Ethics is currently being sought for work to be done in Australia.

Status: Ongoing

Personnel: Jason Grebely, Tanya Applegate, Brendan Jacka, Greg Dore, Francois Lamoury, Gail Matthews Collaborating centres: Mel Krajden (British Columbia Centre for Disease Control), Evan Wood, Thomas Kerr. Richard Harrigan, Art Poon (British Columbia Centre for Excellence in HIV and AIDS), Zabrina Brumme (Simon Fraser University), Jesse Raffa (University of Waterloo), Brandon Marshall (Brown University), Silvana Gaudieri (University of Western Australia)

Funding: The Canadian Institutes for Health Research

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

Transmission networks in recently acquired HCV in ATAHC

Explore clinical and molecular epidemiology of HCV transmission networks in HIV+/- population and assess if networks bridging into HIVcommunities through phylogenetic and molecular clock analysis of HCV sequences.

Status: Ongoing

Personnel: Gail Matthews, Tanya Applegate, Greg Dore, Jason Grebely Collaborating centres: Sean Pham, Fabio Luciani, Peter White, Lei Zhang Funding: National Institute of Health, NHMRC Program Grant

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

THERAPEUTIC RESEARCH

Ribavirin concentrations in subjects with chronic HCV (CHARIOT)

Determinants of plasma ribavirin

concentration during the first 12 weeks of therapy in CHC genotype 1 patients treated within the CHARIOT study.

Status: Ongoing

Personnel: Gail Matthews, Ineke Shaw,

Rachel Ali, Greg Dore

Collaborating centres: John Ray (St

Vincent's Hospital)

Funding: St Vincent's Hospital Sydney,

Roche Products Pty Ltd

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

RAMPT-C cohort

Defining risk and mechanisms of permucosal transmission for acute HCV infection MSM and IDUs within highrisk populations. This includes analysis of transmission events through HCV sequencing, biological and behavioural mechanisms in incident cases.

Personnel: Gail Matthews, Barbara Yeung, Amanda Erratt, Tanya Applegate, Brendan Jacka, Greg Dore

Collaborating centres: Mark Danta, Margaret Hellard, Rose Ffrench, Kylie Goy

Funding: NHMRC Project Grant Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

SEARCH-C: surveillance for Antiviral Resistant variants in chronic hepatitis C patients

There remains a number of critical data gaps in understanding the clinical significance of HCV resistance associated variants: There has been no detailed deep sequencing analysis of the association between baseline RAVs and the outcomes of DAA-treatment regimens; no "real world" data has investigated the relationship between treatment adherence and selection of RAVs; the data is very limited data on the natural history / potential pathogenicity of these RAVs that are selected in patients who fail antiviral therapy; and no data exist concerning whether the selection of HCV resistance-associated variants with firstgeneration DAA-based regimens may compromise future treatment options. **Status**: Ongoing; no enrolments to date. **Personnel:** Gail Matthews, Greg Dore, Amanda Erratt, Pip Marks, Francois Lamoury, Sofia Bartlett, Austin Butcher, Alex Thompson

Collaborating centres: St Vincent's Hospital, Sydney; St Vincent's Hospital Melbourne.

Funding: Kirby Institute

Co-located: Viral Hepatitis Clinical Research Program (laboratory program) and Immunovirology and Pathogenesis Program

VIRAL HEPATITIS **EPIDEMIOLOGY AND PREVENTION PROGRAM 2012 STUDIES**

The Australian needle and syringe program survey (ANSPS)

The Australian Needle and Syringe Program Survey (ANSPS) forms the basis of Australia's sentinel surveillance of HIV and hepatitis C virus (HCV) prevalence and behaviour indices of risk among people who inject drugs (PWID). Since 1995, all clients attending selected Needle and Syringe Program (NSP) sites during a specified one to two week period are asked to complete a brief selfadministered questionnaire and to provide a capillary blood sample for HIV and hepatitis C antibody testing. Demographic and behavioural data captured include injecting and sexual behaviour, blood borne virus testing, drug treatment and needle and syringe acquisition. A National Data Report, summarising national and state/territory data is produced by VHEPP on an annual basis.

Status: Ongoing

Personnel: Jenny Iversen, Lisa Maher Collaborators: Australian State and Territory health authorities; the Collaboration of Australian Needle and Syringe Programs; St Vincent's Centre for Applied Medical Research (AMR) and NSW State Reference Laboratory for HIV at St Vincent's Hospital; Association for Prevention and Harm Reduction Programs Australia (ANEX); Australian Injecting and Illicit Drug Users' League (AIVL); National Drug Research Institute (NDRI); Drug and Alcohol Service, St Vincent's Hospital.

Funding: Australian Government Department of Health and Ageing

Hepatitis acceptability and vaccination incentives trial (HAVIT)

Injecting drug use is the leading exposure for newly acquired hepatitis B virus (HBV) infection in Australia, yet vaccination uptake and coverage among

people who inject drugs (PWID) remains low. The trial aimed to determine the efficacy of financial incentives in increasing hepatitis B vaccine completion among PWID. Secondary endpoints included cost effectiveness and correlates of immunity. HAVIT was the first headto-head comparison of incentives paid on a per-dose basis versus no incentives in increasing vaccination completion in the world. Results indicate that PWID allocated to the incentive condition were more than three times more likely to complete the schedule. Findings suggest that the provision of modest financial incentives to PWID for hepatitis B vaccination completion is a realistic public health strategy with the potential to reduce the burden of HBV disease and, potentially, other vaccine-preventable infections in this group.

Status: 139 PWID completed the experimental procedures; follow up data collection completed.

Personnel: Rachel Deacon, Mofizul Islam, Libby Topp, Lisa Maher Collaborating centres: Kirketon Road Centre, South Eastern Sydney and Illawarra Area Health Service; Sydney South West Area Health Service; Redfern Drug Health Service, South West Sydney Area Health Service; Discipline of Addiction Medicine, University of Sydney; National Drug and Alcohol Research Centre

Funding: NHMRC Project Grant

Hepatitis C vaccine preparedness studies

This program of work, which commenced in 2010, continues and extends earlier work conducted under the UNSW HCV Vaccine Initiative. The project aims to establish the feasibility of conducting efficacy trials of candidate HCV vaccines with PWID by answering key scientific questions, building community capacity and establishing the necessary infrastructure to conduct future trials. Specific aims are to 1) determine HCV incidence and spontaneous clearance in a prospective cohort of uninfected PWID; 2) identify associated risk factors; 3) evaluate retention strategies and factors associated with adherence to the study protocol; and 4) investigate immunisation acceptability, clinical trial literacy and willingness to participate in future vaccine trials in this group. The project includes the Hepatitis C Incidence and Transmission Study - community (HITS-c), an ongoing prospective observational study of HCV antibody negative PWID. By 2011, 150 PWID were

enrolled and retention at 12 months was 86%. A total of 17 incident cases of HCV infection have been observed (9.3/100py; 95% CI 5.8-14.9). Status: By the end of September 2012, 176 PWID were enrolled and retention at 12 months was 85%. A total of 26 incident cases of HCV infection have

Personnel: Anna Bates, Jarliene Enriquez, Sammy Chow, Jessica Jia, Len Liao, Bethany White, Sarah Wright, Lisa Maher

been observed.

Collaborating centres: Academic Medical Centre, University of Amsterdam and Infectious Disease Cluster, Amsterdam Public Health Service; Australian Intravenous and Injecting League (AIVL); Hepatitis Australia; Hepatitis C Council of NSW; Inflammatory Diseases Research Unit, School of Medical Sciences, UNSW; SEALS Microbiology, Prince of Wales Hospital; Burnet Institute; British Columbia Centre for Excellence in HIV/AIDS; University of California San Francisco.

Funding: NHMRC Project Grant

Economic, social and cross-cultural issues in non-pharmaceutical protection of front line responders to pandemic influenza and emerging infections

Non-pharmaceutical interventions such as face masks are one of the few widely available strategies that can be offered to front line health care workers (HCW) in outbreak situations and that can be guaranteed to be available regardless of the type of infection. The aims of this study are: to determine knowledge, attitudes and practices of HCW related to infection control and barriers to adherence to mask use; to conduct a cluster randomised trial in frontline health care workers in Hanoi in order to determine the efficacy of surgical and cloth masks against influenza and other respiratory viruses; to compare knowledge, attitudes and practices of frontline HCW in Australia and Vietnam, and identify both culturally specific and universal issues that may affect behaviour in an emergency; to model the costeffectiveness of surgical and N95 face masks; and to inform disease control policy nationally and internationally on the use of face masks in the control of pandemic influenza, emerging infections or a bioterrorist attack. Status: Fifteen hospitals involving 1,606 HCW were enrolled and the trial was

completed in 2012. Data are currently being analysed.

Personnel: Lisa Maher

Collaborating centres: School of Public Health and Community Medicine, UNSW (lead); Imperial College London, Faculty of Medicine; National Institute of Hygiene and Epidemiology (NIHE), Hanoi; Westmead Hospital, Sydney. Funding: Australian Research Council

Staying safe: How do long-term injecting drug users avoid hepatitis C infection?

Building on data collected from established longitudinal cohort of PWID, this project is focussed on developing hepatitis C virus (HCV) prevention programs to assist both new and experienced PWID to develop and implement strategies to remain uninfected with HCV. Through collaborations with Harm Reduction Victoria and the Centre for Population Health at Burnet Institute, data collected from this project is also being used to assist people who are infected with HCV but who clear the virus to continue to inject to avoid reinfection. In-depth interview data allows comparisons of PWID who have acquired HCV and those who have not ensuring utility for all PWID.

Status: Completed.

Personnel: Peter Higgs, Lisa Maher **Collaborating centres:** The Centres for Population Health, Burnet Institute;

Harm Reduction Victoria. **Funding:** NHMRC

Staying safe Sydney

This study aims to explore the social practices and conditions associated with long term avoidance of hepatitis C virus infection. During 2011 a further 12 participants from South West Sydney were recruited into Stage Two. Initial interviews explored participants' life histories, focussing on constructing a 'timeline' which was later reproduced graphically using 'Timeline Maker Professional' software. Follow-up interviews focused on drug use over time and place with the 'timeline' serving as a prompt. Data from the 23 completed interviews is being coded using 'NVivo9' software, using the coding frame constructed during Stage One of the project.

Status: This study was completed in 2012 Personnel: Lisa Maher, Carla Treloar, Jake Rance, Magdalena Harris Collaborating centre: National Centre for HIV Social Research.

Funding: UNSW

An ethno-epidemiological investigation of social and environmental contexts of HIV vulnerability among injection drug users

By combining ethnographic and epidemiological methods this project seeks to develop an ethnoepidemiological model of HIV vulnerability among PWID. Ethnographic methods are used to generate empirical information regarding key transitional events and social contexts within the lives of PWID and how these shape HIV risks. These ethnographic research activities are integrated with a broad program of social epidemiology, including ongoing epidemiological cohort studies. This design permits identification of cohort participants undergoing key transitions for targeted in-depth interviews, as well as examination of hypotheses regarding the relationship between HIV vulnerabilities and particular social contexts (e.g. street-based drug markets and sex work environments). Status: Completed in August 2012 Personnel: Will Small, Lisa Maher Collaborators: Urban Health Research Institute, British Columbia Centre for Excellence in HIV/AIDS.

Funding: Canadian Institutes of Health Research Post Doctoral Fellowship; Michael Smith Foundation for Health Research Post Doctoral Fellowship

Exploring the natural history of injection drug use: A qualitative study of social and environmental influences in the VIDUS cohort

This study seeks to: (1) examine the influence of social and environmental factors on critical initiation and transitional events among street youth and adults who inject drugs, including transitions in drug use, initiation into drug scenes and sex work; (2) examine the influence of social and physical contexts within 'drug scenes' on HIV risk behaviour; (3) refine and document an evolving ethno-epidemiological approach to investigating the natural history of injection drug use. The study employs observational ethnographic activities, indepth interviews, mapping techniques, photography, and epidemiological data. Observational activities will be conducted in settings where illicit drugs are consumed. Qualitative indepth interviews will be conducted with individuals who are members of existing cohort studies, and will utilise a

longitudinal perspective through annual follow-up of participants.

Status: Completed.

Personnel: Will Small, Lisa Maher **Collaborators:** British Columbia Centre for Excellence in HIV/AIDS, Vancouver (lead)

Funding: Canadian Institutes of Health Research

Relative efficacy of cash versus vouchers in engaging people who inject drugs (PWID) in research

Ethical concerns around reimbursing PWID for research participation have focussed on the potential for cash payments to precipitate drug use. In an effort to overcome perceived ethical complexities, some protocols instead reimburse participants with vouchers rather than cash. This study employed a crossover design at two opioid substitution therapy (OST) clinics. At Time 1, researchers located in each clinic invited OST clients to participate in a survey about alcohol use. Four months later (Time 2), the same protocol was implemented in the same two clinics. However, at Time 1, Clinic 1 offered \$20 cash as reimbursement while Clinic 2 offered a \$20 voucher. At Time 2, the form of reimbursement was reversed, with Clinic 1 offering the voucher, and Clinic 2 offering cash. The main outcome of interest in this study was the proportion of participants willing to participate for cash versus voucher reimbursement. Results indicated that, as expected, participation rates were significantly higher when clients were offered cash than when they were offered vouchers.

Status: Round 1 data collection completed in July 2011; round 2 completed in November 2011. Data entry, cleaning and analysis completed in February 2012.

Personnel: Mofizul Islam, Rachel Deacon, Libby Topp, Carolyn Day

Collaborating centre: Discipline of Addiction Medicine, University of Sydney Funding: UNSW Faculty of Medicine Faculty Research Grant

Assessment and prevention of injection-related injury and disease (IRID) among people who inject drugs

Injecting-related injury and disease (IRID) is a significant health issue among PWID. This study aims to identify prevalence (lifetime and recent) of IRID and associated risk factors among PWID attending the Kirketon Road Centre

(KRC) and to develop and evaluate an intervention to prevent and treat IRID in this group. A clinician-administered screening tool was developed and integrated into routine alcohol and other drug assessment for PWID first attending KRC. The intervention consisted of specific safer injecting messages provided by clinicians at the point of venepuncture to screen for blood borne infections. A survey to assess baseline injecting knowledge and practices was conducted prior to, and following receipts of, the intervention.

Status: Evaluation underway
Personnel: Mihaela Ivan, Lisa Maher
Collaborators: Kirketon Road Centre,
South Eastern Sydney Local Health
District.

Funding: NSW Ministry of Health Mental Health and Drug and Alcohol Office (MHDAO)

Examination of injecting drug use life course and estimating prevalence and health consequences of a dynamic population

This project examines longitudinal datasets of injecting drug users from the UK (e. g. Edinburgh Addiction Cohort Study) and Australia (e. g. Hepatitis Incidence and Transmission Study) taking into account periods of injecting and non-injecting. This will allow for more valid projections of injecting drug use health consequences and associated health impacts and costs of interventions.

Status: Completed **Personnel:** Lisa Maher

Collaborators: University of Bristol; MRC Biostatistics Unit, Cambridge; Muirhouse Medical Group, Edinburgh; London School of Hygiene and Tropical Medicine

Funding: NHMRC (Sidney Sax) Training Fellowship

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

A collaborative project between Australia, Canada and New Zealand to examine resilience to bloodborne viruses (BBVs) and sexually transmissible infections (STIs) in Indigenous communities. With a focus on adolescents and young adults in urban settings, the Australian component of the study seeks to identify factors that protect against acquisition of BBV/STI and promote access to prevention and treatment, and provide capacity building

opportunities for Indigenous researchers and Aboriginal Community Controlled Health Services. In 2011, surveys data were collated and analysis commenced. Health services undertook data analysis training.

Status: Ongoing.

Personnel: Anna Olsen, Lisa Maher,

John Kaldor

Collaborators: Townsville Aboriginal and Islanders Health Service Ltd; The Aboriginal Medical Service Coop Ltd, Redfern: Derbarl Yerrigan Health Service, Perth; Centre for Infectious Disease Prevention and Control, Health Canada; Canadian Aboriginal AIDS Network; University of Ottawa; Ngã Pae o te Mãramatanga, University of Auckland; Auckland University of Technology; University of Otago Medical School

Funding: Tripartite Cooperation Agreement between Canadian Institutes of Health Research (CIHR); National Health and Medical Research Council of Australia (NHMRC); Health Research Council of New Zealand

Co-location: *Viral Hepatitis* Epidemiology and Prevention Program and Public Health Interventions Research Group

Liver Spots: A study of hepatitis B knowledge, treatment and health care among Indigenous Australians

This project aims to engage Indigenous individuals, families and communities affected by hepatitis B, as well as health care providers and policy makers, in addressing the social and treatment needs of Aboriginal and Torres Strait Islander people living with chronic hepatitis B. Working with both urban and rural/ remote communities, the study will investigate facilitators and barriers to biomedical knowledge, cultural healthcare needs, traditional health beliefs and facilitators and barriers of treatment uptake. Information generated from in-depth interviews and survey data will contribute to meeting the chronic health management and treatment needs of participating individuals and communities as well as providing data to inform the development of culturally appropriate resources and services for Indigenous Australians. Pilot work on the project began in late 2010.

Status: Ongoing

Personnel: Anna Olsen, Lisa Maher Funding: NHMRC Training Fellowship

The International Collaboration of Incident HIV and hepatitis C in Injecting Cohorts (InC3) Collaborative

While several prospective studies have been conducted worldwide over the last decade, knowledge of the epidemiology of acute HIV and HCV infection in PWID remains limited. Drawing on a merged international multi-cohort project of pooled data from well characterised cohorts of people who inject drugs (PWID), InC3 offers an unprecedented opportunity to overcome the limitations of current studies and address questions unanswered due to a lack of statistical power, limited observation time. heterogeneous populations or other constraints.

InC3 was established to create a merged international multi-cohort project of pooled data from well characterised cohorts of injecting drug users in order to conduct studies of risk, incidence and the natural history of acute HIV and HCV infection. Specific aims are to: 1) Examine temporal trends in HIV and HCV incidence, and determine the behavioural, social, and biological factors that explain trends over time; 2) Estimate HCV incidence rates by HIV status and sexual behaviour; 3) Estimate the rate and determinants of spontaneous viral clearance of acute HCV infection in IDU; 4) Estimate the rates, outcomes and key predictors of HCV re-infection and re-clearance among HCV resolvers; 5) Examine whether HCV infection disclosure is associated with changes in risk exposures in IDU and; 6) Assess factors associated with initiation, adherence and effectiveness of clinical treatment of acute HCV. This collaboration has been successful in pooling behavioural, clinical and virological data on 522 participants with well-defined HCV seroconversion events from nine cohorts in Australia, Canada, Europe and the United States. This is the largest consortium of investigators assembled to investigate acute HCV infection. The behavioural, clinical and virological data already collected and the access to stored specimens from this merged study has the potential to provide invaluable insight into the control of HCV infection, including the development of novel HCV therapeutics and vaccine strategies.

Status: ongoing

Personnel: Gregory Dore, Jason Grebely, Lisa Maher, Tanya Applegate, Gail Matthews, Maryam Alavi, Kimberly Page, Julie Bruneau, Andrea Cox, Judith Hahn,

Margaret Hellard, Arthur Kim, Georg Lauer, Andrew Lloyd, Barbara McGovern, Maria Prins, Stephen Shiboski, Naglaa Shoukry

Collaborating centres: University of California San Francisco (lead): Burnet Institute; Inflammation and Infection Research Centre UNSW; Johns Hopkins University; Massachusetts General Hospital; University of Amsterdam and Infectious Disease Cluster, Amsterdam Public Health Service; University of

Funding: National Institutes of Health **Co-location**: Viral Hepatitis Epidemiology and Prevention Program and Viral Hepatitis Clinical Research Program

Young Women's Health Study (YWHS) II: Culture and HIV prevention in Cambodia

The YWHS is a prospective study of young (15 to 29 years) women engaged in sex work in Phnom Penh. Women are followed up at quarterly intervals and asked to complete a structured questionnaire in Khmer and to provide blood for HIV testing, self-collected urine for chlamydia, gonorrhoea and ATS testing, and cervical swabs for human papilloma virus (HPV) testing. HPV vaccination is offered to eligible participants. Aims are to: 1) Estimate prevalence and incidence of HIV and STIs including HPV; 2) Examine the socio-cultural factors and risks associated with ATS use and; 3) Assess rates of completion and adherence to a multidose vaccine regimen for the prevention of HPV. As part of the YWHS, trained interviewers also conducted qualitative in-depth interviews to explore social and cultural influences on HIV/STI risk and protective behaviours and ATS use. Status: Data are being analysed and results prepared for publication Personnel: John Kaldor, Lisa Maher, Kimberly Page, Saphonn Vonthanak, Serey Phal, Joel Palefsky, Tooru Nemoto Collaborating centres: University of California, San Francisco (lead); National Center for HIV/AIDS, Dermatology and STDs (NCHADS); Cambodian Women's **Development Association** Funding: National Institutes of Health

New hazards for young women sex workers: Effects and crises arising from recent anti-trafficking laws in Cambodia

This qualitative study aims to assess the impact and effects of the implementation

of recent anti-trafficking and antiprostitution laws on female sex workers (FSW) in Phnom Penh, Cambodia. Specifically, the study aims to 1) Assess the impact of these laws on individual risk and protective behaviours and risk environments (sex work settings) and; 2) Document how women have adapted to the reputed harsh and severe implementation of these laws.

Status: Data collection for this study has been completed and analysis is currently underway.

Personnel: Lisa Maher

Collaborators: University of California, San Francisco (lead); Cambodian Women's Development Association. Funding: University of California Pacific

Rim Research Program

Staying safe: A sociology of how injecting drug users avoid viral infection in the long-term

This study aims to reconstruct the life trajectories of injecting drug users to identify social practices and conditions linked to long term avoidance of hepatitis C virus infection. Using qualitative life history studies from long-term PWID who have not been exposed to hepatitis C alongside those who have been exposed; this is the first research in the UK on long-term avoidance of viral infections associated with injecting drug use. To date a total of 38 in-depth qualitative interviews have been conducted.

Status: Ongoing

Personnel: Lisa Maher, Tim Rhodes, Chris Bonell, Vivian Hope, Carla Treloar,

Samuel Friedman

Collaborators: London School Hygiene Tropical Medicine, University of London (lead); National Development and Research Institutes, New York; National Centre for HIV Social Research.

Funding: Economic and Social Research Council

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State Coordinator, Population Health, Department of Health and Human Services, Hobart

Libby Topp PhD (to March)

Kirby Institute

Tammy Waters Dip AOD

Needle and Syringe Program Coordinator, Directions ACT, Canberra **Jenny Iversen BAppSc** (Secretary) Kirby Institute

■ EXTERNAL BOARDS, COMMITTEES AND ADVISORY GROUPS 2012

1st Canadian Symposium on Hepatitis C Virus, Montreal, Canada, Organising Committee (Jason Grebely)
8th Australasian Viral Hepatitis Conference Organising
Committee (Greg Dore Co-chair, Tanya Applegate)
8th Australasian Viral Hepatitis Conference Organising
Committee, Epidemiology and Public Health Stream (Lisa Maher)
8th Australasian Viral Hepatitis Conference Organising Committee,
Community and Social Research Stream (Peter Higgs)
9th International Congress on Drug Therapy in HIV Infection

Scientific Committee (HIV9) (David Cooper)

12th IUSTI World Congress, Melbourne, 2012, Organising Committee (Basil Donovan)

13th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV Organising Committee (David Cooper) 14th Bangkok Symposium on HIV Medicine Organising Committee (David Cooper)

16th Bangkok Symposium on HIV Medicine Organising Committee (David Cooper, Stephen Kerr)

2012 International Microbicides Conference M2012 Organising Committee (John Kaldor [Chair], Andrew Vallely, Lisa Maher)

2012 Microbicides Conference Organising Committee (Mary Poynten)

ACCESS Aboriginal Community Controlled Health Service steering committee (John Kaldor)

ACCESS family planning network steering committee (Basil Donovan, Rebecca Guy)

ACCESS general practice network steering committee (Basil Donovan, Rebecca Guy)

ACCESS sexual health service network steering committee (Hammad Ali, Basil Donovan, Rebecca Guy, John Kaldor) Addiction and Moral Agency ARC Discovery Project Advisory Committee (Lisa Maher)

AIDS and Behaviour Editorial Board (Garrett Prestage)
AIDS Council of New South Wales Board (Garrett Prestage, Ben Bayinton)

AIDS Council of New South Wales Ethics Review Committee (Garrett Prestage chair)

AIDS Council of New South Wales HIV and Sexually Transmissible Infections Working Group (Garrett Prestage) AIDS Council of New South Wales Lesbian Health Board Advisory Committee (Julie Mooney-Somers)

AIDS Council of New South Wales Research and Policy Advisory Committee (Garrett Prestage)

Alcohol and Drug Foundation NSW, Kathleen York House (Libby Topp, Director)

Altair Trial MRS Substudy Protocol Steering Committee (David Cooper, Sean Emery, Steve Kerr, Rebekah Puls)

Altair Trial Protocol Steering Committee (David Cooper, Sean Emery, Kathy Petoumenos, Rebekah Puls)

ANEX Australian Drugs Conference Reference Group (Lisa Maher) Anex Research Advisory Committee (John Kaldor)

Annecy HIV group for international HIV surveillance (David Wilson, Australian representative)

Asian Network of People who Use Drugs, Hepatitis C Technical Advisory Group (Lisa Maher)

Asian Pacific Journal of Tropical Biomedicine Editorial Board (David Wilson)

ATAHC II Protocol Steering Committee (Greg Dore, Gail Matthews, Jason Grebely, Kathy Petoumenos)

Australasian Health and Research Data Managers Association Executive Committee (Pip Marks)

Australasian Professional Society on Alcohol & other Drugs, 2012 Conference, Scientific Program Committee (Peter Higgs) Australasian Society for HIV Medicine, Board members (Mark Boyd, Greg Dore)

Australasian Society for HIV Medicine, NSW HIV Shared Care Workshop Committee (Mark Boyd)

Australasian Society for HIV Medicine, Risk Management and Audit Sub-Committee (Mark Boyd)

Australasian Society for HIV Medicine, Education and Training Committee (Sarah Pett)

Australasian Society for HIV Medicine, *Hepatitis B for Primary Care Providers Monograph* Editorial Committee (Gail Matthews) Australasian Society for HIV Medicine, HIV and the Body Steering Committee (Sarah Pett)

Australasian Society for HIV Medicine, NSW Hepatitis B Reference Committee (Gail Matthews)

Australasian Society for HIV Medicine, NSW Hepatitis C Reference Committee (Gail Matthews)

Australasian Society for HIV Medicine, NSW Hepatitis Reference Committee (Greg Dore)

Australasian Society for HIV Medicine, reviewer of abstracts (Anthony Kelleher)

Australian Antiretroviral Guidelines Panel (David Templeton, member)

Australian Chlamydia Control Effectiveness Pilot (ACCEPt) Project Executive Committee (Basil Donovan, Rebecca Guy, John Kaldor)

Australian Collaboration for Chlamydia Enhanced Sentinel Surveillance (ACCESS) Coordinating Committee (Basil Donovan, Rebecca Guy, John Kaldor)

Australian Government Department of Health and Ageing Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections (Andrew Grulich member) Australian Government Department of Health and Ageingfunded HIV/AIDS, hepatitis C and sexually transmissible infections, education and health promotion materials, expert working group (John Kaldor)

Australian HIV Observational Database Steering Committee

(Mark Boyd, Matthew Law, Hamish McManus, Kathy Petoumenos, Stephen Wright)

Australian Institute of Policy and Science (David Wilson, associate member)

Australian Liver Association Clinical Trial Network Executive Committee (Greg Dore)

Australian and New Zealand Industrial and Applied Mathematics (ANZIAM) (John Murray, President) Australian New Zealand Breast Cancer Trials Group

Independent Data Safety and Monitoring Committee (Matthew Law)

Australian NSP Survey National Advisory Group (Jenny Iversen, Lisa Maher, Libby Topp)

Australian Radiation Protection and Nuclear Safety Agency Radiation Health and Safety Advisory Council (John Kaldor) Australian Red Cross Blood Service (David Wilson, monitoring advisor)

Australian Society for Infectious Disease, Prosthetic Joint Infection Trial Steering Committee (Mark Boyd)

Cancer Working Group, international epidemiologic databases to evaluate AIDS (Andrew Grulich)

CAS HIV/STI Health Promotion Subcommittee chlamydia working group (Hammad Ali, Rebecca Guy)

Centre for Research Excellence in Injecting Drug Use, Education Subcommittee (Jason Grebely)

CHEST Management Committee (Bette Liu)

Cochrane Collaborative Review Group on HIV infection and AIDS, Biomedical Interventions Reviews Editor (John Kaldor) Communicable Disease Network of Australia Committee, Surveillance and Monitoring Plan for national strategies HIV STI BBV Sub-Committee (David Wilson)

Communicable Diseases Intelligence Editorial Board (John Kaldor)
Communicable Diseases Network Australia (John Kaldor)
Communicable Diseases Network Australia, Human
Papillomavirus (HPV) Surveillance Working Party (John Kaldor)
Communicable Diseases Network Australia, New Developments in HIV Surveillance Committee (John Kaldor, Chair)
Communicable Diseases Network Australia, Subcommittee on Surveillance of Bloodborne Viral and Sexually Transmitted
Infections (Basil Donovan, Rebecca Guy, John Kaldor, Tarana

Lucky, Keira Robinson, Ann McDonald, Melanie Middleton, David Wilson) Communicable Diseases Network of Australia (CDNA), National Strategies HIV STI BBV Sub-Committee, Surveillance and Monitoring Plan (David Wilson)

Comprehensive International Program for Research on AIDS (CIPRA) HIV Research Program in Thailand and Cambodia International Steering Committee (David Cooper)

Council of the PNG Institute of Medical Research (Andrew Vallely, Member)

Current HIV/AIDS Reports Editorial Board (David Cooper, Honorary Member)

Current Opinion in HIV and AIDS (David Cooper, co-editor) Current Opinion in HIV and AIDS Editorial Board (John Kaldor) Developing Papua New Guinea's National HIV Strategy 2011-2015 (David Wilson, expert reviewer)

Drug and Alcohol Review Editorial Board (Peter Higgs, Lisa Maher) eJournal of the International AIDS Society Editorial Board (John Kaldor)

Encore Program Committee (Sean Emery, Rebekah Puls)
Encore1 Central Nervous System Exposure Protocol Steering
Committee (Janaki Amin, Carlo Dazo, Rebekah Puls)
Encore1 Neurocognitive Substudy Protocol Steering Committee
(Rebekah Puls, Anna Donaldson, Steve Kerr, Amanda Clarke)
Encore1 Pharmacokinetic Protocol Steering Committee (Dianne
Carey, Rebekah Puls)

Encore1 Protocol Steering Committee (Janaki Amin, David Cooper, Sean Emery, Rebekah Puls)

Enhancing Hepatitis C Treatment Uptake and Outcomes in Opiate Dependency Pharmacotherapy Settings Steering Committee (*ex officio*) (John Kaldor)

Estimation of HIV Prevalence for European Countries Working Group (David Wilson)

European Developing Country Clinical Trials Partnership (EDCTP) microbicide trial feasibility study, East Africa Steering Committee (Andrew Vallely)

Faculty of Medicine, Expert Review Panel (Sean Emery) Faculty of Medicine, Research Management Committee (Anthony Kelleher)

Faculty of Medicine, Women's Employment Committee (Rebekah Puls)

Family Planning NSW Scientific Advisory Group (Basil Donovan, John Kaldor)

FOXFIRE Data Safety and Monitoring Committee (Matthew Law) Gastroenterology Metropolitan Committee on Hepatitis C (Greg Dore co-chair)

Genital Warts Surveillance Network (Hammad Ali, Basil Donovan, Rebecca Guy, David Regan)

Harm Reduction Journal Editorial Board (Lisa Maher)
Heart Foundation HIV & CVD Consumer Resource Working
Group (Kathy Petoumenos)

Hepatitis Victoria, Board of Directors (Peter Higgs, president) Hepatitis NSW Medical Research Advisory Panel (Greg Dore) HIV Consortium for Partnership in Asia and the Pacific Management Committee (John Kaldor, Louise Causer) HIV DART 2008 Conference Organising Committee (David Cooper co-chair)

HIV Netherlands, Australia, Thailand Research Collaboration (HIV-NAT) International Advisory Board (David Cooper, Co-Director, Chris Duncombe)

HIV Therapy Editorial Board (David Cooper, John Kaldor) HIV+ Health Promotion Interagency (Garrett Prestage, Jack Bradley)

HIVNAT International Advisory Board (Sean Emery)
HPV Evaluation Linkage Partnership Australia (HELPA)
Management Committee (Matthew Law, David Regan)
IeDEA Adherence sub-Working Group (Stephen Kerr)
IeDEA Cancer Working Group (Matthew Law, Stephen Kerr)
IeDEA Data Harmonization Working Group (Azar Kariminia)
IeDEA Executive Committee (David Cooper, Matthew Law)
Immunovirology Research Network Steering Committee
(Anthony Kelleher)

Implementing Expanded Naloxone Availability in the ACT (IENAACT) Committee (Anna Olsen)

Infectious Disease Reports Editorial Board (David Wilson)
INSIGHT network, Executive Committee (David Cooper, Sean Emery)

INSIGHT network, Infrastructure Committee (Sarah Pett, Cate Carey)

INSIGHT network, Monitoring Group Committee (David Courtney-Rodgers, Nisha Seneviratne)

INSIGHT network, Quality Oversight and Performance Evaluation Committee (David Courtney-Rodgers) INSIGHT network, Training Committee (Cate Carey) Intensive Insulin Therapy Trialists' Collaboration Steering Committee (Bette Liu)

International AIDS Society Meeting, Epidemiology and Prevention Stream, Vienna, Austria, Rapporteur (David Wilson) International Centre for Science in Drug Policy, Technical Advisor (Lisa Maher)

International Conference on the Reduction of Drug-related Harm Scientific- Program Committee (Lisa Maher)

International HIV/AIDS Alliance Ukraine, Scientific Advisory Board (Lisa Maher)

International Journal of Drug Policy Editorial Board (Jo Kimber, Lisa Maher)

International Journal of STD & AIDS Editorial Board (Basil Donovan)

International Society for STD Research (Basil Donovan, president elect)

International Society for STD Research organising committee (Basil Donovan, David Cooper, Andrew Grulich, Rebecca Guy, John Kaldor)

International Symposium on Hepatitis Care in Substance Users, Brussels, Belgium, Organising committee (Jason Grebely) International Union against Sexually Transmitted Infections, Executive Committee (Basil Donovan, Senior Counsellor) *Journal of Acquired Immune Deficiency Syndromes* Editorial Board (David Cooper)

Journal of AIDS and Clinical Research Editorial Board (David Wilson)

Journal of Hepatology Editorial Board (Greg Dore) Journal of HIV Therapy Current Trends Advisory Board (David Cooper)

Lao People's Democratic Republic National Strategy and Action Plan on HIV/AIDS/STI 2011-2015 (David Wilson expert reviewer)

Lionel Murphy Foundation (Board of Trustees) (Lisa Maher) Lotus House Refuge Management Committee (Lisa Maher) *Medicine Today* Board of Editorial Consultants (Basil Donovan) MGM Interagency (Iryna Zablotska)

MIMS Annual Honorary Editorial Board (Basil Donovan) Multicultural HIV and Hepatitis Service Advisory Group (Lisa Maher, Chair)

NAPWA Treatments Policy Advisory Group (Fraser Drummond, Sarah Pett)

National Association of People Living with HIV/AIDS, HIV Medication Working Group (Dianne Carey)

National Breast Cancer Foundation Register 4 Epidemiological Questionnaire Design Advisory Group (Bette Liu)

National Centre for HIV/AIDS, Dermatology and STD

(NCHADS) Steering Committee for Cambodian Treatment Access Program (CTAP) and AusAID funded HIV projects (John Kaldor)

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

National Centre in HIV Social Research (NCHSR) Scientific Advisory Committee (Lisa Maher)

National Gay Men's Syphilis Action Plan NSW Implementation Committee (Rebecca Guy)

National Gay Men's Syphilis Action Plan Steering Committee and Monitoring and Evaluation Subcommittee (David Wilson, Rebecca Guy)

National Gay Men's Syphilis Action Plan Technical Working Group (Basil Donovan, Andrew Grulich, Rebecca Guy, Garrett Prestage, David Wilson)

National Health and Medical Research Council, Council (Greg Dore)

National Health and Medical Research Council Grant Review Panel (Panel 5E) (Sean Emery)

National Health and Medical Research Council Partnership Projects Grant Review Panel (Basil Donovan)

National Health and Medical Research Council Centres of Research Excellence Grant Review Panel (John Kaldor) National Health and Medical Research Council Project Grant External Reviewer (Anthony Kelleher, Kersten Koelsch) National Health and Medical Research Council Project Grant Review Panel Virology and Microbiology (Stuart Turville) National Health and Medical Research Council, Project Grant Review Panel, Clinical Trials (Greg Dore)

National Health and Medical Research Council Project Grant Review Panel, Indigenous Health (John Kaldor)

National Health and Medical Research Council Public Health Discipline panel (Andrew Grulich)

National Health and Medical Research Council Centres of Research Excellence (Immunisation in Under Studied and Special Risk Populations), Scientific Advisory Board (Lisa Maher) National Health and Medical Research Council Research

Translation Faculty (Lisa Maher) National HIV Post Exposure Prophylaxis Guidelines Reference Group (Andrew Grulich)

National Prison Entrants Bloodborne Virus Survey Steering committee (Tony Butler, chair)

National Prisoner Health Indictor Project, Technical Expert Group (Tony Butler, chair)

National Prisoner Health Indictor Group (Tony Butler) National Strategies STI HIV BBV project working groups (Rebecca Guy, John Kaldor, Garret Prestage)

National Surveillance Committee (Ann McDonald) Netherlands AIDS Foundation Grant Scheme (David Wilson, reviewer)

Northern Territory Sexual Health Advisory Group (John Kaldor) NPA-IH Aboriginal Hepatitis C Advisory Committee (Brigitte Gerst)

NSW Chief Health Officer Report Special Topic: STI (Basil Donovan, David Wilson, advisory group members) NSW Department of Corrective Services Ethics Committee (John Kaldor)

NSW Greater Metropolitan Clinical Taskforce Hepatitis C Subcommittee (Greg Dore, co-chair)

NSW Health CAS Health Promotion Sub-Committee Chlamydia Working Group (Rebecca Guy)

NSW Health Expert Advisory Panel - Wide bore syringes (Lisa Maher)

NSW HIV Point of Care Testing Working Group (Andrew Grulich, Damian Conway, Rebecca Guy, Garret Prestage) NSW Ministerial Advisory Committee on Hepatitis (MACH) (Greg Dore, Lisa Maher)

NSW Ministerial Advisory Committee on HIV/AIDS and Sexually Transmissible Infections, Health Promotion Subcommittee (Andrew Grulich chair, Garrett Prestage member)

NSW Ministerial Advisory Committee on HIV/AIDS and Sexually Transmissible Infections Health Promotion Sub-Committee - Chlamydia Working Group (Hammad Ali, Rebecca Guv)

NSW Users and AIDS Association Expert Advisory Committee (Lisa Maher)

NSW Users and AIDS Association Peer Distribution Advisory Committee (Lisa Maher)

NSW Users and AIDS Association Research Ethics Advisory Committee (Lisa Maher)

Office of Management and Budget (OMB) Peer Reviewer, Public Health Services (PHS) *Guidelines for Pre-Exposure Prophylaxis* (PrEP) for HIV Prevention with Men Who Have Sex with Men, Centres for Disease Control (John Kaldor)

OpiCare Leadership Team (Greg Dore, Jason Grebely) Papua New Guinea Annual Medical Symposium 2011 Organising Committee (Andrew Vallely)

Papua New Guinea HIV Modelling Reference Group (John Murray) Papua New Guinea Policy Forum on Male Circumcision for HIV Prevention Organising Committee (Andrew Vallely, John Kaldor)

PEARL study (HN152) Data and Safety Monitoring Board Committee (Matthew Law)

Practical Advances in Treating HIV (PATH II) Steering Committee (Sean Emery, Chair)

Project Coordinating Committee for the NSW Aboriginal Sexual and Reproductive Health Evaluation Program (Brigitte Gerstl)

ProPrems Trial Data Safety Monitoring Committee (John Kaldor) Public Health Association of Australia (Tony Butler)

Queensland Ministerial Advisory Committee on HIV/AIDS,

Hepatitis C and Sexual Health Member (Andrew Vallely) Repatriation Medical Authority (John Kaldor)

Review of the Australian National HIV Testing Policy, Member Expert Reference Committee, (Andrew Grulich)

Sax Institute (David Wilson)

Sexual Health (David Cooper, Editor)

Sexual Health Editorial Board (Basil Donovan, Andrew Grulich, John Kaldor, Garrett Prestage)

Sexual Health of Adolescents Living with HIV (Unicef Thailand and the We Understand Group) (Stephen Kerr, Advisory Board member)

Sexual Reproductive Health Program Resource Advisory group (Brigitte Gerstl)

Sexually Transmitted Infections Programs Unit (STIPU) Advisor Group, NSW (Rebecca Guy)

Sexually Transmitted Infections, Editorial Board (David Cooper) Sexually Transmitted Infections, Elsevier, New Delhi (Basil Donovan, Section Editor)

Sidney Myer Health PhD Scholarship Selection Committee (Peter Higgs)

SIRFLOX Independent Data and Safety Monitoring Board Committee (Matthew Law)

SPARTAC Trial Steering Committee (David Cooper, Anthony Kelleher)

St Vincent's Centre for Applied Medical Research/UNSW Research degree review committee (Anthony Kelleher) St Vincent's Hospital Campus Institutional Biosafety Committee (Anthony Kelleher)

St Vincent's Hospital Human Research Ethics Committee (Kathy Petoumenos, Handan Wand, Dianne Carey)

St Vincent's Research & Biotechnology Precinct Hub

Governance Council (David Cooper)

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

STIGMA - NSW Implementation committee for the National Syphilis Action Plan (Rebecca Guy)

STIGMA (Iryna Zablotska)

SydPath Research Committee (Anthony Kelleher)

The Cancer Council NSW Cancer Research Committee (Andrew Grulich)

The Data Collection on Adverse Events of Anti-HIV Drug Study International Steering Committee (Matthew Law)

The HIV/AIDS Legal Centre (HALC) Management Board (Iryna Zablotska)

Overdose Awareness Day Committee (Peter Higgs)

Therapeutic Goods Administration (TGA) expert advisory panel for influenza vaccine testing (Anthony Kelleher)

TREAT Asia HIV Observational Database Steering Committee (Matthew Law)

TREAT Asia Paediatric HIV Observational Database Steering

Committee (Matthew Law, Azar Kariminia)

TREAT Asia Steering Committee (David Cooper)

UNAIDS Estimation of Australia's HIV/AIDS indicators (David Wilson)

United Kingdom Medical Research Council/National Health Service Clinical Research Panel (Sean Emery) UNSW Academic Board Committee Member (John Kaldor) UNSW Academic Board Higher Degree Research Committee (John Kaldor)

UNSW Faculty of Medicine Higher Degree Research Committee (Libby Topp)

UNSW Faculty of Medicine Postdoctoral Advisory Committee (Jason Grebely, Mary Poynten)

UNSW Faculty of Medicine Research Grant/Early Career Grant Review (Anthony Kelleher)

UNSW Hepatitis C Vaccine Initiative Steering Committee (John Kaldor)

UNSW Human Research Ethics Advisory Panel: Medical/Community (Greg Dore, Mark Boyd)

UNSW Institutional Biosafety Committee (Stuart Turville) UNSW School of Public Health and Community Medicine Research Committee (Tony Butler)

User's News and New South Wales Users and AIDS Association Advisory Group (Jason Grebely)

VAC/GMHC Sexually Adventurous Men's Project Committee (Garrett Prestage)

World Health Organisation Guidelines Development Working Group: Guidance for Viral Hepatitis B and C Prevention in People Who Inject Drugs; Surveillance, Screening and Antiretroviral Management in People with HIV and Viral Hepatitis B and C Coinfections (Lisa Maher)

World Health Organisation Strategic and Technical Advisory Committee for HIV/AIDS (David Cooper)

World Health Organisation Working Group on Incidence Assays for HIV Infection (John Kaldor co-Chair)

World Health Organisation/UNAIDS HIV Vaccine Advisory Committee (David Cooper, Chair)

World Hepatitis Day Clinical and Public Health Advisory Panel (Greg Dore)

STAFF 2012

DIRECTOR'S OFFICE

Director and Scientia Professor of Medicine

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

Executive Assistant

Janette Button

Research Assistant

Damien Cordery BSc(Hons), MPH, PhD Vaccines program grant co-ordinator John Wilkinson BSc(Hons), PhD Manager, Research Communication Louisa Wright M Journalism, MPH

ABORIGINAL AND TORRES STRAIT ISLANDER PROGRAM

Program Heads (acting)

John Kaldor PhD

Rebecca Guy BAppSc, MAppEpid, PhD

Research Manager

Simon Graham BIS, MApplEpid

Clinical Project Leader

Mary Ellen Harrod BA, Dip Arts, M

Prelim, PhD

Project Coordinator

Linda Garton RN, Grad Cert Adv Prac,

Sex Hlth

Senior Research Officers

Amalie Dyda BHSc, MAppEpid

Brigitte Gerstl BSoc, MPH

Project Officers

Belinda Ford BSc, MPH

Rebecca Lorch DipNurs BSc(Hons)

Research Officer

Imogen Green BSc MSc

Administrative assistant

Andrew Nakhla BComm, LLB

BIOSTATISTICS AND DATABASES PROGRAM

Head and Professor

Matthew Law MA, MSc, PhD

Associate Professor

John Murray BSc(Hons), MSc, PhD (part time)

Senior Lecturer

Janaki Amin BSc(Hons), MPH(Hons), PhD Stephen Kerr BPharm(Hons), MIPH, PhD (based at HIV-NAT, Thailand) Kathy Petoumenos BSc, MA,

MPH(Hons), PhD

David Regan BA, BSc(Hons), PhD

Handan Wand MA, MSc, PhD

Lecturer

Azar Kariminia BSc, MSc, PhD

Associate Lecturer

Ben Hui BE(computer engineering),

MBiomedE

Research Associates

Igor Korostil MSc

Statisticians

Amit Achhra MBBS MPH

David Boettiger MPharm MSC Epi

Awachana Jiamsakul BSc, MS Hamish McManus BEcon, BActS, MBIOS

Cecilia Moore MSc MPH

Stephen Wright BMath, MAppStat

Computer Systems Officers

Noorul Absar BTech, Grad Dip(Inf Sc),

MComp(SW Eng)

Rossitza Chevkenova BSc

Program co-ordinator

Courtney Bendall DipBus

Administrative assistant Supreet Mehik B Homoeop Med Surg

HIV EPIDEMIOLOGY AND PREVENTION PROGRAM

Head, Professor and NHMRC Principal Research Fellow

Andrew Grulich MBBS, MSc, PhD,

FAFPHM

Associate Professor

Garrett Prestage BA, PhD, JP

Senior Lecturers (Fengyi) Jeff Jin MB, MPH, PhD

(Isobel) Mary Poynten MBBS, DCH, MPH

(Hon), PhD

David J Templeton MBChB, DipVen, MForensMed, PhD, MACLM, MFFLM,

FAChSHM

Iryna Zablotska-Manos PhD, MD, MPH

Lecturer

Jeanne Ellard BA (Hons), MPhil, PhD

Associate Lecturers

Ben Bavinton BA (Hon), MPH

Ian Down MPH

Michelle McKechnie BMedSci (Hon), PhD

Research Assistants

Brian Acraman

Lara Cassar CertIVBusAdmin

Patrick McGrath BA, Dip Ed, Grad Dip

Matthew O'Dwyer BLibStud, MPH (Hons)

Project Officer

Jack Bradley

Program Coordinator

Anna Checkley BA (Hons)

Conjoint Associate Professor

Richard Hillman MD FRCP FAChSHM

University of Sydney

Adjunct Lecturer

Kathy Triffitt BA, Grad Dip, Ph D Positive

Life NSW

IMMUNOVIROLOGY AND PATHOGENESIS PROGRAM

Professor and Head

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

Senior Lecturer and NHMRC CDA

Fellow

Stuart Turville BSc (Hons) PhD

Lecturer

Kersten Koelsch MBBS, MD

Clinical Project Co-ordinator

Patricia Grey BA, Post Grad Dip App Sci,

CNS, Dip (Counselling)

Research Fellows

Anupriya Aggarwal PhD

Chantelle Hood PhD

Mee Ling Munier PhD

David van Bockel PhD

Research Assistants

Mehreen Arshi BSc MPhil Michelle Bailey BSc(Hons)

Susanna Ip BSc

Glen Lockwood BSc

Data Administrator

Ansari Shaik BA, MBA

Administrative assistant Tracey Barrett

JUSTICE HEALTH PROGRAM

Head and Professor

Tony Butler MSc (Quant methods) MSc (IT) PhD DipAppEpi

Research assistant

Michael Doyle Grad Dip (Indig H Promotion)

Research Fellows

Claudette Satchell BSc (Hons) PhD Lorraine Yap PhD

Senior Research Officer

Joanne Reekie BSc (Hons), MPhil, PhD Research Officers

Shamin Kinathil MSc, BE (Hons), BSc Paul Simpson BSc (Psych)

PUBLIC HEALTH INTERVENTIONS RESEARCH GROUP

Head and Professor of Epidemiology

John Kaldor PhD

Associate Professor

Andrew Vallely MBBS, MRCP, MSC, DTMH, PhD

Senior Lecturer

Bette Liu MBBS (Hons) MPH (Hons) DPhil Lecturers

Louise Causer MB BS, MSc, DTM&H Joanne Jackson (Micallef) BMedSc (Hons), PhD

Bradley Mathers MSD, MBChB, BHB

Clinical Trials Co-ordinator

Lucia Romani BSocSci MA

Senior Research Officer

Joanne Reekie BSc (Hons), MPhil, PhD

Program Manager

Skye McGregor BA, BSc, MA

SURVEILLANCE AND EVALUATION PROGRAM FOR PUBLIC HEALTH

Head and Associate Professor

David Wilson BSc, BInfTech,

BAppSc(Hons), GradCert(Biostats), PhD

Senior Health Economist

Klara Henderson BA, MCOM, PhD

Senior lecturer

Lei Zhang BSc(Adv Hons), MSc, PhD, MPH **Lecturer**

Richard Gray BSc(Hons), PhD

Post Doctoral Research Fellows/

Associate Lecturers

Mehala Balamurali BSc(Hons), PhD Alexander Hoare BSc(Hons), PhD Josephine Reyes BS, MS, PhD

Research Associate

Cliff Kerr BSc(Hons), LMusA, DipArts, PhD

HIV Surveillance Coordinator

Ann McDonald BSc, MPH

Senior Surveillance Officer

Carleigh Cowling BNurs, PGDipMid

Surveillance Officers

Melanie Middleton BMedSci, MPH Tarana Lucky MBBS, MPH

Research Assistants

Andrew Craig BSc Corrine Iu BScEd, MPH

Shamin Kinathil BE(Hons). BSc

Elizabeth Mlambo BSc, MPH

Gordana Popovic BEd, BSc(Hons) Andrew Shattock BSc, MSc

Program Coordinator

Megan Tapia

SEXUAL HEALTH PROGRAM

Head and Professor of Sexual Health

Basil Donovan MB BS, DipVen (Lond), MD, FAFPHM, FRCPI, FAChSHM Senior Lecturer and NHMRC Post-

doctoral Fellow

Rebecca Guy BAppSc, MAppEpid, PhD

Lecturers

Hammad Ali BSc, MBBS, MPH Damian Conway, MB BCh MMed(STD/ HIV) FAChSHM MRCGP DRCOG DFF Fraser Drummond MB ChB, MRCA, DA

(UK) (to June)

Senior Research Officer

Kirsty Smith RN, Grad Dip Education, MPH

Project Co-ordinators

Lisa Edwards BNurs MPH

Rebecca Lorch DipAdultNurs BSc(Hons)

Research Assistants

Larissa Lewis BA

Muhammad Shahid Jamil MBBS MPH

Denton Challander BA, BMT

Visiting research fellow

Hsin-Chun (Grace) Lee MD

Program Coordinator

Lucy Watchirs Smith BA, MPH

THERAPEUTIC AND VACCINE RESEARCH PROGRAM

Head and Professor

Sean Emery BSc(Hons), PhD

Senior Lecturer

 $Mark\ Boyd\ BA,\ BM,\ BS,\ DCTM\&H,$

MHID, MD, FRACP

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

Rebekah Puls BSc(Hons), PhD

Lecturer

Dianne Carey BPharm, MPH, PHD

Senior Clinical Project Co-ordinators

Cate Carey RN, BA, MAppSc(Research) Allison Humphries BSc, MSc (Med), Grad Dip PH

David Courtney-Rodgers

Clinical Project Co-ordinators

Maria Arriaga BSc, MScMed (STD/HIV) Megan Clewett BappSc HIM

Carlo Dazo BMedSc (Hons)

Anna Donaldson MSC

Hila Haskelberg BSc

Sally Hough BAppSci, Postgrad Cert PM Simone Jacoby BSc, Dip Nutrition, Adv

Dip Bot Med

Joe Levitt AAS

Nisha Berthon-Jones BMedSc. BBus

Megan Evans BappSc HIM

Natalie Espinosa BS (Biomed),

MA.AppSc (Ex&Sc)

Jessica Taylor (BNurs)

David Silk BSc (Hons)

Elise Tu BSc (Hons), PhD

Program Managers

Helen Kriketos BA

Cathy O'Connell

Data Managers Kymme Courtney-Vega Dip Sp Th

Andrea Redgrave BEng, MSEc

Jose Aurelio Vieira Vulcao BA

Administrative Assistants

Pamela Findlay

Tanya Johannesen BDes

Rosemary Robson

VIRAL HEPATITIS EPIDEMIOLOGY AND PREVENTION PROGRAM

Professor and Head

Lisa Maher PhD

Senior Lecturer

Libby Topp BSc(Psychol) (Hons), PhD

Associate Lecturer

Sarah Wright BSc, PGDip Sci, PhD

(Physiology)

Lecturer

Mihaela Ivan MD MSc FAFPHM

Post Doctoral Research Fellows

Peter Higgs PhD, MA, BSW

Anna Olsen PhD

Study Co-ordinators

Jenny Iversen BAppSc

Bethany White BA (Psych), MPH

Research Assistants

Anna Bates BA, MPH

Sammy Chow BSc (Hons)

Jarliene Enriquez

Program Coordinator

Rachel McCleave BA(Hons), BEd(Prim)

VIRAL HEPATITIS CLINICAL RESEARCH PROGRAM

Head and Associate Professor

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

Senior Lecturers

Gail Matthews MBChB, MRCP(UK),

FRACP PhD

Tanya Applegate BSc (Hons), PhD

Jason Grebely BSc, PhD

Associate lecturer

Daniel Bradshaw BMBCh MA MRCP (UK)

Clinical Trials Manager

Pip Marks BSc, MPH (Hons)

Clinical Project Co-ordinators

Marianne Byrne B.Sci (Hons); Grad Cert

ClinTrialsMan

Amanda Erratt ADip (Med Record

Admin)

Michelle Micallef Phd, BBMedSci (Hons)

John J Morrison, BSc (Hons), PhD

Sophie Quiene MSc

Barbara Yeung RN, BHSc (Nursing), MPH

Systems manager

Ineke Shaw BSc, Grad Cert BioStats

Senior Research Officer

Francois Lamoury EICnam (Biology)

Research Assistants Sofia Bartlett BSc (Hons)

Data Managers

Sharmila Siriragavan BMedSci Mahshid Tammadoni BE, MAppSc

Labkey Database Developer

Trent Schafer BA IT **Laboratory Coordinator**

Austin Butcher

Program Coordinator

Dee Bryant

Conjoint senior lecturer

Dr Alex Thompson MBBS, PhD, FRACP, St Vincent's Hospital Melbourne

OPERATIONS AND ADMINISTRATION

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Finance Manager

Eilis Duggan BBS(Hons), ACA

Accountants

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Teresa Wong BAcc, CPA

Finance officer Daisy Kibir Librarian

Coralie Kronenberg BA, Dip IM Lib, AALIA

IT Specialist

Sergio Sandler MSc, EE, Dip Ed **Computer Systems Officers**

Lisa Howard Dip IT Charles Tran BCompSc

Manager, Human Relations

Brigette Sharp BA(Hons), MAppSc

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Collaboration (HIV-NAT)

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DFFP, DipHIV, MPH, FAChSHM

Post-graduate Fellow, Sydney Sexual

Health Centre, Sydney Hospital

Kathy Triffitt BA, Grad Dip, Ph D

Manager, Health Promotion

Positive Life NSW

■ POSTGRADUATE STUDENTS AND STUDENT SUPERVISION

PHD CANDIDATES AT THE KIRBY INSTITUTE

Amit C Achhra

Bio-markers and other predictors of AIDS and non-AIDS diseases in HIV observational (cohort) studies Supervisors David Cooper; Janaki Amin; Matthew Law

Maryam Alavi

Barriers to the assessment and treatment of hepatitis C virus infection in injecting drug users

Supervisors: Greg Dore, Jason Grebely

Hammad Ali

Epidemiology of Chlamydia and development of national systems to measure incidence in Australia. Supervisors: Rebecca Guy, Basil Donovan,

David Wilson Jonathan Anderson

The role of economic evaluation in decision-making about HIV Supervisors: David Cooper; Sean Emery; Kathy Petoumenos

Maria Arriaga

Aspects of Human Immunodeficiency Virus (HIV) management

Supervisors: Sarah Pett, Mark Boyd

Ben Bavinton

HIV viral load and transmission in serodiscordant male homosexual couples. Supervisors: Andrew Grulich, Garrett Prestage

Louise Causer

Rapid points of care (RPOC) tests for diagnosis of sexually transmitted infections (STIs): evaluation of accuracy, acceptability and impact in Australia and Papua New Guinea (PNG).

Supervisors: John Kaldor, Rebecca Guy

Eric Pui Fung Chow

Understanding the past, forecasting the future – investigating the epidemiology of HIV/AIDS in China

Supervisors: Lei Zhang, David Wilson **Paul Clark**

Barriers to Hepatitis C treatment and cure.

Supervisors: Greg Dore; Alex Thompson

(St Vincent's Hospital, Melbourne); Gail Matthews

Damian Conway

Novel approaches to HIV testing for men who have sex with men.

Supervisors: Rebecca Guy, Martin Holt (NCHSR), Andrew Grulich

Laura Cook

Characterisation of T regulatory cells Supervisors: Tony Kelleher, Nabila Seddiki

Andrew Peter Craig

Biomathematical and biostatistical modelling of Chlamydia infection, immunity, pathology and vaccine strategies

Supervisor: David Wilson

Ian Down

Meanings of HIV and 'safe-sex' among a sample of recently diagnosed gay men in Australia

Supervisors: Garrett Prestage, Jeanne Ellard

Fraser Drummond

Chemoprophylaxis for syphilis in MSM - a trial of systemic chemoprophylaxis for syphilis in HIV positive men who have sex with men

Supervisors: Basil Donovan; John Kaldor; Rebecca Guy; Jeff Klausner

Brigitte Gerstl

Biostatistics, epidemiology, public health Supervisor: Handan Wand

Simon Graham

Quality improvement in Aboriginal Community Controlled Health Services in New South Wales

Supervisors: Rebecca Guy; Handan Wand

Behzad Hajarizadeh

Diagnosis and natural history of acute hepatitis C virus infection

Supervisors: Greg Dore; Jason Grebely; Tanya Applegate

Hila Haskelberg

Antiretroviral toxicity in HIV-infected patients

Supervisors: Sean Emery; Andrew Carr (St Vincent's Hospital); Janaki Amin

William Hey-Cunningham

Delineation of the latent HIV reservoir with subpopulations of Memory CD4 T cells

Supervisors: Tony Kelleher, Kersten Koelsch, John Zaunders (SVH)

Denise Chee Hsu

Using novel biomarkers to define the role of TB specific effector T cell and TB specific regulatory T cell in patients with Mycobacterium tuberculosis (TB) and HIV co-infection

Supervisors: David Cooper; Jintanat Ananworanich (HIVNAT); Tony Kelleher

Tina Iemma

The Role of Dynamin-II in HIV Pathogenesis

Supervisors: Stuart Turville; Phillip Robinson (University of Sydney)

Mofizul Islam

The impact of targeted primary health care on injecting drug users' health Co-supervisor: Libby Topp

Jennifer Iversen

Enhanced sentinel sero-surveillance among people who inject drugs in Australia

Supervisors: Lisa Maher; Libby Topp; Handan Wand

Brendan Jacka

Viral epidemiology of multiple Hep C infections in international high risk populations

Supervisors: Tanya Applegate; Jason Grebely; Greg Dore

James Jansson

Mapping HIV outcomes: geographical and clinical forecasts of people living with HIV in Australia

Supervisors: David Wilson, Richard Gray

Amy Kwon

Using mathematical modelling to evaluate public health interventions for viral epidemics

Supervisors: David Wilson; Rosie Thein; Cliff Kerr

Linh-Ve Le

HIV incidence and predictors of sexual and drug injecting behavioural risk among female sex workers/men who have sex with men in Vietnam Supervisors: John Kaldor; Lisa Maher; Keith Sabin (WHO, Hanoi)

Frederick Ji-Yoon Lee

Chronic non-AIDS effects of HIV infection and anti-retroviral therapies.

Andrew Carr

Scott Ledger

The effects of anti-attachment and fusion inhibitor gene-therapies in the protection of HIV susceptible cells

Supervisors: Geoff Symonds, John Murray

Dorothy Machalek

The natural history of anal human papillomavirus infection and anal cellular abnormalities in mature aged homosexual men

Supervisors: Andrew Grulich, Jeff Jin, Mary Poynten

Kylie-Ann Mallitt

Geospatial Models of HIV Transmission Supervisors: Handan Wand, David Wilson

Allison Martin (Humphries)

Toxicities associated with antiretroviral treatment of HIV-1 antiretroviral treatment effects on HIV Infection Supervisors: Sean Emery, Janaki Amin, Andrew Carr (St Vincent's Hospital)

Elizabeth Mlambo

Developing enhanced surveillance and evaluating available data for monitoring HIV among culturally and linguistically diverse (CALD) populations living in Australia.

Supervisors: David Wilson, Rebecca Guy

Kristin McBride

Studies of the latent reservoirs of HIV-1 Supervisors: David Cooper; Tony Kelleher; Kersten Koelsch

Skye McGregor

Capacity building for health research in developing countries

Supervisors: John Kaldor, Klara

Henderson

Hamish McManus

Evaluation of survival in HIV-positive patients

Supervisors: Kathy Petoumenos,

Matthew Law

Catalina Mendez

Understanding siRNA induced transcriptional silencing of HIV-1. Supervisors: Tony Kelleher, Kazuo Suzuki (St. Vincent's Hospital)

Brian Mulhall

Sexually transmitted infections (STI) in patients in the Australian HIV Observational Database

Supervisors: Matthew Law, Christopher Fairley (University of Melbourne).

Mee Ling Munier

The role of HIV-specific CD4+ T-cells at primary infection

Supervisors: Tony Kelleher; Bill Sewell (Garvan Institute); John Zaunders (St Vincent's Hospital)

Daniel Murray

The role of microRNAs in HIV-1 infection and pathogenesis

Supervisors: Tony Kelleher, Kazuo Suzuki

(St. Vincent's Hospital)

Lisa Natoli

Supervisor: Rebecca Guy

Chansavath Phetsouphanh Characterisation of CD4+ Antigen

specific T cells to HIV

Supervisors: Tony Kelleher, Nabila

Seddiki

Suzanne Polis

Adherence to hepatitis B antiviral therapies

Supervisors: Lisa Maher, Armany Zekry (St George Hospital)

Phillip Read

Clinical and epidemiological aspects of syphilis

Rebecca Guy, Basil Donovan,

Lucia Romani

Factors associated with scabies in a highly endemic population

Supervisors: John Kaldor, Andrew Steer (Murdoch Childrens Research Institute)

Karen Schneider

Economic evaluation of HIV monitoring Supervisors: David Wilson; Matthew

Law; Basil Donovan

Kirstine Sutherland Smith

Home-based sample collection to increase chlamydia retesting and detect reinfections following treatment.

Supervisor : Rebecca Guy

Sowbhagya Somanadhan Influence of civil society on HIV policies and services in India and the participation of people living with HIV/

AIDS

Supervisor: Lisa Maher

Dam Anh Tran

Accessibility to anti retroviral (ARV) treatment in Vietnam.

Supervisors: Lei Zhang, Anthony Shakeshaft (NDARC), David Wilson, Chris Doran (University of Newcastle)

Winnie Wing Yin Tong

Measurement of immune responses to clinically significant viral pathogens in immunocompromised adults Supervisors: Andrew Carr (St Vincent's

Hospital), Tony Kelleher

Lucy Alexandra Watchirs Smith

Supervisor: Bette Liu

Edward (Ned) Waters

The analysis, ecology and implications of HPV variants in HPV related cancers. Supervisors: David Regan; David Philp (SPHCM); Andrew Grulich; Anthony Smith

Chris Weatherall

Immunology of HIV infection

Supervisors: Tony Kelleher, David Cooper

Bethany White

Hepatitis C vaccine preparedness Supervisors: Lisa Maher, Greg Dore

Stephen Wright

Antiretroviral therapies and immunological outcomes in HIV-positive patients

Supervisors: Kathy Petoumenos,

Matthew Law

Yin Xu

Mechanisms for SIV entry into T

follicular helper cells

Supervisors: Tony Kelleher, John

Zaunders

MASTERS STUDENTS AT THE KIRBY INSTITUTE

Anna Charisse Farr

Evaluation of HIV in the Philippines

(Masters by Research) Supervisor: David Wilson

Belinda Hengel

What works? Improving Primary Health Care Centre access and STI amongst young people in remote Aboriginal and Torres Strait Islander communities in Australia

Supervisors: John Kaldor; Rebecca Guy;

Lisa Maher **Phillip Keen**

Late HIV diagnoses among gay and other men who have sex with men in Australia

between 2003–2012 Supervisor: Garrett Prestage

Rebecca Lorch

Role of the Practice Nurse in chlamydia testing in general practice

Supervisors: Rebecca Guy, Jane Hocking and Meredith Temple-Smith (both

University of Melbourne)

Tarana Lucky Masters by Research Using quantitative techniques to improve monitoring and evaluation of HIV epidemics in Australia

Supervisors: David Wilson, Handan Wand

Quang Duy Pham

Modelling HIV drug resistance in

Vietnam

Supervisors: Lei Zhang, David Wilson

Bronwyn Silver

Sexual and reproductive health of Aboriginal women in remote communities Supervisors: John Kaldor; Rebecca Guy; Alice Rumbold (Menzies School of Health Research)

James Ward

Sexual health and risk factors among young Aboriginal people

Supervisors: John Kaldor, Basil Donovan

SUPERVISION OF NON-KIRBY INSTITUTE STUDENTS

Leon Pierre Botes (The University of Sydney) PhD Candidate Validation of the acceptability and reliability of self collected anal swabs used for cytological screening, to detect anal squamous intra-epithelial lesions in HIV-positive men who have sex with men

Supervisor: Richard Hillman, Jeff Jin **Danielle Horyniak** (Monash University) Improving health and reducing harm among young people who inject drugs

Co-supervisor: Peter Higgs Robert Kemp (University of

Queensland)

Development of the Needle and Syringe

Program in Queensland Co-supervisor: Lisa Maher **Stephen Lambert** (University of

Queensland)

Chlamydia in the Australian Defence Forces Supervisors: Scott Kitchener (University of Queensland), Basil Donovan

Samantha McAllery (University of

Sydney)

Proteomics of True de novo HIV in the Context of Productive Infection Supervisor: Stuart Turville

Loay Othman (La Trobe University),

PhD Candidate

HIV and stigma in the United Arab

Emirates

Supervisor: Garrett Prestage

Tim Read (Melbourne University), PhD

Candidate

Sexually transmitted viruses in men

having sex with men

Supervisors: Christopher Fairley, Andrew

Grulich

Rachel Sacks-Davis (Monash

University)

Hepatitis C virus transmission and progression in cohorts of people who inject drugs

Supervisors: Margaret Hellard and Campbell Aitken (Burnet Institute);

Jason Grebely

Ivy Shih (University of Sydney)

Characterization of Human

Immunodeficiency Virus (HIV) spread between physiologically relevant cell

targets of the immune system

Supervisor: Stuart Turville, N Nasr

(University of Sydney)

Huachun Zou (University of

Melbourne), PhD Candidate

HPV infection in young men who have

sex with men

Supervisors: Marcus Chen (Melbourne),

Andrew Grulich

Karen Hawke (University of South

Australia)

Epidemiology of HIV resistance and

subtypes in South Australia Co-supervisor: John Kaldor

COLLABORATING ORGANISATIONS 2012

and Advocacy (CAHMA)

Communicable Diseases Network

NATIONAL

Association for Prevention and Harm Reduction Programs (ANEX), Melbourne Australasian Chapter of Sexual Health Medicine, Sydney Australasian Faculty of Public Health Medicine, Sydney Australasian Professional Society on Alcohol and other drugs (APSAD) Australasian Society for HIV Medicine, Sydney Australasian Society of Clinical

Immunology and Allergy (ASCIA) Primary Immunodeficiency Register,

Australia and New Zealand Cardiothoracic Transplant Registry, Sydney

Australia and New Zealand Dialysis and Transplant Registry (ANZDATA),

Australia and New Zealand Liver Transplant Registry, Brisbane Australian Agency for International Development (AusAID), Canberra Australian Centre for Hepatitis and HIV Virology Research (ACH2), UNSW, Sydney

Australian Centre for Perinatal Science (ACPS), Sydney

Australian Federation of AIDS Organisations, Sydney

Australian Gonococcal Surveillance

Program, Sydney

Australian Government Department of Health and Ageing, Canberra

Australian Injecting and Illicit Drug Users League (AIVL), Canberra

Australian Institute of Health and

Welfare, Canberra

Australian Liver Association, Sydney Australian Paediatric Surveillance Unit, Sydney

Australian Red Cross Blood Service, Sydney

Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne

Canberra Alliance for Harm Minimisation

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College of Psychiatrists

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Sydney

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Public Health Laboratory Network

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Therapeutic Goods Administration,

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Aboriginal Health and Medical Research Council of NSW Aboriginal Medical Service Western Sydney, Mount Druitt Village AIDS Council of NSW (ACON), Sydney, Lismore, Newcastle, Penrith, Port Macquarie and Wollongong AIDS Project Management Group Albion Street Centre, Sydney Albury Community Health Centre, Albury Armajun Aboriginal Health Service Incorporated, Inverell Bigge Park Medical Centre, Sydney Blacktown Needle and Syringe Program Services, Sydney Blue Mountains Sexual Health Clinic, Katoomba Burwood Road General Practice, Sydney Central Access Service, Sydney Central Coast Harm Reduction Service, Gosford, Long Jetty and Woy Woy Central Coast NSP Services, Gosford and Long Jetty Centre for Addiction Medicine, Westmead Hospital Centre for Health Informatics, UNSW Centre for Health Initiatives, University of Wollongong Centre for Health Protection, NSW Ministry of Health, Sydney Centre for Health Research in Criminal Justice, Justice Health, NSW Health Department, Sydney

Centre for Infection and Inflammation

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Palmerston Northern Territory Department of Health and Families

Western Diagnostic Pathology

QUEENSLAND

AIDS Medical Unit, North Quay Apunipima Cape York Health Council, BungalowBiala Alcohol and Drug Services, Brisbane Australasian Leukaemia and Lymphoma Group (AALG) Tissue Bank Biala Alcohol and Drug Treatment Services, Brisbane Brisbane Sexual Health & HIV Service (formerly AIDS Medical Unit, Queensland Health) Cairns Base Hospital Cairns Base Hospital NSP Services Cairns ATODS NSP Service Cairns Sexual Health Service (also known as the Dolls House Sexual Health Clinic 87, Sunshine Coast-Wide Bay Health Service District, Nambour Clinical Medical Virology Centre, University of Queensland Communicable Disease Unit, Queensland Health, Brisbane Gladstone Road Medical Centre, Brisbane Gold Coast Sexual Health Clinic, Miami Goondir Health Service, Dalby Kobi House, Toowoomba James Cook University, Cairns Princess Alexandra Hospital, Brisbane Princess Alexandra Sexual Health, South Brisbane Queensland Aboriginal and Islander Health Council, Brisbane Queensland Health, Brisbane Queensland Health Scientific Services, Coopers Plains Queensland Injectors Health Network (QuIHN), Brisbane, Gold Coast and Sunshine Coast Queensland Paediatric Infectious Diseases Laboratory, Queensland Children's Medical Research Institute

Queensland Positive People

Brisbane

Queensland University of Technology,

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School of Population Health, The
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Sexual Health & HIV Service, Brisbane
Spiritus Positive Directions
Townsville Aboriginal and Islanders
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Townsville ATODS NSP Service
Townsville Sexual Health Services
West Moreton Sexual Health Service,
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SOUTH AUSTRALIA

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TASMANIA

Anglicare NSP Services, Glenorchy and Hobart
Clarence Community Health Service,
Hobart
Department of Health and Human
Services Tasmania
Hobart, Devonport and Launceston
Sexual Health Service
Salvation Army Launceston
Tasmanian Council on AIDS, Hepatitis
and Related Diseases (TasCAHRD),
Hobart
Tasmanian Aboriginal Centre, Hobart

VICTORIA

Alfred Radiology, Melbourne Barwon Drug and Alcohol Services, Geelong Burnet Institute, Melbourne Centre for Population Health, Burnet Institute, Melbourne Centre for Women's Health, Gender and Society, Melbourne School of Population Health, University of Melbourne Darebin Community Health Centre, Northcote Deakin Health Economics Unit, Deakin University, Melbourne Deakin University, Melbourne Department of Health, Victoria Department of Microbiology and Immunology, The University of Melbourne, Melbourne Harm Reduction Victoria Health Informatics Unit, Rural Health Academic Centre, University of Melbourne Health Information Exchange, Salvation Army, Melbourne Health Works, Footscray Indigenous Eye Health Unit, School of Population Health, The University of Melbourne Inner Space, Melbourne La Trobe University, Melbourne Living Positive Victoria Melbourne Sexual Health Centre The Microbiological Diagnostic Unit, University of Melbourne Middle Park Clinic, Melbourne Monash Medical Centre, Melbourne Murdoch Childrens Research Institute, Melbourne National Reference Laboratory Nexpep, Victoria North Richmond Drug Safety Program, Melbourne Northside Clinic, Fitzroy North Nossal Institute Prahran Market Clinic, Melbourne Royal Melbourne Hospital, Melbourne Royal Women's Hospital, Melbourne

School of Population Health, The

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The Care and Prevention Program,

Adelaide University, Adelaide

University of Adelaide

Adelaide

University of Melbourne, Melbourne
Southern Hepatitis/HIV/AIDS Referral &
Prevention Service (SHARPS), Frankston
St Vincent's Hospital, Melbourne
The Alfred Hospital, Melbourne
The Centre Clinic, Melbourne
The University of Melbourne
Victorian Aboriginal Community
Controlled Health Organisation,
Melbourne
Victorian Aboriginal Health Service, Fitzroy
Victorian AIDS Council/Gay Men's
Health Centre (GMHC), Melbourne
Victorian Cervical Cytology Registry

Victorian Cytology Service Inc, Melbourne

Victorian Infectious Diseases Reference

WESTERN AUSTRALIA

Laboratory, Melbourne

Aboriginal Community Controlled Health Services, Western Australia Aboriginal Health Council of Western Australia, Perth Centre for Clinical Immunology and Biomedical Statistics, Perth Communicable Disease Control Branch, Department of Health, Perth Curtin University of Technology Data Linkage Western Australia, Perth Department of Health, Western Australia Department of Microbiology and Infectious Diseases, PathWest Laboratory Medicine, Royal Perth Hospital Derbarl Yerrigan Health Service, Perth Fremantle Hospital Fremantle Hospital Sexual Health Service Kimberley Aboriginal Medical Services Council, Broome M Clinic Murdoch University, Perth National Drug Research Institute, Curtin University of Technology Royal Perth Hospital, Perth Royal Perth Hospital Sexual Health Clinic Royal Perth Hospital, Department of Clinical Immunology Sexual Health and Blood Borne Virus Program, Department of Health, Perth University of Western Australia, Perth WA AIDS Council Mobile Exchange, Perth Western Australian AIDS Council (WAAC), Perth Western Australia Country Health

INTERNATIONAL

Service (WACHS), Perth

1 Military Hospital, Pretoria, South Africa Academic Medical Centre, University of Amsterdam, Amsterdam Africa Centre for Health and Population

Western Australian Substance Users Association (WASUA), Perth Studies, University of Kwzulu-Natal, South Africa

Agence Nationale de Sécurité du Médicament et des Produits de Santé, France

ANMAT, Argentina

Arkansas Children's Hospital Research Institute

ARUD (Arbeitsgemeinschaft für risikoarmen Umgang mit Drogen), Zurich, Switzerland

Asian Network of People Who Use Drugs (ANPUD)

Auckland University of Technology Avdeling Spesialiserte Ruspoliklinikker, Norway

Bach Mai Hospital, Hanoi, Vietnam Bamrasnaradura Hospital, Bangkok Barts and the London NHS Trust, London, UK

Beijing Ditan Hospital, Beijing

BFARM, Germany

Bill and Melinda Cates Foundation

Bill and Melinda Gates Foundation Bingham University Teaching Hospital, Jos, Nigeria

Brighton & Sussex University NHS Trust, Argentina

British Columbia Centre for Disease Control, Vancouver, Canada British Columbia Centre for Excellence in

HIV/AIDS, Vancouver, Canada Brown University, Providence, USA

CAICI, Rosario, Argentina CAICI, Rosario, Argentina

Calgary Regional Health Authority, Canada Cambodian Women's Development

Association (CWDA)
Canadian Aboriginal AIDS Network

CEADI, Buenos Aires, Argentina CEIN – Unidad Infectológica de Prevención, Diagnóstico y Tratamiento.

Neuquén, Argentina

Centers for Disease Control and

Prevention, USA

Centre for Infectious Disease Prevention and Control, Health Canada

Centre for Excellence in HIV/AIDS,

Vancouver, British Columbia, Canada; Centre for Research on Drugs and Health Behaviour, London School of Hygiene &

Tropical Medicine, UK

CETI, La Plata, Buenos Aires, Argentina Chaing Mai University, Chaing Mai, Thailand

Chelsea and Westminster Hospital, London

Chiang Rai Regional Hospital, Chiang Rai, Thailand

Children Hospital No. 1, Ho Chi Min City, Vietnam

Children Hospital No. 2, Ho Chi Min City, Vietnam

Chonburi Regional Hospital, Chonburi, Thailand

Chris Hani Baragwanath Hospital, Soweto, South Africa Chulalongkorn Hospital, Bangkok Cipto Mangunkusumo General Hospital, Jakarta

Clinica Alemana, Argentina

Clinique OPUS/LORI, Montreal, Canada Clinton HIV/AIDS Initiative

Columbia University, New York, USA Concept Center for Addiction Treatment, Munich, Germany

Concerted Action on Seroconversion to AIDS and Death in Europe (CASCADE) and its contributors, Coordinating Unit,

Copenhagen HIV Programme, Hvidovre University Hospital, Copenhagen Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore USA

Department of Statistical Science, University College, London, UK Desmond Tutu HIV Foundation, Cape Town, South Africa

Division of Infectious Diseases,

Department of Internal Medicine, Yonsei University College of Medicine, Seoul Duke Clinical Research Institute, Duke University, Durham, North Carolina, USA East Toronto Hepatitis C Program,

Toronto, Canada

ESPOO Treatment and Rehabilitation A-Clinic, Finland

Faculté Créteil Henri Mondor, Créteil, France

Faculty of Medicine, Udayana University and Sanglah Hospital, Denpasar, Bali, Indonesia

Family Health International (FH), Cambodia

FHI 360 Cambodia

Foundation for AIDS Research (amfAR), New York

Fundacion Arriaran, Santiago, Chile Fundacion Centro de Estudios Infectologicos (FUNCEI), Clinica La Sagrada Familia, Buenos Aires Fundacion IDEAA, Argentina Fundación IDEAA, Buenos Aires,

Argentina

Gemeinschaftspraxis Jessen, Berlin, Germany 3

German Cancer Research Center, Heidelberg

Goroka General Hospital, Goroka, Papua

New Guinea Hanoi School of Public Health, Vietnam

HART Consulting, Malaysia
Harvard University, Boston

Health Canada

Health Research Council of New Zealand HIV Netherlands, Australia, Thailand Research Collaboration (HIV-NAT), Thailand

Hôpital Pitié-Salpêtrière, Paris Hôpital Saint-Louis, Paris Hospital Almenara, Lima, Peru

Hospital de la Santa Creu i Sant Pau, Barcelona, Spain Hospital de la Universidad Catolica Pontifica, Santiago, Chile Hospital Dos de Mayo, Lima, Peru Hospital Dr Diego Paroissien, Argentina Hospital General de Agudos JM Ramos Mejia, Buenos Aires Hospital General de Agudos Teodoro Álvarez, Buenos Aires Hospital General de Guadelajara, Mexico Hospital General de Leon, Mexico Hospital General Universitario Gregorio Marañón (HGUGM), Spain Hospital Germans Trias i Pujol, Badalona, Spain Hospital Interzonal General de Agudos Dr. Diego Paroissien, Buenos Aires, Argentina Hospital Italiano de Buenos Aires, Buenos Aires, Argentina Hospital Kuala Lumpur, Malaysia Hospital La Paz, Madrid, Spain Hospital Likas, Kota Kinabalu, Malaysia Hospital Nacional Prof Dr Alejandro Posadas, Buenos Aires Hospital Paroissien, Buenos Aires, Argentina Hospital Principe de Asturias, Madrid, Spain Hospital Privado - Centro Médico de Córdoba, Argentina Hospital Pulau Pinang, Malaysia Hospital Raja Perempuan Zainab II, Kelantan, Malaysia Hospital Rawson, Bajada Pucara, Argentina HOSPITAL REGIONAL CARLOS HAYA DE MÁLAGA, Spain Hospital San Borja-Arriaran, Santiago, Chile Hospital Sungai Buloh, Kuala Lumpur Hospital Universitari i Politecnic La Fe, Spain ICH Study Center Hamburg Klinik für Immunologie und Rheumatologie, Medzinische Hochschule Hannover IMPACTA, Lima, Peru Imperial College, St Mary's Hospital, London Indonesia National AIDS Commission, Indonesia Indonesian Ministry of Health, Indonesia Infections and Immunity, Avenir Group, Hôpital Pitié Salpêtrière, Université Pierre et Marie Curie-Paris, France Institut für Virologie, der Universität zu Köln, Cologne, Germany Institute of Human Virology Nigeria (IHVN), Abuja, Nigeria Institute of Infectious Disease, Pune, India Institute of Social and Preventative ANNUAL REPORT 2012

Hospital Central, Mendoza, Argentina

Hospital Clínic de Barcelona, Spain

Hospital CLínico Universitario de

Valencia, Spain

Medicine, University of Bern, Switzerland Instituto de Enfermedades Tropicales Alexander von Humboldt Baumgarten, MIB medical center for infectious diseases Instituto de Medicina Tropical Alexander von Humboldt, Lima, Peru Instituto Nacional de Ciencias Médicas y Nutricion Salvador Zubrián, Mexico City Integrated Treatment Centre, Hong Kong International AIDS Society, Geneva International Consortium of Investigators Working on Non-Hodgkin's Lymphoma Epidemiologic Studies (InterLymph) Irish Medicines Board Johann Wolfgang Goethe-University Hospital, Medical HIVCENTER Johns Hopkins University, Baltimore Jos University Teaching Hospital, Jos, Nigeria JOSHA Research, Bloemfontein, South Africa JW Goethe Universität, Frankfurt Khon Kaen Hospital, Khon Kaen, Thailand Khon Kaen University, Khon Kaen, Thailand Klinikum der Universitat Zu Koln Koda Bern/Poliklinik Fur Infektiologe, Bern Switzerland Kumamoto University, Japan La Agencia Española de Medicamentos y Productos Sanitarios, Spain Mai Hoa Do Consulting, Vietnam Malaysian AIDS Council, Malaysia Malaysian Ministry of Health, Malaysia Malaysia National Anti-Drug Agency, Malaysia Malaysian Prison Department, Malaysia Massachusetts General Hospital, Boston Mater Misericordiae University Hospital, Medical Group Practice, Berlin 3 Medical Research Council, Durban, South Africa Medical Research Council Clinical Trials Unit, London MHRA, UK Ministry of Health and Population, Nepal Ministry of Health Japan Ministry of Health, Chile Ministry of Health, Mexico Ministry of Public Health, Bangkok Mt Hagen General Hospital, Mt Hagen, Papua New Guinea Nagoya Medical Centre, Nagoya, Japan Nantong University, China National Cancer Institute, National Institutes of Health, Bethesda, USA

Institutes, New York National Epidemiology Center, Department of Health, Philippines National Harm Reduction Association, Nepal National Hospital for Tropical Diseases, Hanoi, Vietnam National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, USA National Institute of Hygiene and Epidemiology (NIHE), Vietnam National Institute on Drug Abuse, National Institutes of Health, Bethesda, **USA** National Institute of Public Health, Cambodia National Taiwan University Hospital, Taipei Ngã Pae o te Mãramatanga, University of Auckland Nottingham University Hospitals NHS Trust, Nottingham, UK NRL, Fitzroy, Victoria, Australia; Orleans hospital (CHR Orleans La Source), Orleans, France Oslo University Hospital, Oslo, Norway P.H. Diagnostic Centre, Pune, India Papua New Guinea Institute for Medical Research (PNGIMR), Goroka, Papua New Guinea Papua New Guinea National AIDS Council (NAC), Port Moresby, Papua New Papua New Guinea National Department of Health (NDoH), Port Moresby, Papua New Guinea Pacific Adventist University (PAU), Port Moresby, Papua New Guinea Port Moresby General Hospital, Port Moresby, Papua New Guinea Papua New Guinea Institute for Medical Research, Goroka, Papua New Guinea Partners AIDS Research Center, Boston Pasteur Institute, France Philippines National AIDS Council Plateau State Specialist Hospital, Jos, Nigeria Praxiszentrum Im Tal (PIT), Ludwig-Maximilians-Univesitat, Munich, Germany Providence Health Care, Vancouver Public Health Service (GGD), Amsterdam, the Netherlands Queen Elizabeth Hospital, Hong Kong Ragon Institute of MGH, MIT and Harvard, Boston, USA Ramathibodi Hospital, Mahidol University, Bangkok Rambam Medical Centre, Haifa, Israel Research Institute for Health Science, Chiang Mai, Thailand Royal Malaysian Police, Malaysia Sanglah Hospital, Bali, Indonesia Sanpatong Hospital, Chiang Mai, Thailand School of Public Health, University of Minnesota, USA

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National Center for Global Health and

Medicine, Tokyo, Japan

and Prevention, China

Phnom Penh

National Center for HIV/AIDS,

Dermatology and STDs (NCHADS),

National Center for AIDS/STD Control

National Development and Research

Siriraj Hospital, Bangkok South Riverdale Community Health Centre, Toronto, Canada Srinagarind Hospital, Khon Kaen, Thailand St Luc Hospital, Centre Hospitalier de l'Universite de Montreal (CHUM), St. Thomas's Hospital, London, UK Tan Tock Seng Hospital, Singapore Tel Aviv Sourasky Medical Centre, Israel Thai Ministry of Health, Thailand Thai Ministry of Public Health/US Centre for Disease Control & Prevention Collaboration (TUC) Bangkok Thai Red Cross Society, Thailand The United Nations Children's Fund (UNICEF), New York, USA Toronto General Research Institute. Toronto, Canada TREAT Asia. American Foundation for AIDS Research (amFAR), Bangkok, Thailand Tsinghua University Uduyana University, Sanglah Hospital, Bali UNAIDS, Geneva UNAIDS, Vietnam Universitas Gadjah Mada, Yogyakarta, Indonesia Universitätsklinikum Düsseldorf, Klinik für Gastroenterologie, Hepatologie und Infektiologie-MX- Amb Université Laval, Quebec, Canada University of Amsterdam and Infectious Disease Cluster, Amsterdam Public Health Service University of Bonn, Bonn, Germany University of Bristol, UK University of British Columbia University of California, San Diego University of California, San Francisco University of Health Sciences, Phnom Penh, Cambodia University of Indonesia, Indonesia University of Malaya, Malaysia University of Malaya Medical Centre,

Kuala Lumpur

Canada

USAID, USA

Vietnam

University of Maryland, Baltimore, USA University of Minnesota, Minneapolis, USA University of Missouri, St Louis, USA University of Montreal, Canada University of Otago Medical School,

University of Papua New Guinea (UPNG), Port Moresby, Papua New Guinea University of Toronto, Canada Urban Health Research Initiative, Vancouver, British Columbia, Canada

US Centres for Disease Control (CDC),

Virgen del Rocio University Hospital, Spain

Vaccine and Gene Therapy Institute (VGTI) Port St. Lucie, Florida, USA

VIA LIBRE, Lima, Peru

University of Ottawa, Canada University of Oxford, UK Waikato Hospital, Hamilton NZ Wellington Hospital, Wellington NZ Western General Hospital, Edinburgh Wojewodzki Szpital Zakazny, Warsaw, Poland The World Bank The World Health Organisation, Geneva The World Health Organization, Manila, Philippines Viet Nam Administration of HIV/AIDS Control, Vietnam Yale University, USA Yonsei University, Seoul, Korea YRG Centre for AIDS Research and Education, Chennai, India Zentrum für Suchtmedizin ZfS, Basel, Switzerland Ziekenhuis Oost Limburg, Genk, Belgium

PHARMACEUTICAL AND BIOMEDICAL INDUSTRY

ZNA Stuivenberg, Antwerp, Belguim

Abbott Australasia Pty Ltd, Sydney
Boehringer Ingelheim Pty Ltd, Sydney
Bristol-Myers Squibb Pharmaceuticals,
Melbourne
Calimmune, USA
CSL Limited, Melbourne
Gilead Sciences, Foster City, California
GlaxoSmithKline Australia, Melbourne
Janssen-Cilag Pty Ltd, Sydney
Matrix Laboratories, Hyderabad, India
Merck Sharp and Dohme, Sydney
Roche Pharmaceuticals
Roche Products Pty Ltd, Sydney
SpeeDX Pty Ltd, Sydney
ViiV Healthcare, Sydney



NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL (NHMRC) PROGRAM GRANTS HIV & HCV vaccines and immunopathogenesis Sexually transmitted infections - causes, consequences and interventions Building research capacity for health interventions to improve Aboriginal health (subcontract from University of Sydney)	AUD\$ 1,979,206 1,177,856 14,188
PROJECT GRANTS A population-based record linkage study of the impact of chlamydia infection on reproductive health in women A randomised controlled trial to evaluate the effectiveness and cost-effectiveness of chlamydia testing in general practice A randomised trial of rapid point-of-care tests for chlamydia and gonorrhoea infections in remote aboriginal communities A randomised trial to control sexually transmitted infections in remote Aboriginal communities A randomised trial to determine the safety and efficacy of early vs deferred treatment of HIV Evaluation of naturally occurring resistance to Direct Acting Antiviral Drugs (DAAs) in individuals with acute hepatitis C infection HCV incidence cohort: 10 year mortality study Hepatitis C, prisons and treatment opportunities Hepatitis C vaccine preparedness study HIV assembly, transport, egress and transfer from infected dendritic cells Modelling and economic evaluation of hepatitis C epidemic mitigation strategies in Australia Modelling the interaction between sexually transmitted infections and HIV transmission to inform public health policy Neisseria gonorrhoeae antimicrobial resistance, detection and propagation Social norms regarding HIV/STI risk and risk reduction behaviours among men who have sex with men in Australia Viral load, HIV treatment and HIV transmission in serodiscordant male homosexual couples	165,181 20,252 465,913 237,994 206,790 13,518 27,500 209,599 233,354 86,759 157,714 194,766 34,363 182,660 395,740
PARTNERSHIP GRANTS Evaluation of a model for assessment and treatment of hepatitis C virus among injecting drug users in the opiate pharmacotherapy setting (ETHOS)	253,941
CAPACITY BUILDING GRANTS From Broome to Berrima: Building Australia-wide research capacity in Indigenous offender health and health care delivery	442,798
CENTRES OF CLINICAL RESEARCH EXCELLENCE Aboriginal Health: Blood borne viral and sexually transmitted infections	142,653
EQUIPMENT GRANTS Upgrade from BDFACSAria 1 to BDFACSAria II	80,000
FELLOWSHIPS Prof. Basil Donovan (Practitioner Fellowship) Prof. Greg Dore (Practitioner Fellowship) Dr Jason Grebely (Career Development Fellowship) Prof. Andrew Grulich (Principal Research Fellowship) A/Prof. Rebecca Guy (Postdoctoral Training Fellowship) Dr Peter Higgs (Postdoctoral Training Fellowship) Dr Fengyi Jin (Postdoctoral Training Fellowship) Prof. John Kaldor (Senior Principal Research Fellowship) Prof. Anthony Kelleher (Practitioner Fellowship) Dr Bette Liu (Postdoctoral Training Fellowship) Prof. Lisa Maher (Senior Research Fellowship) Dr Anna Olsen (Postdoctoral Training Fellowship) Dr Mary Poynten (Postdoctoral Training Fellowship) Dr David Templeton (Postdoctoral Training Fellowship) Dr Andrew Vallely (Postdoctoral Training Fellowship)	106,526 106,526 99,431 142,949 36,240 93,834 93,521 161,674 106,526 82,833 118,157 75,068 71,654 36,457 82,391

POSTGRADUATE SCHOLARSHIPS Maryam Salehi Alavi Paul Clark Damian Conway Denise Hsu Tina Iemma Bethany White	58,928 55,576 12,750 73,865 25,979 13,525
ALISTRALIANI DESEADELL COLINCIL (ADC)	
AUSTRALIAN RESEARCH COUNCIL (ARC) DISCOVERY PROJECTS	
Understanding spatial trends in HIV/AIDS infections in South Africa and Australia	75,370
LINKAGE PROJECTS In vivo molecular imaging using engineered affinity reagents and fluorescent laser scanning confocal endomicroscopy Sexual health and relationships in young Indigenous people	95,634 194,988
FUTURE FELLOWSHIPS	216 620
Prof. Tony Butler A/Prof. David Wilson	216,630 188,508
AUSTRALIAN GOVERNMENT FEDERAL DEPARTMENT OF HEALTH AND AGEING Research activities for blood borne virus and sexually transmissible infections Establishment and maintenance of a trachoma surveillance and reporting unit	7,002,861 214,224
Evaluation of chlamydia pilot in general practice (subcontract with University of Melbourne)	104,065
NSW OFFICE OF MEDICAL RESEARCH Institute of Virology infrastructure funding	2,843,194
NSW MINISTRY OF HEALTH The eTEST project: An initiative to enhance STI testing in gay men	56,339
Evaluation of a model for assessment and treatment of hepatitis C virus amonginjecting drug users in the opiate pharmacotherapy setting (ETHOS)	200,000
Mapping of the community networks and groups among men who has sex with men in NSW (The Mapping Study) NCHECR HIV surveillance and epidemiology support	10,000 125,000
NPA-IECD Aboriginal sexual/reproductive health project NPA-IH Aboriginal hepatitis C project	187,846 41,238
NSW Aboriginal sexual health and BBV research study (SHIMMER) NSW needle and syringe program enhanced data collection	112,550 121,000
Reducing impulsive behaviour in repeat violent offenders using a selective serotonin reuptake inhibitor Sexual health and relationships in young Indigenous People	297,637 20,500
OTHER STATE DEPARTMENTS	
Australia-Canada-India Chlamydia Research Alliance (Queensland Department of Employment, Economic Development and Innovation) HIV seroconversion and PASH studies (Victoria Health)	35,000 150,000
Sexual health and relationships in young Indigenous people (ACT Health) Sexual health and relationships in young Indigenous people (Queensland Health)	2,000 50,000
Sexual health and relationships in young Indigenous people (Queensiand Health) Sexual health and relationships in young Indigenous people (Tasmania Health & Human Services) Sexual health and relationships in young Indigenous people (Victoria Health)	3,000 31,000
Sexual health and relationships in young Indigenous people (Victoria Health) Sexual health and relationships in young Indigenous people (Western Australia Health) Study of risk and HIV among men who have sex with men in Western Australia (Western Australia Health)	3,000 3,000 15,390
	10,070

NATIONAL INSTITUTES OF HEALTH, USA Asia Pacific HIV research collaboration: cancer studies (subcontract with American Foundation for AIDS Research) Asia Pacific HIV research collaboration: tuberculosis studies (subcontract with American Foundation for AIDS Research) Eco-pathogenomics of chlamydial reproductive tract infection (subcontract with University of Maryland) International collaborative of prospective studies of HIV and Hepatitis in IDU (subcontract with University of California) INSIGHT - Leadership (subcontract with University of Minnesota) INSIGHT - FLU 002 & FLU 003 (subcontract with University of Minnesota) STALWART study (subcontract with University of Minnesota) START study (subcontract with University of Minnesota) TREAT Asia HIV Observational Database (subcontract with American Foundation for AIDS Research) TREAT Asia studies to evaluate resistance (TASER) (subcontract with American Foundation for AIDS Research) Treatment of recently acquired hepatitis C virus infection (ATAHC 2)	20,725 38,538 29,534 29,036 308,190 299,805 8,843 854,821 248,251 185,500 54,715 350,252
OTHER GRANTS AND CONTRACTS AUSTRALIAN A prospective cohort study of hepatitis C treatment delivery in primary care settings (Australian Society for HIV Medicine) Epidemiology, prevention and management of liver cancer in NSW: towards a strategic partnership (Cancer Council NSW/University of Sydney) Evaluation of improving sexual health in Aboriginal and Torres Strait Islander youth demonstration projects (Australian Institute of Health and Welfare) Identifying predisposing factors for, and the consequences of, common and emerging infectious diseases in a large prospective cohort study of adults (Ramaciotti Foundation) In vivo molecular imaging using engineered affinity reagents and fluorescent laser scanning confocal endomicroscopy (Medlmmune Limited) Inhibition of Dynamin ii (dynii) as a HIV therapeutic and microbicide strategy (Australian Centre for HIV and Hepatitis Virology Research) Monitoring transfusion transmissible infections among blood donors (Australian Red Cross Society) Papua New Guinea-Australia HIV & AIDS program (AusAID/JTA International Pty Ltd) Qualitative longitudinal study to investigate masculinity sexuality and agency among male youth in PNG (AusAID/JTA International Pty Ltd) Support for clinical and epidemiological HIV research capacity in Indonesia (AusAID/Australian Society for HIV Medicine)	34,235 50,000 13,018 74,688 94,268 122,733 23,376 9,750 127,050 484,032
INTERNATIONAL A randomised open-label study of second-line combination ART (American Foundation for AIDS Research, USA) ENCORE: Evaluation of novel concepts in optimization of antiretroviral efficacy (Bill and Melinda Gates Foundation, USA) Evaluation of HIV epidemics and programs in Asia (World Bank, USA)	100,939 3,106,310 286,651
PHARMACEUTICAL INDUSTRY Abbott Australasia Pty Ltd CSL Limited Gilead Science Pty Ltd Janssen-Cilag Pty Ltd Merck Sharp & Dohme Tibotec Pharmaceuticals Ltd via Quintiles Pty Ltd	140,000 47,415 6,690 18,255 573,786 10,420 28,525,952

PUBLICATIONS 2012

PEER-REVIEWED

A

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C.....

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E-PUBLICATIONS

These publications have appeared electronically in 2012 in advance of their appearance in print. Publications which have appeared in online-only journals are listed above.

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ABOUT THE KIRBY INSTITUTE

The Kirby Institute was launched on 4 April 2011. It was formerly known as the National Centre in HIV Epidemiology and Clinical Research (NCHECR), which was established in 1986 by the Australian Government to fulfil a number of key roles in Australia's fight against HIV/AIDS. The Kirby Institute is affiliated with the Faculty of Medicine, University of New South Wales.

The Kirby Institute's primary functions relate to the co-ordination of national surveillance programs, clinical research and clinical trials. While its original focus was exclusively on HIV/AIDS, the Kirby Institute's work has expanded to encompass hepatitis B and C, and sexually transmissible infections. The Kirby Institute also conducts research into the transmission, prevention and natural history of these infections.

The Kirby Institute's research program has increasingly taken on a regional focus, with major collaborative programs in Thailand and Cambodia. The Kirby Institute conducts research through eleven programs. Dissemination of the Kirby Institute's research output is undertaken through publication in scientific journals and a range of surveillance reports.

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