# KIRBY INSTITUTE
# Annual Report 2016

Kirby Institute

UNSW SYDNEY

Kirby Institute

**The Kirby Institute**
is a leading global research institute dedicated to the prevention, treatment and cure of infectious diseases.


4 Message from our Director
6 Message from our Patron
8 Kirby at a glance
10 **Our Research**
12 Mass drug administration trials shifting the spotlight on scabies
14 An epic end to HIV transmission in NSW
16 Delivering a cure for HIV
18 Optimising HIV treatment when first-line therapy fails
20 Elimination is the goal for hep C in Australia
22 Improving STI treatment in remote Aboriginal communities
24 Research highlights
36 **Our People**
38 We are Kirby
44 2016 Memorable moments
50 2016 Funding


Ms Kate Whitford, Dr Muhammad Jamil, Dr Hamish McManus and Dr Laila Khawar from the Surveillance Evaluation and Research Program.

# SCIENTIA PROFESSOR DAVID A COOPER AO

## Message from our Director

In 2016, the Kirby Institute celebrated our 30th anniversary year. Together with our colleagues, collaborators and supporters, we commemorated three decades of outstanding research achievements and the partnerships that have made our work possible.

Our beginnings stemmed from the explosion of HIV into our health system. We quickly expanded into our second major area of research interest, viral hepatitis, and many exciting advances have also taken place in that field.

Over 30 years we have also built substantial expertise in epidemiology and surveillance, biostatistical analysis, sexual health, Indigenous health, justice health, and a world-class laboratory program of immunology and virology. We have developed clinical trial expertise as sophisticated as anywhere in the world, and export our knowledge, training and experience throughout the Asia Pacific region. We have now had a presence in Thailand, Cambodia, Myanmar and Vietnam, and closer to home in Papua New Guinea, Indonesia and the Pacific Islands, a presence which should serve us well in the face of emerging regional health threats. So the enormous social and financial investment which brought about the advances in HIV treatment has been hugely beneficial to a much wider field.

So what lies ahead for the next thirty years?

In March 2016, the Australian Pharmaceutical Benefits Scheme listed new oral highly curative direct-acting antiviral treatments for hepatitis C. Since that time, Australia has achieved one of the most rapid uptakes of treatment worldwide and is now presented with a unique opportunity to eliminate a major infectious disease, potentially the first opportunity through treatment intervention. Our team has led the way in informing international treatment guidelines and continues to provide evidence to support the availability of treatment without restrictions based on drug or alcohol use.

In the lab, we are refining our understanding of how HIV continues to hide away in the body's reservoirs and remains out of reach of a cure. In the same way that we chipped away throughout the early years at these questions, we are also digging for the secrets that might eventually allow us to achieve HIV eradication.

There are many more exciting projects happening at home in Australia and around the world. I invite you to read in this publication about some of the challenges we are addressing and the global impact our research is having.

We continue to ask how our achievements to date can translate to inform or influence health conditions of the future. Because, inevitably, as with recent epidemics such as avian flu and swine flu, SARS and Ebola, we know that there are more to come. We need to look ahead and accept that in these days of immense international connectedness, the global community as a whole is vulnerable.

Epidemics will always emerge first in the vulnerable populations, the poor, the socially excluded, those with food insecurity, or crowded housing, or chronically unemployed. These are the people who need our help and our foresight as to where the next threat is coming from.

We have been fortunate to have formed effective collaborations with many people and groups in Australia and internationally including people living with HIV, bodies representing the sex work industry, people who inject drugs and other affected groups. These partnerships have led directly to some of the most important early research outcomes and continue to be integral to the success of our research. We also continue to rely strongly on our friends and donors to keep our work moving forward. As science and medicine become more sophisticated and more complex, they also of course become more expensive, and we are grateful for all the help we receive.

We are on the precipice of major breakthroughs in our quest to end HIV, hepatitis C and other infectious diseases. But now is not the time to stand still. There is more to do. Lasting change requires unwavering determination to completely reshape existing boundaries. It's a challenge that energises us every day.

David Cooper

# THE HON. MICHAEL KIRBY AC CMG

## Message from our Patron

The year 2016 has been an exciting and productive one for the Kirby Institute.

It celebrated 30 years of excellence in scientific research, healthcare development, community engagement and dedicated service and inventiveness.

Among the stand-out events of the last year was an anniversary dinner at which serious speeches competed with magnificent artistic performances and ironic humour, glitzy showmanship and moments of sadness as participants remembered the bitter days that gave birth to urgent global scientific breakthroughs on blood-borne diseases. The devoted endeavours of the research, administrative and support staff of the Institute were praised. Future achievements were foreshadowed. The strong, imaginative and steady leadership of David Cooper and his team was loudly honoured.

The year also saw the arrival of vitally necessary funds. The Kirby Institute continues to be successful in securing important project funding through the National Health and Medical Research Council of Australia. Such grants, gained against stern competition, acknowledged the Kirby Institute's place as a world leading centre for infectious diseases. As progress has been made in tackling HIV, the new funding will contribute attention to fresh and additional targets. These include the mighty coming challenges of sexually transmissible infections, hepatitis C and neglected tropical diseases, together with new issues in women's reproductive health and health within the justice system that demand fresh and energetic attention within the Institute.

A magnificent grant from Unitaid of AUD$12 million will support the clinical trial of HIV positive patients, already under treatment, where standard therapies have failed. The figures of failure are higher than many observers anticipated—between 10–15 per cent of all who start the standard antiretroviral therapy. The question of how best to shift to " second-line" and other treatments presents a great challenge in the ongoing global struggle against HIV.

In the past year, I have myself been busy with the work of the High Level Panel (HLP) established by the retiring Secretary-General of the United Nations, Ban Ki-moon. This panel was set up by him courageously in 2015 to tackle impediments that stand in the way of the access by people everywhere to essential health technologies. Establishment of the HLP was courageous because, inevitably, its work and recommendations attracted fierce opposition from some industries and also a few countries which look at the problem from an exclusively economic standpoint. Yet beyond the economics is the universal human right of access to essential healthcare. That right has now been acknowledged and embedded in the Sustainable Development Goals (SDGs), Goal 3. The SDGs were endorsed by the General Assembly of the United Nations in September 2015. They set out the objectives of the United Nations for the next 15 years, so far as development and fundamental rights are concerned. Unless we have such goals, we risk adopting uncoordinated activities that diminish our chances of success. Most human beings would accept the centrality of access to life-saving and health-restoring medicines and technologies for everyone with essential needs for them. Through its research and many engagements in the struggle, the Kirby Institute proudly contributes to make the SDGs a reality for our world.

I applaud and admire the outreach of the Kirby Institute, especially to leaders in Australia's region of the world: particularly those from Indonesia, Cambodia, Papua New Guinea, Myanmar, Fiji and Solomon Islands. Working together we can achieve much more than would be the case, working separately.

A fresh partnership aims to eliminate hepatitis C in Australia with the aid of new drugs. I am particularly proud to record the exciting collaboration between the Kirby Institute and the Burnet Institute. Years ago, I knew Sir Macfarlane Burnet, Nobel Laureate. How proud I am that the Institute that bears his name is now working closely with the Kirby Institute that bears my name, to achieve hepatitis C elimination.

Clearly, the Kirby Institute is an outstanding example of the best there is in Australian science and research working cooperatively with civil society, patients, individuals and medical practice to defend and guard our people. And to help attain the SDGs adopted by the United Nations.

To David Cooper and all the heroes who work at the Kirby Institute, I offer praise, encouragement and a message of admiration.

# KIRBY AT A GLANCE

**The Kirby Institute is a leading global research institute dedicated to the prevention, treatment and cure of infectious diseases.**

We were established in 1986 in response to the then emerging HIV epidemic. We now contribute to knowledge on a broad range of diseases, including viral hepatitis and sexually transmissible infections.

Our primary work relates to the coordination of national surveillance programs, population health and epidemiological research, clinical and behavioural research and clinical trials. Our research projects are conducted in partnership with communities most affected by epidemics. Together we implement trials of behavioural and biomedical interventions designed to prevent the spread of infectious diseases in vulnerable populations.

Our work in the laboratory is focused on finding ways to control infections, develop new therapies and ultimately towards the development of preventative vaccines. Outside of the laboratory, we provide critical leadership to decision makers in Australia and internationally on the most effective, efficient and sustainable strategies to address deadly epidemics.

Our research has increasingly taken on a regional focus. Over the past two decades, we have developed collaborative programs in several countries that have involved training health workers and health researchers in the Asia Pacific region, advising governments on public health and clinical policy, informing international treatment guidelines and working to increase access to essential medicines. We have particularly strong partnerships in Thailand, Papua New Guinea, Indonesia, Cambodia, Myanmar, Fiji and the Solomon Islands.

Our world-class team comprises over 250 public health, clinical and laboratory scientists, research assistants and postgraduate students.

**381**
peer reviewed publications in 2016

More than
**650**
collaborations in over 40 countries on 6 continents

More than
**200**
staff

More than
**50**
students

**16**
PhD graduations

**20**
international students studying their PhD

**3** NHMRC program grants

**11** NHMRC project grants

**5** NHMRC partnership grants

**3** ARC discovery projects

**20** NHMRC Fellowships

**$29,770,289**
funding from grants in 2016

**$2,066,047**
in donor funding in 2016

# OUR RESEARCH

**The Kirby Institute conducts leading edge research, working closely with vulnerable populations to address public health issues and improve outcomes now and into the future.**

Ms Katherine Ognenovska, Ms Christina Fichter and Ms Vera Klemm from the Immunovirology and Pathogenesis Program

Chief Investigator Dr Lucia Romani

# MASS DRUG ADMINISTRATION TRIALS SHIFTING THE SPOTLIGHT ON SCABIES

When Dr Lucia Romani commenced her first scabies project as a Masters student at the Kirby Institute in 2007, she did not expect it to lead to what has become one of the world's most ground-breaking findings on the management of the neglected yet prolific infectious disease.

Scabies is a parasitic infestation that is estimated to affect over 200 million people worldwide each year. It causes extreme itching and discomfort, and if left untreated, can lead to secondary bacterial infections of the skin that in turn can cause serious complications including severe skin and soft tissue infections, bloodstream infection and kidney and rheumatic heart disease.

The results of Dr Romani's very first project, a national prevalence survey of scabies and impetigo in Fiji, indicated that scabies affects one in five people, and one in two children. It was these shocking figures that compelled her to undertake her PhD in the field and contribute to managing the infestation that affects predominantly disadvantaged populations.

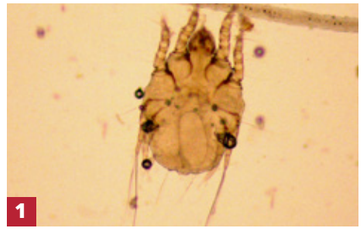
It was here that the Skin Health Intervention: Fiji Trial, or SHIFT, was born. "We received project grant funding by NHMRC for a comparative trial to look at mass drug administration (MDA) strategies to control scabies in Fiji, comparing oral ivermectin MDA, topical permethrin MDA, and standard care of treating symptomatic cases and their contacts," explains Dr Romani. SHIFT involved each of the three treatments being administered to a different island community, and the results were impressive.

After one year of the comparison treatment, the prevalence of scabies declined in all groups, but by far the most dramatic reduction was in the ivermectin group with a fall in prevalence of 94 per cent. In the permethrin group prevalence declined by 62 per cent, and in the standard-care group by 49 per cent.

With SHIFT having been successfully conducted on a relatively small sample (2,051 people), and the ivermectin MDA proving such a widespread success, the Azithromycin Ivermectin Mass drug administration (AIM) trial was developed to ascertain whether this treatment could be applied on a much larger scale.

In 2015 and 2016, AIM was rolled out in the province of Choiseul in the Solomon Islands on a population of over 26,000, and not only looked at the treatment of scabies using the oral ivermectin MDA, but also investigated whether ivermectin could be administered in conjunction with treatment for trachoma, an eye condition that is also endemic in these communities. "The novelty of this trial was not only that it was the largest MDA of scabies ever conducted, but also that we integrated scabies MDA with trachoma MDA, so co-administration of ivermectin and azithromycin," says Dr Romani. "The results were as astonishing and very comparable to those of SHIFT".

SHIFT and AIM will potentially revolutionise the way in which neglected but treatable tropical diseases such as scabies and trachoma are managed in the future. The success of these trials has certainly raised the profile of scabies in particular, with the results of SHIFT being published in the *2015 New England Journal of Medicine*, placing it on the global health agenda. But at the core of this success are the individuals whose lives have been changed by the treatment, and it is this aspect which keeps Dr Romani so dedicated to her work. "I visited those communities seven times over two years; I lived in their huts, was fed their food and was very much part of their day to day life for some time", says Dr Romani, reflecting on her SHIFT field work. "It was humbling to see how communities were so involved in the project because they trusted our team and the work we were proposing. Seeing kids and parents coming to me after a year to show me how their skin had no scars or scabies lesions anymore was invaluable and reminded me of why I fell in love with this job".



**1.** Close up of the mite Sarcoptes scabiei. By laboratorio diagnostica ancona IZSUM (CC BY 2.0) bit.ly/2jNS08p.

**2.** Dr Romani inspecting a child's hands for scabies and impetigo in Choiseul, Solomon Islands.


Professor Andrew Grulich, Kirby Institute and Karen Price, ACON

# AN EPIC END TO HIV TRANSMISSION IN NSW

When Professor Andrew Grulich began working in HIV/AIDS in 1995 as a young, gay doctor desperate to help his community, he could not have imagined that he would one day oversee a research project with the aim of the virtual elimination of HIV transmission in NSW.

“1995 was the peak year of deaths from AIDS in NSW. My desk was at a window overlooking Victoria Street, just a block north of St Vincent’s, and I would often see sick young men walking down Victoria Street, headed for the Emergency Room. It was a bleak time with very few answers,” Professor Grulich recalls.

But now, 21 years later, no one has to die from HIV infection, and Professor Grulich’s latest research is setting the groundwork for the virtual elimination of HIV transmission in Australia. “Virtual elimination means they are unable to transmit the virus to their partners. It means at least an 80 per cent reduction in new HIV infections acquired in Australia,” says Professor Grulich.

In Australia, we are in a position to talk about HIV elimination thanks to decades of dedicated research, policy and community action. But the latest piece in the puzzle has been the development of pre-exposure prophylaxis, or PrEP. PrEP is a pill that can be taken by HIV negative people and, if taken as prescribed, is almost 100 per cent effective in stopping the transmission of HIV. The pill is a daily dose of the medication currently being used as a component of standard HIV treatment in Australia, and it works by stopping the virus from being able to replicate in an HIV negative person who comes into contact with HIV.

On World AIDS Day in 2015, the Kirby Institute announced a world-first trial of PrEP among high risk gay men called Expanded PrEP Implementation in Communities, or the EPIC-NSW trial. Professor Andrew Grulich is leading the trial, along with the Kirby Institute’s Director Professor David Cooper, and working closely with policy and community sectors. “This trial holds the potential to change the face of HIV transmission forever. We are already seeing early results of reduced transmissions in NSW,” says Professor Grulich.

The EPIC-NSW trial enrols people who are HIV negative at high risk of acquiring HIV, who in Australia are predominantly gay and bisexual men. The aim is to prevent HIV transmission not only among people enrolled in the trial, but also, through herd immunity, to all high-risk individuals in the population.

“There were three important targets we needed to reach in the initial rollout of this trial. We needed to sign up the large majority of people at high risk of HIV, we needed to do it quickly, and we needed to ensure we were targeting the right people for enrolment. With the help of the extraordinary health promotion work of ACON, we enrolled 1,000 people in the first month of the trial. By late 2016, we’d hit our enrolment target, and we’re still accepting more people. We could not be in a better position to achieve our objective of virtual HIV elimination in NSW.”

EPIC-NSW is funded by NSW Health and is conducted in close collaboration with ACON and more than 20 public and private health clinics across the state, which Professor Grulich believes will be central to the success of EPIC-NSW. “That fact we can talk about the virtual elimination of HIV in NSW is a direct result of the strength of our partnerships in this area,” said Professor Grulich. “We are eternally grateful for the leadership of the NSW Minister for Health Jillian Skinner, who has long championed evidence-based public health policy for HIV prevention in NSW.”

Professor Grulich has witnessed the transformation of HIV from a deadly virus to what is now a chronic manageable illness. “And the next step is elimination. We have a long way to go, but when you witness how far we’ve come in just over 30 years, there’s good reason to be optimistic. It has been an incredible privilege to participate in successful research that is having real-world impacts, which are unfolding before me.”

*"We're turning the virus against itself. We're using the virus, but we are reprogramming it so that it is not only safe but also full of genetic tools that will lead to various forms of attack against the virus."*

Associate Professor Stuart Turville

# DELIVERING A CURE FOR HIV

Despite life-saving advances in treatment, a cure for HIV remains elusive. This is partly due to the virus' ability to replicate by inserting a DNA copy of itself into cells in our immune system. Even when an HIV positive person is on successful treatment, the virus sits in immune cells that are "resting" for long periods of time. The problem faced for those on therapy is that because the infected cells remain asleep, the immune system cannot see them, and HIV treatment is unable to target and attack the virus.

This is why continuous HIV treatment is still necessary. The sleeping state of HIV, often referred to as HIV latency, is one of the major challenges in developing a HIV cure.

Associate Professor Stuart Turville from the Kirby Institute believes that by using the "nuts and bolts" of the HIV virus in a safe and effective way, we can genetically modify our immune cells in various ways to enable a functional cure for HIV. His plan is to use elements of HIV to fight HIV. These HIV elements enable the delivery of tools into various immune cells that will fight the virus that is hidden, or "asleep", in infected cells in the body.

"We're turning the virus against itself," says Associate Professor Turville. "We're using the virus, but we are reprogramming it so that it is not only safe, but also full of genetic tools that will lead to various forms of attack against the virus".

Scientists have been working on a range of genetic tools that target the virus and have the potential to cure HIV. Some of these tools are designed to prevent the virus from waking up; others are looking at cutting the virus out of our genomes using a new generation of molecular scissors referred to as CRISPR. However, the problem with these tools is that they are very difficult to get into the cells—and to date they remain mostly clinically inaccessible.

Associate Professor Turville believes that the best way to use this emerging "gene tool-kit" is to learn from what the HIV virus does best: the delivery of genes into cells in our immune system.

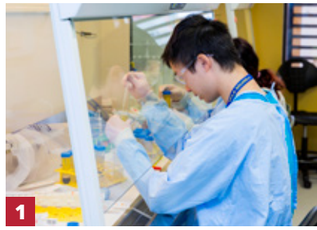
"The dream would be to take the portfolio of genetic approaches that are currently being developed, and to deliver them quietly and efficiently to our immune system. What my colleagues and I working on is the best way to get the genetic material into our immune cells, without the need to wake them up. Most approaches wake up the immune cells to deliver genes, but this also wakes up HIV. Our primary challenge remains delivering genes to cells that are asleep."

While a number of research centres are trialling HIV as a tool for gene delivery, the Kirby Institute is one of only a few centres world-wide attempting to deliver genes to sleeping immune cells using a newly developed gene delivery platform. Currently, gene delivery is achievable in 30 to 40 per cent of cells that are resting, but Associate Professor Turville is aiming to push past 80 per cent. "After that, the next step is to test this platform in various pre-clinical models, so that we can then establish any protocols that maybe applicable to future human trials," he says.

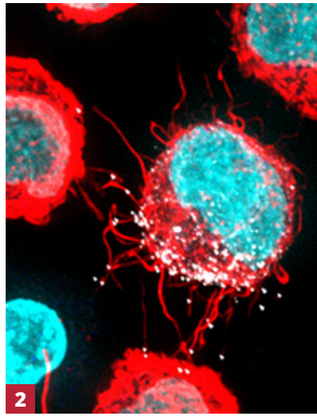
Associate Professor Turville admits that it can be easy to get disheartened by what can feel like slow progress in HIV basic science. However, he believes that gene therapy may move more quickly than other cure approaches. "I really feel that we're on the edge of something here with genetic therapy. What we've been able achieve in a relatively short amount of time, and the fact that we're realistically talking about clinical trials for genetic cures over the coming years, is truly remarkable."

"I'm optimistic that we'll soon be talking about HIV in the way that we're currently talking about hepatitis C," says Associate Professor Turville. "With a cure in our belt, we will start to look at how we can strategically roll it out to have the most impact—and legitimately end HIV."

Funded by the NHMRC.



**1.** PhD Student Mr Andrew Wong isolating fresh CD4 T cells from blood to genetically manipulate.



**2.** HIV infected cells. The blue is the nucleus and the red is the outside of the cell called the Actin cytoskeleton. Our study genetically manipulates HIV to attack these infected cells or render HIV silent.

Scientia Professor David Cooper

10 to 15 per cent of people who start ART each year experience treatment failure.

# OPTIMISING HIV TREATMENT WHEN FIRST-LINE THERAPY FAILS

Three decades of impressive medical advancements mean that HIV can now be treated by a single daily dose of combination antiretroviral therapy (ART). In most HIV positive people, standard combination therapy will suppress the virus to undetectable levels, minimising the harm the virus causes to the body. However, 10 to 15 per cent of people who start ART experience treatment failure, requiring them to switch to a second line of drug therapy to achieve an undetectable viral load. Current second-line treatments have a number of limitations, which create significant burdens in low-income settings.

In 2016, the Kirby Institute was awarded an AUD$12 million grant from Unitaid to conduct a clinical trial to improve treatment options for people with HIV infection who experience treatment failure. The trial, called D²EFT, is a multicentre, multinational, randomised trial in 610 people with HIV who have experienced failure of first-line ART.

Scientia Professor David Cooper, Director of the Kirby Institute, is Chief Investigator on the trial. "At the moment, there are no standard, clinical recommendations for how to treat HIV in people where first-line therapy has failed. This is a particular problem in low-income countries, where there are higher rates of HIV, and therefore larger numbers of treatment failures," says Professor Cooper. "There is an urgent need for a better regimen of ART for use in second-line therapy, particularly in low and middle-income countries, as the current second-line regimens are both complex and economically unsustainable."

Dr Mark Polizzotto is head of the Therapeutic and Vaccine Research Program at the Kirby Institute, which is coordinating the D²EFT clinical trial. "In order to determine the most effective and sustainable second-line treatment option, we will compare a simplified alternative second-line treatment regimen—dolutegravir in combination with ritonavir boosted darunavir—with the currently recommended standard of care regimens," says Dr Polizzotto.

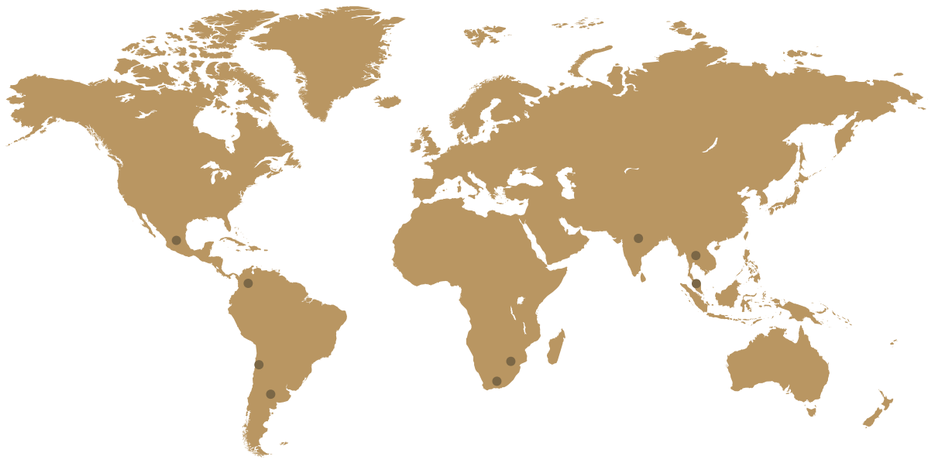
*"There is an urgent need for a better regimen of ART for use in second-line therapy, particularly in low and middle-income countries, as the current treatment regimens are both complex and economically unsustainable."*

Participants are recruited through participating sites all around the world, and will be followed up for two years to determine the most effective treatment regimen. "We have a large clinical trials network, with approximately 20 investigational centres in nine countries on four continents," says Dr Polizzotto. "This ensures that we can assess the clinical utility and cost-effectiveness of these treatments in a range of settings, and that the conclusions of our research will be both robust and applicable internationally."

"Our simplified treatment regimen could in future be adapted into a single daily pill. The simplified regimen also allows prescriptions to be written by clinical nurses or physician assistants, meaning distribution of treatments will be easier and more widely accessible for people in low-income settings."

Professor Cooper believes that trials like D²EFT are essential for enhancing treatment options at all stages of disease in the global fight against HIV, and that the results are likely to have global impact. "If the regimen of ART trialled during D²EFT is shown to be clinically superior or equal to the currently recommended regimens of therapy, then there will be substantial evidence to support modification of global recommendations, which will impact the treatment of millions of people in resource-limited settings."

D²EFT is funded by Unitaid at sites in low and middle-income countries, and NHMRC elsewhere. The study is supported by ViiV Healthcare and Janssen Pharmaceuticals by donation of the study drugs.



# ELIMINATION IS THE GOAL FOR HEP C IN AUSTRALIA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**1.** Professor Greg Dore in the "Elimination is the Goal" t-shirt designed by Reg Mombassa.

**2.** Professor Margaret Hellard, Burnet Institute and Professor Greg Dore at the signing of the MoU on hepatitis C research.

**3.** Members of the Viral Hepatitis Clinical Research Program wearing the "Elimination is the Goal" t-shirt.

Around 200,000 Australians are living with chronic hepatitis C. Hepatitis C is a virus that causes inflammation of the liver and is transmitted primarily through blood-to-blood contact, with approximately 80 per cent of current infections and 90 per cent of new infections thought to result from unsafe injecting drug use. If left untreated, hepatitis C can lead to liver cancer and liver failure, which claims hundreds of Australian lives each year. But the World Health Organisation (WHO) has set a target to eliminate hepatitis C as a major public health threat by 2030, and Australia is well on track to achieving the ambitious WHO elimination goals (80 per cent reduction in new infections; 80 per cent treated; 65 per cent reduction in liver-related mortality) even sooner: by 2026.

Whilst there is no vaccine to protect against hepatitis C, the infection can now be treated and cured at extremely high rates in all strains thanks to new direct acting antiviral (DAA) drugs, with cure rates of 95 to 100 per cent in clinical trials. What's more, these game-changing drugs were made available by the Australian Government on the Pharmaceutical Benefits Scheme (PBS) without restrictions in March 2016, which has made the treatment widely accessible and the goal of elimination achievable.

Professor Greg Dore is an infectious diseases physician at St Vincent's Hospital in Sydney, and heads up the Kirby Institute's Viral Hepatitis Clinical Research Program, which undertakes world-class clinical and laboratory research that improves outcomes for people living with viral hepatitis. Through his position at St Vincent's, Professor Dore has participated in the registration studies of the new treatments on the PBS, and with his team at the Kirby Institute, he works on projects to provide evidence that support the use of the new medications in specific populations such as people who inject drugs, prisoners, and people with acute hepatitis C; populations whom have often been excluded from these registration studies.

The Kirby Institute is now responsible for monitoring the uptake of hepatitis C treatment in Australia, which is proving to be a widespread success. Previously, only about one to two per cent of people living with hepatitis C were treated each year, with low treatment rates being blamed on the toxicity associated with interferon, the treatment previously used, as well as the long treatment course and low success rate. But the new treatments on the PBS are interferon-free, have exceptionally high cure rates, shorter treatment durations and minimal side-effects. "We have made amazing progress this year, with over 32,500 people treated in 2016; that's 15 per cent of all people living with chronic hepatitis C in Australia," says Professor Dore. "Other countries obtained access to these new treatments earlier (some from late 2014), but treated less than 10 per cent of their infected population in their initial year".

The Kirby Institute is also committed to collaborating with other institutes and organisations with the shared objective of hepatitis C elimination by 2026. In May 2016, an historic memorandum of understanding was signed between the Kirby and Burnet Institutes that will create opportunities to undertake joint research, education, professional training and program design and evaluation.

The collaboration, known as the Australian Hepatitis C Elimination Program, launched the initiative "Elimination is the Goal" at the 2016 Australasian Viral Hepatitis Conference on the Gold Coast with t-shirts designed by Reg Mombassa. "Addressing the stigma and discrimination faced by many people living with hep C will be fundamental to success", explains Professor Dore, and the campaign, with the help of the t-shirts, is an excellent start.

There are other challenges in meeting the elimination goals, especially around sustaining the momentum of the initial surge in treatment. With 19 per cent of people still undiagnosed, screening will be key, as will the development of enhanced access for the most marginalised populations, including people who inject drugs, the homeless, and prisoners. But Professor Dore is optimistic. "The potential of these revolutionary new hep C treatments to empower the whole sector, together with continued advocacy and government support, should see Australia achieve elimination over the next decade".

# IMPROVING STI TREATMENT IN REMOTE ABORIGINAL COMMUNITIES


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**1.** Associate Professor Rebecca Guy, Chief Investigator of TTANGO and TTANGO2.

**2.** A TTANGO poster.

**3.** Machine that tests and diagnoses a person's STI within one visit.

Young people living in many remote Aboriginal communities have very high rates of sexually transmissible infections (STI). A big challenge for improving sexual health in remote areas is to overcome the barriers to testing and treatment. Timely STI testing and treatment is needed to break cycles of transmission, but in many remote Aboriginal communities, geographic distances between health services and laboratories, population mobility, staff turnover, and social and cultural factors can affect healthcare provision and healthcare seeking behaviour.

The Kirby Institute's Associate Professor Rebecca Guy is the Chief Investigator on two studies that are looking at ways to use the latest technological advancement in STI testing to improve testing and treatment in remote communities. The Test, Treat and Go (TTANGO) study trialled the acceptability and effectiveness of technology that tests and diagnoses a person's STI within one visit to the clinic. "This is called point-of-care testing," says Associate Professor Guy. "A health worker, nurse or doctor can collect a urine sample or swab from the patient and analyse it using a device called GeneXpert, with a result for chlamydia and gonorrhoea available in 90 minutes. If the result is positive, a patient can begin treatment immediately."

The Kirby Institute launched the first TTANGO trial in 2013. Early findings of the TTANGO trial showed access to the new point-of-care technology more than doubled the proportion of patients treated for gonorrhoea or chlamydia within three days (72 per cent versus 30 per cent) compared to laboratory testing only. Reducing time to treatment also has the potential to reduce the risk of complications such as pelvic inflammatory disease and infertility. At the public health level, it can reduce onward transmission. Staff also reported reduced time and effort associated with client recall thanks to point-of-care testing. The GeneXpert chlamydia/gonorrhoea test, when performed by clinical staff at the point-of-care, was also demonstrated to be as accurate as laboratory-based tests.

The success of the TTANGO trial led to the launch of TTANGO2, an expanded program which aims to evaluate the sustainability and impact of the use of STI point-of-care testing in a larger network of remote and regional health services. The TTANGO2 program is being implemented by the Finders University International Point-of-Care Centre and the Kirby Institute is responsible for program evaluation. "We will be collaborating with up to 33 health centres in the Northern Territory, South Australia, Far North Queensland and Western Australia to identify barriers to STI testing and treatment, and to develop and evaluate resources to facilitate a larger scale implementation of point-of-care testing. Australia is a huge and geographically diverse country. There is a lot we need to consider when we are talking about scale-up," says Associate Professor Guy.

She adds that while point-of-care testing is an exciting development in public health, the biggest challenge is how to utilise the technology in the best possible way for each community. "It is important that we implement new health developments in ways that are acceptable and practical for Aboriginal communities," she explains, and this would not be possible without the expertise and collaboration of community-led organisations. "Our partnerships are hugely important here. We work very closely with Aboriginal Community Controlled Health Organisations, who really lead the way in terms of understanding and overcoming important cultural and practical barriers to STI testing and treatment," says Associate Professor Guy. "It is these partnerships, and the on-the-ground knowledge that comes with them, that are essential to the success of trials like TTANGO."

TTANGO is funded by NHMRC and TTANGO2 is funded by NHMRC, the Australian Government and Western Australian Department of Health, with in-kind support from collaborating organisations.

# EXPERIENCES OF HIV: THE FINAL SEROCONVERSION STUDY REPORT

## The challenge

Until recently, the annual number of new HIV diagnoses has not decreased. Testing rates in key populations had also changed little. Recent advances have begun to see some early signs of shifts in these long-term trends. Both, Treatment as Prevention (TasP) and Pre-Exposure Prophylaxis (PrEP), offer effective methods of HIV-prevention that can complement condom use. The benefits of early initiation of treatment for the health of those with HIV have become increasingly clear, and are now firmly established. Combined, these changes offer a real possibility of achieving the virtual elimination of HIV transmission in Australia. Apart from structural limitations, the main challenge to achieving this goal is how at-risk individuals respond to these changes: can they, and will they, make the necessary adaptations to these changes that will make them both effective and successful?

## How we are helping

Since 1992, the Seroconversion Study has collected essential qualitative and quantitative data from individuals who have been diagnosed with HIV. Since the Seroconversion Study relaunched in December 2007, 637 gay and bisexual men have completed an online survey, while more than 100 have been interviewed in-depth. The information collected through the study not only provides invaluable information about how to prevent new HIV infections, but helps us to understand how we can support people newly diagnosed with HIV and prevent onward transmission.

## Impact

Launched in 2016, the final Seroconversion Report provides essential information for policy makers and health communicators. It has informed the development of targeted health promotion responses for those living with, or most at risk of HIV and improved our understanding of people's behaviour in relation to HIV infection on an ongoing basis, including providing critical information about how to prevent HIV in the future.  The Kirby Institute will be implementing a new version of this study to launch in 2018, which will explore service delivery and peer support among people recently diagnosed with HIV.

Funded by the Health Departments of New South Wales, Victoria, Queensland, Western Australia, South Australia, Tasmania, Australian Capital Territory and Northern Territory.

*More than 100 gay and bisexual men have been interviewed in-depth.*

# NEW THERAPIES TO TACKLE HIV-RELATED CANCERS

## The challenge

People with HIV remain at a substantially elevated risk of cancer even with effective antiretroviral therapy (ART), with cancer now the leading cause of death in people living with HIV. As people with HIV are living longer, cancers are becoming increasingly important causes of morbidity and mortality. However people living with HIV are excluded from clinical trials of new cancer therapies, partly due to the complexity of their medical condition. It is therefore essential that dedicated trials are available to enable them to reap the benefits of ongoing advances in cancer therapy.

## How we are helping

In 2016, the Kirby Institute developed a number of studies with the goal of improving the prevention and treatment of cancers in people living with HIV.

The cornerstone of this effort is a new collaboration with the U.S. National Cancer Institute AIDS Malignancy Consortium (AMC), supported by Cancer Institute of New South Wales. The Kirby Institute, and our clinical site at St Vincent's Hospital Sydney, is the first international institution selected as a core clinical site for the AMC. This collaboration is now giving Australian patients with HIV and cancer access to cancer clinical trials for the first time. The first trial within this collaboration is an early phase study of two immune targeted anti-cancer drugs, nivolumab and ipilimumab, in people with HIV and certain advanced cancers. These immune acting drugs have proved highly successful in the treatment of many types of cancer, and this study is the first to assess their safety and utility in people with HIV. It is now open and recruiting patients.

In addition to treatment trials, we are also working in partnership with clinical sites around the country to establish the region's first "biobank" for people with HIV and cancer. The biobank is a collection of samples, including tissue and blood, linked to clinical information that is stored and made available to researchers all over the world. This will enable clinical and laboratory researchers access to patient material to accelerate their studies of the development and treatment of cancers in this group. Development of this key research infrastructure is a crucial step in facilitating science and contributing to advancing knowledge.

## Impact

These studies will for the first time provide people with HIV in Australia access to trials of new agents to improve treatment of established cancers. They have the potential to transform outcomes for people with HIV who develop cancer, and reduce the burden of cancer in this group. Studies in this group will also provide insights that benefit the broader population regarding the pathogenesis of cancers and of HIV itself.

Funded by the Cancer Institute of NSW, the National Health and Medical Research Council, and the U.S. National Cancer Institute AIDS Malignancy Consortium.

**There are more than 200,000 children living with HIV in the Asia Pacific.**

afao.org.au/asia-pacific

# TREAT ASIA PAEDIATRIC HIV OBSERVATIONAL DATABASE

## The challenge

In the past few years, significant progress has been made in low and middle-income countries on increasing access to HIV/AIDS services. In 2009, HIV treatment was available to 37 per cent of people in need living in East, South and South-East Asia. However, currently there is limited information available regarding HIV disease progression, treatment practices, clinical outcomes and mortality in HIV-infected children in many countries in Asia.

## How we are helping

The Kirby Institute is part of the TREAT Asia network—a regional collaboration of clinics, hospitals, and research institutions working with civil society to support the safe and effective delivery of HIV/AIDS treatments throughout Asia and the Pacific, through research, education and policy initiatives. In 2006, TREAT Asia launched the TREAT Asia Paediatric HIV Observational Database (TApHOD) for epidemiologic research. TApHOD currently includes data on 6,303 HIV-infected children from 18 clinics in Cambodia, India, Indonesia, Malaysia, Thailand, and Vietnam. Further recruitment is planned over the next five years.

## Impact

TApHOD aims to inform optimal care and treatment for paediatric HIV disease in the region. It does this by developing capacity for systematic paediatric HIV clinical data collection and analysis, and by examining HIV clinical and treatment outcomes among HIV-infected children across the region.

An initiative of TREAT Asia, a program of amfAR, with support from the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Cancer Institute, National Institute of Mental Health, and National Institute on Drug Abuse as part of the International Epidemiology Databases to Evaluate AIDS (IeDEA; U01AI069907), and the LIFE+, Austria.

# MONITORING HIV AND HEPATITIS C AMONG PEOPLE WHO INJECT DRUGS: THE AUSTRALIAN NEEDLE SYRINGE PROGRAM SURVEY

## The challenge

People who inject drugs are at risk of HIV transmission and are the key population affected by hepatitis C virus (HCV) infection globally. HIV and HCV prevalence estimates among people who inject drugs are essential for planning, implementing and evaluating blood borne virus prevention programs.

## How we are helping

The Australian Needle Syringe Program Survey (ANSPS) provides annual estimates of HIV and HCV antibody prevalence and monitors sexual and injecting behaviour among people who inject drugs in Australia. Led by the Kirby Institute, the survey is conducted at around 50 needle syringe programs (NSPs) over a one to two week period in October. The project is conducted in all states and territories and recruits between 2,000–2,500 NSP attendees each year. Participants complete a brief self-administered questionnaire and provide a capillary blood sample which is subsequently tested for HIV and hepatitis C antibodies.

The Australian Needle and Syringe Program Survey has been conducted since 1995 and annual results are published in the ANSPS National Data Report. HIV prevalence has remained low at 2.1 per cent nationally in all years since 1995, while HCV antibody prevalence has remained high at 50 per cent or more nationally.

## Impact

Results from the ANSPS continue to inform NSP policy and practice, including monitoring progress against the objectives of Australia's National HIV and Hepatitis C strategies.

Funded by the Australian Government Department of Health.

# REACT: A STUDY OF TREATMENT FOR RECENTLY ACQUIRED HEP C

## The challenge

Globally, an estimated 3-4 million people acquire the hepatitis C virus (HCV) each year. People who inject drugs and HIV-positive men who have sex with men are two groups at highest risk of transmitting and acquiring hepatitis C. The arrival of direct acting antiviral treatments has changed the therapeutic landscape for individuals with chronic HCV infection. These new therapies offer highly effective and tolerable cures, even in "difficult-to-treat" populations. In light of new treatments, strategies are urgently needed to enhance HCV assessment, treatment and prevention, especially among people who inject drugs and HIV-positive men who have sex with men.

## How we are helping

The REACT study is a phase III, randomised controlled trial comparing the efficacy and safety of sofosbuvir/velpatasvir administered for either 6 or 12 weeks in a total of 250 people with recent HCV infection. It is a multicentre, international trial with a total of 15 sites in 8 countries; Australia, New Zealand, United States of America, United Kingdom, Switzerland, Canada, Germany and The Netherlands. The Kirby Institute study will evaluate whether a reduced treatment time of 6 weeks among people who have recently acquired hepatitis C will achieve the same outcomes as the standard 12 week treatment course. This understanding is crucial in order to prevent ongoing transmission of hepatitis C and to enhance the cost-effectiveness of treatment.

It is anticipated that the results from REACT study will support shortened treatment duration for recently acquired hepatitis C infection.

## Impact

The availability of an oral once-daily short course interferon-free combination therapy for recently acquired HCV infection will maximise acceptability to patients, encourage uptake of treatment, limit further transmission and prevent progression to chronic liver disease.

Funded by the National Institutes of Health, the Australian Government Department of Health and Ageing, and UNSW. Study drug provided by Gilead Sciences Inc.

Research reported in this publication was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R01DA040506.

**While there is no vaccine to prevent hepatitis C infection, new treatments can cure hepatitis C in more than 90 per cent of cases.**

# NATURAL IMMUNITY AGAINST HEPATITIS C WILL GUIDE VACCINE DEVELOPMENT

## The challenge

The World Health Organisation estimates that 71 million people have chronic hepatitis C infection and that a significant number will develop cirrhosis or liver cancer. Although new antiviral medications can cure more than 95 per cent of people with hepatitis C, access to testing and treatment remains low worldwide. Development of a vaccine to prevent hepatitis C infection therefore remains a key priority in the goal of global elimination. However, hepatitis C is a highly diverse and rapidly mutating virus, which represents a major challenge for vaccine development.

## How we are helping

Following initial infection, one person in four naturally clears hepatitis C infection, but most remain susceptible to reinfection—suggesting poor immunity. However, rare groups of individuals who appear to have a strong natural immunity have been identified in prospective cohort studies of individuals at high risk of infection through injecting drug use as they remain uninfected or repeatedly clear episodes of infection. Our researchers are examining blood samples collected from these rare individuals over many years of follow-up to understand the characteristics of the virus using high throughput next generation "deep" sequencing. They are also examining the immune responses using state-of-the-art methods to identify and characterise the hepatitis-specific T and B cells as well as virus-neutralising antibodies.

## Impact

The virus first detected after infection—the transmitted-founder virus—appears to have unique characteristics which may make it susceptible to immune responses conferred by a vaccine. However, early generation of potent hepatitis C-specific T cell responses has been associated with development of escape mutations in the transmitted-founder virus, which can lead to chronic infection. By contrast, early generation of broadly reactive hepatitis C neutralising antibodies has been linked to clearance of infection.

The findings from these studies will guide design of the next generation of hepatitis C vaccine candidates for field trials.

Funded by the National Health and Medical Research Council of Australia, Gilead Sciences Inc, ACH2 and Bristol Myers Squibb.

*Flux is one of the largest cohort studies of legal and illicit drug use among gay and bisexual men in the world.*

# THE HIGHS AND LOWS OF DRUG USE AMONG GAY AND BISEXUAL MEN

## The challenge

The prevalence of licit and illicit drug use among gay and bisexual men is higher than in other population groups. Behavioural surveillance research among gay and bisexual men indicates that more than half report recent illicit drug use in the previous six months. Few studies have reported the incidence of, or the harmful consequences associated with drug use in this population.
An additional challenge is that condomless anal intercourse with casual male partners, the primary risk factor for HIV infection among gay and bisexual men, is strongly associated with drug use.

## How we are helping

Since 2014, researchers from the Kirby Institute have been collecting and analysing information from over 3,000 gay and bisexual men about their drug use. The study is called Flux, which stands for "Following Lives Undergoing Change" and is being conducted nationally using a world-first study-specific, fully automated methodology that tracks participants' drug using behaviours over time. This innovative technology is instrumental in making the Flux study one of the largest cohort studies of legal and illicit drug use among gay and bisexual men in the world. The Flux Study will be among the first in the world to report on the incidence of drug initiation and explore, in detail, the contexts and consequences of, and motivations for, drug use initiation over time.

## Impact

Early results from the Flux study show that although drug use was common among this sample, most use was infrequent and associated harms and dependency were low. The 2016 Flux report on baseline data showed that the most commonly and frequently used drugs were marijuana and amyl nitrite. Although used infrequently, over a quarter of men surveyed had used some sort of "party drugs" in the previous six months, including cocaine and amphetamine-type stimulants such as ecstasy, speed and crystal methamphetamine. These results provide evidence to underpin practical recommendations for health promotion, alcohol and other drugs, and HIV/hepatitis C virus prevention agencies and policy makers to improve the targeting of prevention messages to local gay communities, and to promote sustainable behaviour change.

To learn more, go to www.flux.org.au

Funded through an Australian Research Council grant.

# MALE SEX WORK IN AUSTRALIA – EXPLORING NEW NORMS

## The challenge

In Australia, male sex workers and their clients face a host of new challenges and opportunities. Dominant among these are rising rates of STIs, new biomedical methods of HIV prevention, the proliferation of internet technologies in commercial sex, and the popularity of crystal methamphetamine and other drugs in sexual subcultures.  There is no question that these and other factors are contributing to new norms for sex work and so it is important to understand how male sex workers and their clients can address challenges in a way that enhances their health, safety and overall satisfaction.

## How we are helping

The Kirby Institute has partnered with sex worker advocacy organisations to undertake a detailed, ethnographic study of male sex work in Australia.  Centred around a male brothel, this study explores the physical and virtual spaces of sex work to observe the interactions between male sex workers and their clients, including how they negotiate expectations.  Through interviews with a diverse collective of sex workers and clients, this study is gathering new information on what matters for the male sex industry today.

## Impact

This study will produce one of the most comprehensive explorations of male sex work in Australia to date, with a focus on how sex workers and clients can achieve safe and satisfying commercial sex encounters. The new information generated by this research will be used in the development and planning of policy and practice by diverse organisations related to community advocacy and health to improve the lives of those involved with male sex work.

Funded by the Australian Research Council.

# SEXUAL COERCION OF MEN IN PRISONS

## The challenge

In prison, sexual violence can have particularly devastating mental, physical, and sexual health consequences for individuals and the communities to which most prisoners return. Failure to prevent sexual violence and to respond to the victim's trauma violates the human rights of prisoners, breaches the duty of care and puts correctional services at risk of litigation from victims. It may also contribute to recidivism.

## How we are helping

Researchers from the Kirby Institute conducted the first population-based analysis of factors associated with sexual coercion of men in Australian prisons, using a computer-assisted telephone interview to collect this information in a prison setting. 2,000 men randomly drawn from a list of current inmates participated in the study.

Of the 2,000 study participants, 136 men (7 per cent), reported they had been threatened with sexual coercion in prison, and 53 (2.3 per cent) of the participants had experienced sexual coercion.

Men who identify as non-heterosexual were over seven times more likely to report having experienced sexual coercion in prison, and more than twice as likely to report having experienced a threat of sexual coercion, compared with their heterosexual counterparts.

Those who reported unwanted sexual activity outside of prison were four times as likely to report being threatened with sexual coercion and over eight times as likely to report experiences of sexual coercion in prison compared to those who had not reported unwanted sexual activity outside prison.

## Impact

This study has important implications for future research and policy and service responses.

Further research from the Kirby Institute will examine the prevalence of sexual coercion again and whether it has changed over time.

Funded by the National Health and Medical Research Council of Australia with some additional funding from the New South Wales and Queensland Governments.

**7x**

Gay and bisexual identified men were more than seven times more likely to report having experienced sexual coercion in prison, and more than twice as likely to report having experienced a threat of sexual coercion, compared with their heterosexual counterparts.

# EXPANDING THE GENITAL WARTS SURVEILLANCE NETWORK

## The challenge

The Genital Warts Surveillance Network, run by the Kirby Institute, is designed to monitor the population effects of the national human papillomavirus (HPV) vaccination program, introduced in Australia in 2007. Genital warts are caused by HPV types 6 and 11 and affect areas such as the vagina and anus. Other types of HPV also cause cervical, anal, and oropharyngeal cancers. In order to understand the impact and effectiveness of the HPV vaccine, the Genital Warts Surveillance Network monitors the proportion of patients diagnosed with genital warts as a proxy for the presence of HPV in the population.

## How we are helping

The Genital Warts Surveillance Network comprises 54 sexual health clinics in all states and territories of Australia. Routinely collected information at sexual health clinics includes data on demographics, sexual behaviour, wart diagnosis and (in a subset of clinics) HPV vaccination status. These data are extracted directly from patient management information systems at each clinic and are collated and analysed at the Kirby Institute.

## Impact

In 2013, the Kirby Institute received a grant from the Australian Government Department of Health to expand the surveillance network and this was completed in 2016. This grant means that we are now able to generalise the findings of the network to the entire population, not just the inner cities. This type of surveillance is essential to evaluate the effectiveness of public health initiatives.

Funded by the Australian Government Department of Health.

**Half of the world's 3.2 billion people remain at risk of malaria.**

# UNDERSTANDING MALARIA INFECTION AND TREATMENT IN HUMAN CLINICAL TRIALS

## The challenge

Malaria is both preventable and treatable, yet it remains one of the leading causes of mortality and morbidity around the world, with children and pregnant woman particularly vulnerable. According to The Global Fund, new methods of testing and prevention have led to a 29 per cent drop in malaria mortality rates between 2010 and 2015, but half of the world's 3.2 billion people remain at risk of malaria. New tools are urgently needed to support the goals of malaria eradication.

## How we are helping

Our work in malaria aims to improve our understanding of how the malaria parasite grows in the human body and how this interacts with available treatments. We analyse data collected from a unique series of clinical trials in which volunteers receive deliberate blood-stage malaria inoculation followed by treatment with different antimalarial drugs (well before illness presents). Through the use of mathematical modelling and statistical approaches we have been working to analyse this data and improve our understanding of both parasite growth in a host (pre-treatment), and the mechanisms driving the kinetics of parasite clearance under therapy (post-treatment).

## Impact

Understanding the effects of current drugs, and predicting the "ideal" drug action for new drugs will aid the development of choice of new drug regimes. This work will allow us to better understand how parasite kinetics prior to treatment in an individual affects parasite clearance after treatment. In addition, comparing the dynamics of parasite "clearance" after treatment with different drugs gives insight into what determines the effectiveness of antimalarial drugs, and what criteria might be used in comparing novel antimalarial drugs and selecting them for further clinical study. This understanding will contribute to new tools to support malaria eradication.

Funded by NHMRC Program and Project grants.

# PROVIDING MORE OPTIONS FOR STI TESTING IN REMOTE ABORIGINAL COMMUNITIES

## The challenge

High levels of sexually transmitted chlamydia, gonorrhoea, syphilis and trichomonas have persisted among young people in many remote Aboriginal communities, despite the wide availability of accurate diagnostic tests, effective single dose therapies, and clinical guidelines recommending annual testing of all sexually active young people.

## How we are helping

The More Options for STI Testing, or MOST study, aims to provide new ways to increase the frequency of testing for sexually transmissible infections (STIs) among 16–29 year olds, which is an important component of STI control programs. In 2015–16, formative qualitative research was conducted by Kirby Institute researchers, in partnership with Central Australian Aboriginal Congress in Alice Springs, in remote communities to inform the design of innovative strategies to be tested during the trial. Given the substantial reported barriers for having a test for STIs among young Aboriginal people, the study will examine the effectiveness of strategies which encourage more young people to access the clinic for testing, through the offer of incentives, as well as the provision of youth-only periods at health services to encourage young people to get tested.

The effectiveness of these strategies will be evaluated quantitatively, using an interrupted time series analysis in six health services, of the number of young people tested for STIs, and the number found to have infection.

## Impact

This study is the first rigorous investigation of new strategies for increasing the uptake of STI testing among young Aboriginal people in remote communities in Central Australia. An innovation in our methodology will be the incorporation of changes in organism load as a marker of effect, complementing conventional quantitative and qualitative indicators that will form the core of the evaluation. If successful, study outcomes will be readily transferable to other remote communities with endemic STIs, and are likely to be adaptable to other settings of high prevalence.

Funded by NHMRC project grant.

# OUR PEOPLE

**It takes a team of passionate and talented people to keep the Kirby Institute working towards a future free from the burden of disease.**

Mrs Elizabeth Keoshkerian and Dr Auda Eltahla from the Viral Immunology Systems Program

# WE ARE KIRBY

**A global research institute is made up of many people, doing a myriad of different jobs to make the place work. Here is a glimpse into the minds of some of the people who make up the Kirby.**



## RATA JOSEPH

### RECEPTIONIST AND FACE OF THE KIRBY

It has been a bit over 10 years since my first move to Sydney from Auckland, New Zealand. I had no expectations with this venture as I was initially travelling for holiday to visit my sister who was living in Sydney. But, it seems that fate brought me to the Kirby Institute, and being part of the Kirby family has made it a colourful decade to say the least!

I have a real interest in public health, as it affects all of us, and it is so exciting to be part of this dynamic group of people who make such a huge contribution to society. I am constantly inspired by the people I encounter day to day at the Kirby—it really is a diverse workplace and I am so fortunate to get to speak with people from such different walks of life and from literally four corners of the world.

There are so many amazing memories I have of the Kirby Institute that so many people have been a part of, but one of the highlights has got to be the flash mob we dropped in the CFI Building!

## GARRETT PRESTAGE
### THE ASSOCIATE PROFESSOR

I've been at the Kirby for 25 years, starting out as coordinator of the Sydney Men and Sexual Health cohort study, and gradually transitioning into an academic role. I started out as a gay community activist in the 1970s, who happened to have some training and skills in conducting research. I conducted the first research among gay and lesbian youth in 1983, with a small amount of funding from NSW Health—the first ever funding for an explicitly gay community-based project. I used the research findings to lobby for funding to establish Twenty-Ten, the first ever publicly-funded gay and lesbian youth project in NSW. Through the 1980s, I shifted between living in the US and working on several research projects concerning HIV, one of which was an early project on the 'HIV education needs of gay men'. This study led to Australia's first safe sex campaign: 'Rubba Me' in 1985.

Community-based and community-focussed research has always been my priority. I began working in research among gay men because I could see that building evidence was the best way I could support the gay community to address issues related to health, stigma, and sexuality.

We have built a terrific team dedicated to this work, and we have really led the way in making use of online and digital technologies to enhance our capacity to do this work. The technological innovations adopted for the Flux study, and then adapted to EPIC-NSW, have been particularly exciting.

## KRISTIN MCBRIDE
### THE LABORATORY MANAGER

I did my undergraduate Science degree at UNSW, and then went to complete my honours degree at the University of Melbourne, looking at Equine Infectious Diseases. I always wanted to be in the field of HIV research and was lucky enough to complete my PhD with the Kirby Institute. As the leading HIV research institute in Australia, it was an excellent opportunity, and I was fortunate enough to move into the laboratory manager role, which I'm still in today.

When I first came to the Kirby Institute we were known as National Centre for HIV Epidemiology and Clinical Research and the wet lab was located at the Centre for Immunology building. After a stint in Darlinghurst, we now reside within the Medicine Faculty at UNSW in a purpose-built laboratory. The group has expanded and we see many honours and PhD students come through and complete their projects, many of whom then go on to do post-docs overseas. It is great to follow their progress.

The laboratory group are amazing people and are more than just colleagues—we're a tight-knit group that enjoy socialising both at and outside work. The work we do ensures that changes are made in the future, not just in the way HIV and hepatitis are treated, but also in policy and behaviour within the wider community.



## ROSHANA SULTAN
### THE PROGRAM MANAGER

I've worked in the Viral Immunology Systems Program for seven years. Originally based at the School of Medical Sciences, I started as a part-time admin assistant and am now the program manager. We moved across to the Kirby Institute in May 2016

The Kirby has a very strong culture of inclusiveness and a strong sense of social justice through its work in less developed countries and disadvantaged groups. This resonates particularly strongly with me, as I have always had an interest in these themes and am currently completing a Masters in Human Rights Law and Policy.

Over the years, we've witnessed significant changes in the treatment of hepatitis C, particularly with the introduction of new drug regimens, making treatment easier and more successful, while at the same time substantially reducing the side effects of such treatment. Unfortunately, as such a large section of the affected population are either prisoners and/or people who inject drugs, there are still challenges in total elimination of this disease but these latest developments are a huge step in the right direction. I've had the opportunity to work with leaders in this field and meet some promising up-and-comers. It is a great privilege to be working together to overcome these really important health challenges.

## ROBERT MONAGHAN
### THE PROJECT OFFICER

I am a descendant of the Bundjalung Nation on my mother's side; my family and extended family are from the North Coast of NSW alongside the Clarence River at Baryulgil. On my Dad's side there is a long and rich history of descendants from Ireland. I reside in the glorious jacaranda city of Grafton (no bias). For two years I have coordinated a sexual health continuous quality improvement program in six Aboriginal Community Controlled Health Services in NSW with an overall goal of improving levels of testing and management for STIs. It involves working in partnership with health services and we discuss actions required to improve practice and assess change every six months.

I'm inspired by the people I work with and the Aboriginal communities I have lived in and visited as part of my role at the Kirby Institute. In Aboriginal health, you see so much despair in a fragile culture, but then you also see many things that give you hope and inspiration that make you realise that what we are doing is making a difference. It will be a legacy for the present and next generation of Aboriginal families and children, but most of all my own grandchildren. We at the Kirby are changing the face of research in Aboriginal communities and how it is perceived. That alone is exciting for me and for our Aboriginal communities across Australia now and for the generations that will follow.

## DEBORAH CROMER

### THE POSTDOCTORAL RESEARCH FELLOW

I completed an undergraduate degree in pure mathematics and realised I wanted to be able to apply my mathematical skills to help improve human health. At the Kirby Institute, I can use mathematics to understand infectious diseases and apply this to a broad range of questions. From HIV immunity to drug treatment for malaria, right through to evaluating the impact of changes in government vaccination policy, I use my mathematical skills to work with experimental and clinical scientists to answer fundamental questions in infectious disease research today.

Working as a mathematical biologist, it's most rewarding when I can uncover a whole new way of looking at a disease, or a new understanding of a biological phenomenon—simply by using my mathematical models. This is a rapidly expanding research area, and it is only in recent years that the field has started to realise the power of mathematics to help solve biological problems. With current advances in technology and data acquisition, there is a real opportunity for mathematicians and other quantitative scientists to influence medical research.

The Kirby Institute is full of researchers from many different backgrounds, with a common focus on improving our ability to control infectious diseases. Working with the dedicated scientists and clinicians at Kirby opens my eyes to even more areas in which mathematics can play a role in this challenge.

## KATHY PETOUMENOS

### THE POSTGRADUATE COORDINATOR

When I joined the Kirby (or NCHECR as it was known then), I had just completed my Masters of Public Health and wanted to join an organisation that would allow me to develop my epidemiological skills in an important clinical area and with a reputable organisation, and I found all of this at the Kirby Institute. I was not disappointed at all with my decision—almost 20 years later, I am still here!

My main research focus is on the long-term outcomes of HIV positive people, particularly on age-related comorbidities. At the Kirby, I've been fortunate to be involved in several impactful projects that assess the effectiveness of new treatments among both HIV positive and hepatitis C positive people in collaboration with a large team of very inspirational investigators.

There is rarely a dull moment at the Kirby, and the culture is inclusive, collegial and inspiring. Our research interests and expertise has broadened over the years, but we continue to work for communities that are often neglected or stigmatised with an approach that strives for equity for all, and we have made significant impact over these years. I am incredibly proud to be part of this, which alone inspires me to come to work every day.

## DENTON CALLANDER

### THE RESEARCH FELLOW

My research focuses on sex, sexualities and sexual health, so I get to ask a lot of different questions. One day, I might be calculating rates of gonorrhoea among gay men who inject drugs; the next I might be interviewing women who hire sex workers or exploring the online lives of straight men who have sex with men. I love this diversity. For me, it reflects the need for holistic research on sex and health that encompasses satisfaction and pleasure and the social and historical contexts as all playing a part in individual and public sexual health.

I'm inspired by sex! Sex is relevant to everyone in one way or another and this universality is both inspiring and humbling. Sex is one of the great expressions of our humanity and it remains something that is at once basic and primal but also relentlessly complex. I'm inspired by those who have tried to unravel its mysteries through science.

The Kirby Institute has allowed me to do research in a setting that values many different perspectives. Working alongside those with different expertise than mine has really improved my research by affording new opportunities for collaboration and inviting me to look at problems in new ways.

## REEM WAZIRY

### THE PHD CANDIDATE

The Kirby is one of the most successful research institutes nationally and internationally, evidenced by the diversity of its people, the welcoming culture and the highly influential research output. I have had a thrilling scientific journey over the past three years of my PhD candidature! My PhD, under the supervision of Professor Greg Dore, focused on investigating the impact of hepatitis B and hepatitis C treatment on risk of "Primary Liver Cancers"—Hepatocellular carcinoma in particular, which typically has very poor prognosis. Using population based and clinical data, we have established solid evidence that effective hepatitis B antiviral therapy and hepatitis C cures are capable of not only reducing the risk of liver cancer but also improving survival and reducing cancer recurrence in people who were treated with surgery.

The most rewarding project I have led in my PhD is a comprehensive study where we summarised and analysed the evidence published on risk of liver cancer in the interferon and the direct acting antiviral era, over 17 years. This study has direct clinical implications as our results show no evidence for higher risk of cancer following the new hepatitis C therapies, a controversy that caused considerable debate in our field recently. It was selected for a late breaker oral presentation and highlighted in the press program of the 52nd meeting of the European Association for the Study of the Liver (EASL) 2017.

# 2016 MEMORABLE MOMENTS

## MARDI GRAS
**05.03.16**

We celebrate 30 years of research and community partnerships at Mardi Gras.

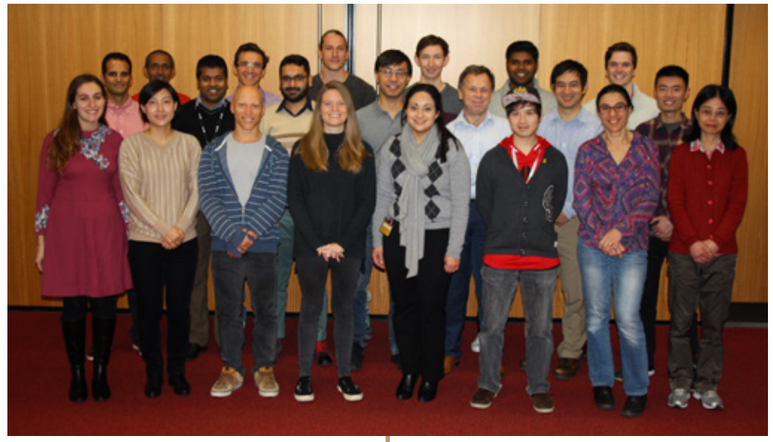



## TIME TO SEE EXHIBITION
**27.04.16**

We partnered with the Fred Hollows Foundation, The Queen Elizabeth Jubilee Trust, PWC and the University of Melbourne to host a reception and photographic exhibition to highlight the importance of addressing blindness globally.

## EPIC-NSW LAUNCH
**20.05.16**

Our EPIC-NSW trial enrols its 1,000th participant.




## VIRAL IMMUNOLOGY SYSTEMS PROGRAM
**01.06.16**

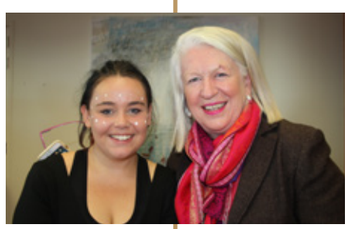
The Viral Immunology Systems Program, headed by Professor Andrew Lloyd, joins the Kirby Institute.

## NAIDOC
**05.07.16**

Celebrating Indigenous health research.

## MINISTER JILLIAN SKINNER VISIT
**07.06.16**

Minister Jillian Skinner visits the Kirby Institute to announce the Cancer Institute NSW's 2016 grants. Kirby Institute researcher Dr Mark Polizzotto received a grant to develop a clinical trial program in cancers associated with HIV infection.



## WEAR IT PURPLE DAY
**26.08.16**

Our annual expression of support and acceptance of rainbow young people.



## AUSTRALIAN AWARDS FELLOWSHIP PROGRAM
**23.09.16**

The Kirby Institute welcomed 14 current and future leaders from Indonesia, Cambodia, Fiji and the Solomon Islands for a research training program.



## HEP C ELIMINATION
**29.09.16**

The launch of the "Elimination is the Goal" campaign, a joint initiative with the Burnet Institute.


## KIRBY INSTITUTE SYMPOSIUM 2016

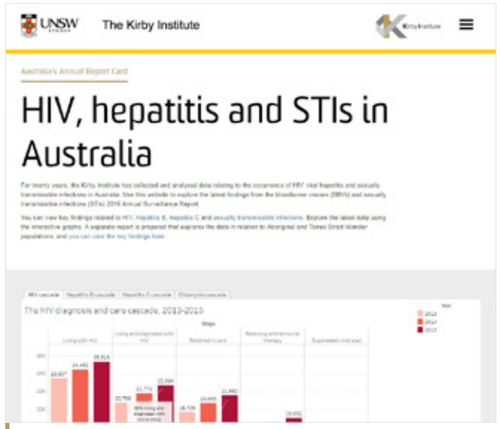
**03.11.16**

This year's theme was "Health research for development: How can we do it better?"

## 30TH ANNIVERSARY GALA DINNER

**05.11.16**

Celebrating three decades of lifesaving research and the support that has made our work possible.




## ANNUAL SURVEILLANCE REPORT

**14.11.16**

Launch of a new, interactive data site alongside our Annual Surveillance Reports on HIV, hepatitis and STIs.

## KEYS TO THE CITY

**17.02.17**

In recognition of 30 years of outstanding service to communities affected by HIV, the Kirby Institute is awarded the Keys to the City by Sydney Lord Mayor Clover Moore.


Credit: City of Sydney

# 2016 FUNDING

## National Health and Medical Research Council (NHMRC)

| Program Grants | AUD$ |
|---|---|
| Discovery and translation of interventions to control sexually transmitted infections and their consequences | 1,282,434 |
| Hepatitis C infection: epidemiology, pathogenesis and treatment | 571,712 |
| HIV latency, pathogenesis and immunity | 1,445,124 |

| Project Grants | |
|---|---|
| A randomised trial to compare dolutegravir+darunavir/r versus recommended standard of care antiretroviral regimens in patients with HIV infection who have failed recommended first-line therapy | 482,626 |
| A randomised trial to determine the safety and efficacy of early versus deferred treatment of HIV | 220,995 |
| Aboriginal and non-Aboriginal women perpetrators of violence: a trial of a prison-based intervention (Beyond Violence) | 100,267 |
| Dissecting the dynamics of malaria infection | 142,196 |
| Health outcomes and service utilisation in a cohort of people who inject drugs, sex workers and at-risk youth – a record linkage study | 130,818 |
| HIV treatment as prevention: a longitudinal assessment of population effectiveness | 82,632 |
| New strategies to increase testing and treatment for endemic sexually transmitted infections in remote aboriginal communities | 310,708 |
| Point-of-care diagnosis of sexually transmitted infections to improve maternal and neonatal health outcomes in resource-limited, high-burden settings | 495,281 |
| Point-of-care HPV-DNA testing for cervical cancer screening in high-burden, low-resource settings | 243,706 |
| Serological responses to anal HPV infection: characterising the natural history of anal HPV | 69,461 |
| Sexual and reproductive health and behaviours of young offenders (14–18 years) in NSW and QLD | 43,009 |

| Partnership Grants | |
|---|---|
| Reducing impulsive behaviour in repeat violent offenders using a selective serotonin reuptake inhibitor | 10,000 |
| Striveplus: refinement and translation of an intervention designed to improve sexual health service delivery in remote communities | 82,244 |
| Surveillance and treatment of prisoners with hepatitis C (STOP-C) | 336,665 |
| The HIV prevention revolution: measuring outcomes and maximising effectiveness | 223,971 |
| Uptake, sustainability and impact of scaling up point-of-care testing for sexually transmissible infections in remote and regional Aboriginal communities (TTANGO2) | 249,247 |

| Centres of Clinical Research Excellence | |
|---|---|
| Offender Health | 499,987 |

| European Union Collaborative Research Grants | |
|---|---|
| European AIDS vaccine initiative 2020 | 50,000 |

| Fellowships | |
|---|---|
| A/Prof Mark Boyd (Career Development Fellowship) | 52,487 |
| Prof. Miles Davenport (Senior Research Fellowship) | 139,521 |
| Prof. Basil Donovan (Practitioner Fellowship) | 113,843 |
| Prof. Greg Dore (Practitioner Fellowship) | 113,844 |
| Dr Jason Grebely (Career Development Fellowship) | 117,536 |
| Prof. Andrew Grulich (Principal Research Fellowship) | 152,769 |
| A/Prof Rebecca Guy (Career Development Fellowship) | 106,262 |
| Dr Bridget Haire (Early Career Fellowship) | 79,692 |
| Dr Behzad Hajarizadeh (Early Career Fellowship) | 79,692 |
| Dr Jennifer Iversen (Early Career Fellowship) | 79,693 |
| Prof. John Kaldor (Senior Principal Research Fellowship) | 172,781 |
| Prof. Anthony Kelleher (Practitioner Fellowship) | 113,844 |
| Prof. Matthew Law (Principal Research Fellowship) | 152,769 |
| Prof. Andrew Lloyd (Practitioner Fellowship) | 50,512 |
| Prof. Lisa Maher (Senior Research Fellowship) | 126,274 |
| Dr Bradley Mathers (Postdoctoral Training Fellowship) | 87,192 |
| Dr Gail Matthews (Career Development Fellowship) | 106,262 |
| Dr Mark Polizzotto (Early Career Fellowship) | 87,192 |
| A/Prof Vanessa Venturi (Career Development Fellowship) | 58,768 |
| Dr Huachan Zou (Early Career Fellowship) | 103,361 |

| Postgraduate Scholarships | AUD$ |
|---|---|
| Angie Pinto | 41,892 |
| Lise Lafferty | 14,270 |

**Australian Research Council (ARC)**

| Discovery Projects | |
|---|---|
| Drug using behaviours and beliefs, and associated harms, among gay and bisexual men | 213,300 |
| Partner choice and sexual behaviour among gay and bisexual men | 107,455 |
| Understanding global biomedical technologies in local realities | 180,127 |

**Australian Government**

| Federal Department of Health | |
|---|---|
| Extended genital warts surveillance network | 61,010 |
| National trachoma surveillance and reporting 2015–2017 | 280,590 |
| Research activities for blood-borne virus and sexually transmissible infections | 4,144,234 |
| Surveillance activities | 1,072,728 |

| NSW Ministry of Health | |
|---|---|
| ACCESS-Plus – a national sentinel surveillance system for STIs | 29,005 |
| Implementation of HIV pre-exposure prophylaxis with antiretroviral medications among people at high risk for HIV infection | 325,286 |
| EPIC-NSW: extended prep implementation in communities in NSW | 767,432 |
| The HIV prevention revolution: measuring outcomes and maximising effectiveness | 291,000 |
| The HIV seroconversion study | 1,000 |
| The NSW research program for HIV, STIs and viral hepatitis | 499,403 |

| Other Government Departments | |
|---|---|
| Australia Awards Fellowships (Department of Foreign Affairs and Trade) | 186,622 |
| Australian collaboration for chlamydia enhanced sentinel surveillance (Department of Health and Human Services, Victoria) | 33,823 |
| National HIV seroconversion study (Queensland Health) | 34,356 |
| National prison entrants' blood-borne virus survey (ACT Health) | 10,000 |
| National prison entrants' blood-borne virus survey (Department of Justice and Regulation, Victoria) | 25,000 |
| National prison entrants' blood-borne virus survey (Queensland Health) | 25,000 |
| National prison entrants' blood-borne virus survey (South Australia Health) | 15,000 |
| Prepatory study on the impact of peer support programs (Department of Health and Human Services, VIC) | 50,766 |
| Systematic review peer-reviewed & grey literature-prison cell size & health effects (Department of Justice, Corrective Services NSW) | 14,601 |
| The 2016 national prison entrants blood-borne virus and risk behaviours survey (Department of Health and Human Services, TAS) | 10,000 |
| The relationship between psychotic mental illness and offending in NSW (Mental Health Commission of NSW) | 54,200 |

**National Institutes of Health, USA**

| | |
|---|---|
| A randomised study of interferon-free treatment for recently acquired hepatitis C in people who inject drugs and people with HIV coinfection (The REACT study) | 497,593 |
| AIDS malignancy consortium (AMC) and anchor | 68,804 |
| Anti-influenza Hyperimmune intravenous immunoglobulin (FLU – IVIG) international | 156,099 |
| Asia Pacific HIV research collaboration: cancer studies (subcontract with American Foundation for AIDS Research) | 69,208 |
| Cambodia integrated HIV and drug prevention implementation (subcontract with University of California) | 17,932 |
| Hepatitis C Treatment – HCV (subcontract with American Foundation for AIDS Research) | 13,012 |
| Hepatitis C Virus (HCV) (subcontract with American Foundation for AIDS Research) | 10,984 |
| INSIGHT – FLU 002 & FLU 003 (subcontract with University of Minnesota) | 861,626 |
| INSIGHT – Leadership (subcontract with University of Minnesota) | 464,904 |
| International collaboration of prospective studies of HIV and hepatitis in injecting drug users | 69,457 |
| Mechanisms limiting neonatal immunity (subcontract with Cornell University) | 52,289 |
| Opposites Attract study (subcontract with American Foundation for AIDS Research) | 198,241 |
| START study (subcontract with University of Minnesota) | 1,303,862 |
| TREAT Asia HIV Observational Database (subcontract with American Foundation for AIDS Research) | 457,824 |
| TREAT Asia paediatric HIV observational database (TApHOD) (subcontract with American Foundation for AIDS Research) | 227,942 |

## Other Grants and Contracts

| Australian | AUD$ |
|---|---|
| Double-blinded, placebo-controlled, cross-over study of modafinil to relieve the postexertional exacerbation of fatigue in patients with chronic fatigue syndrome undertaking exercise (The Mason Foundation) | 53,697 |
| Exploring circadian rhythm disturbances in chronic fatigue syndrome: towards a biomarker (The Mason Foundation) | 1,897 |
| Filling in the gaps – using a big data approach and text mining to enrich cops data to inform prevention strategies in domestic and family violence (Australian Institute of Criminology) | 27,926 |
| Future Research Leadership Fellowship – Dr Mark Polizzotto (Cancer Council NSW) | 168,525 |
| HCC outcome improvements through translational research in Western Sydney (Westmead Millennium Institute) | 25,000 |
| Immune modulation with pomalidomide for prevention of anogenital cancer in people with persistent high-grade anal intraepithelial neoplasia | 150,000 |
| Online education in CFS management (The Mason Foundation) | 36,963 |
| Preventing morbidity and mortality from anal cancer (Cancer Council NSW) | 392,795 |
| Scholarship: Robert Monaghan (The Lowitja Institute) | 33,612 |
| Visualisation of activated microglia in post-infective and chronic fatigue syndromes (The Mason Foundation) | 5,964 |

| International | |
|---|---|
| Assessing the impact and cost-effectiveness of needle/syringe provision on hepatitis C transmission among people who inject drugs: an analysis of pooled datasets and economic modelling (London School of Hygiene and Tropical Medicine) | 2,642 |
| Consultancy work ENCORE1 clinical study (Clinton Health Access Initiative) | 17,315 |
| Evaluation of HIV epidemics and programs in Asia (World Bank, USA) | 852,178 |
| Field trial of co-administration of azithromycin and ivermectin mass drug administration (The Task Force for Global Health Corporation) | 160,134 |
| Key population integrated bio-behavioural survey in Papua New Guinea (Oil Search Foundation Limited) | 206,279 |
| Point-of-care testing and treatment of sexually transmitted infections to improve pregnancy outcomes in resource-limited, high-burden settings (PNG Institute of Medical Research) | 207,321 |
| Scholarship: Alison Marshall (Canadian Institutes of Health Research) | 5,294 |
| Scholarship: Evan Cunningham (Canadian Institutes of Health Research) | 25,354 |
| The DAD Study, Data Collection on Adverse Events of Anti-HIV Drugs – Copenhagen HIV Programme (European Medicines Evaluation Agency) | 35,544 |
| The epidemiology and treatment of advanced liver disease among people with hepatitis C in Australia, Scotland and Canada (European Commission) | 86,772 |

## Pharmaceutical Industry

| | |
|---|---|
| Abbott Molecular Inc | 143,568 |
| AbbVie Pty Ltd | 1,028,716 |
| Callimmune Australia Pty Ltd. | 56,868 |
| Cepheid | 10,150 |
| CSL Limited | 148,964 |
| Gilead Science Inc (USA) | 2,226,691 |
| Gilead Science Pty Ltd | 233,982 |
| Janssen-Cilag Pty Ltd | 56,654 |
| Merck Sharp & Dohme | 379,768 |
| Pfizer Inc | 753,462 |
| ViiV Healthcare UK Ltd | 111,002 |

| | |
|---|---|
| **TOTAL** | **$29,770,289** |

| | |
|---|---|
| **DONATIONS** | **$2,066,047** |

It is through the valued support of our funders that the Kirby Institute is able to conduct the leading edge research that is improving health outcomes in Australia and beyond.

Together, we can work towards developing new therapies, preventative vaccines and better solutions for those who are currently affected by infectious diseases and for those who are most at risk.

Mr Bing-Ru Wu from the Viral Immunology Systems Program


**Editors**

Lucienne Bamford
Estelle Jones

**Contributors**

Lucienne Bamford
Janette Button
Denton Calendar
Daren Draganic
David A. Cooper
Deborah Cromer
Rata Joseph
Eilis Duggan
Elaine Lee
Estelle Jones
Laurie Legere
Michael Kirby
Kristin McBride
Robert Monaghan
Kathy Petoumenos
Garrett Prestage
Roshana Sultan
Reem Waziry

**Design & Layout**

Elaine Lee

**Photography**

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blimaging.com.au

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The Kirby Institute
Wallace Wurth Building
UNSW Sydney NSW 2052

T: +61 (2) 9385 0900
F: +61 (2) 9385 0920
E: recpt@kirby.unsw.edu.au

KIRBY.UNSW.EDU.AU
FACEBOOK.COM/THEKIRBYINSTITUTE
@KIRBYINSTITUTE


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