



HIV

AUSTRALIA

**HIV prevention at the crossroads:
new targets, treatments and technologies**

Volume 9 • Number 3

Editors Finn O'Keefe and Linda Forbes

Treatments Editor Jason Appleby

Design + Production Ascending Horse www.ascendinghorse.com

Correspondence

HIV Australia C/- AFAO, PO Box 51 Newtown NSW 2042 Australia

Telephone +61 2 9557 9399

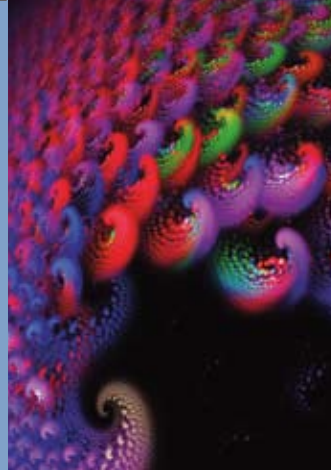
Facsimile +61 2 9557 9867

Email editor@afao.org.au

Website www.afao.org.au

HIV Australia gratefully acknowledges the assistance of the Commonwealth Department of Health and Ageing

Print post approved PP225920/00016



AFAO is the national federation for the HIV community response, providing leadership, coordination and support to the Australian policy, advocacy and health promotion response to HIV/AIDS. Internationally, AFAO contributes to the development of effective policy and programmatic responses to HIV/AIDS at the global level, particularly in the Asia Pacific region.

AFAO's aims are to:

- Advocate on behalf of its members at the federal level, thereby providing the HIV community with a national voice;
- Stop the transmission of HIV by educating the community about HIV/AIDS, especially those whose behaviour may place them at high risk;
- Assist its members to provide material, emotional and social support to people living with HIV;
- Develop and formulate policy on HIV issues;
- Collect and disseminate information for its members;
- Represent its members at national and international forums; and
- Promote medical, scientific and social research into HIV and its effects.

AFAO Board

President Graham Brown **Vice President** Alison Edwards

Secretary Nic Parkhill **Treasurer** Andrew Burry

Ordinary Member Chris Lemoh **Staff Representative** Danica Gluvakov

AIVL Jenny Kelsall **Anwernekenhe National Alliance** Colin Ross

NAPWA Robert Mitchell **Scarlet Alliance** Kane Matthews

In recognising the fundamental importance of information and education in working against the HIV/AIDS epidemic, all material in this publication may be reproduced for non-commercial use, personal research or educational purposes free of charge, provided the following citation is made: "Reprinted from Volume 9, No. 3 of *HIV Australia*, published by the Australian Federation of AIDS Organisations". Copyright of all images remains with the individual artists.

Requests for permission to reproduce any written material in this publication for commercial purposes should be made to AFAO directly.

AFAO is a member of Copyright Agency Limited (CAL). If you have been engaged by AFAO as a contributor to one of our publications in the past and are a member of CAL, we may be holding CAL funds in trust for you. If you think this may be the case, please contact AFAO directly (editor@afao.org.au).

This edition of *HIV Australia* examines testing, treatment and prevention in the era of combination prevention. Authors consider the impact of new prevention targets, HIV treatments and new technologies on the response to HIV.

The views and opinions expressed by the authors are their own and do not necessarily represent the views of AFAO or the organisations that the authors represent.

***HIV Australia* online includes additional content not published in the printed edition.**

Read more of *HIV Australia* at www.afao.org.au

We want to hear what you think about

***HIV Australia*.** Please send your feedback to the Editor, editor@afao.org.au or write to us at:

HIV Australia

C/- AFAO, PO Box 51, Newtown NSW 2042 Australia

HIV AUSTRALIA

Volume 9, No. 3

Australian news

News from the Asia Pacific

International news

Australia should lead a global HIV prevention revolution

BILL WHITTAKER calls for new prevention targets to guide Australia's response to HIV and outlines the steps needed to achieve them

PrEParing the way

DEAN MURPHY presents an overview of major biomedical prevention studies to date, and discusses perceptions and implications of pre-exposure prophylaxis within Australia and internationally

Are we prepared for biomedical HIV prevention? 11

The case of pre-exposure prophylaxis

MARTIN HOLT, JEANNE ELLARD and JOHN DE WIT draw on their recent research into biomedical HIV prevention in the Australian context, highlighting both risks and opportunities that new prevention technologies bring

The policy pendulum: can testing policy increase testing rates and reduce HIV transmission in Australia? 15

LEVINIA CROOKS reports on changes to the new Australian National HIV Testing Policy, tracing its development and exploring some of its aims

Rapid HIV Testing in Australia: what are the next steps? 17

PHILLIP KEEN proposes an action plan for rapid testing in Australia, following the introduction of the revised National HIV Testing Policy

The future of HIV testing: exploring new strategies to improve access to testing through community-based testing 20

ALISA PEDRANA and MARK STOOVÉ present a range of findings from their research into community-based testing in Australia

Who's calling the shots on gay men's health? 24

ANDREW BURRY and DAVID MILLS call for greater involvement of gay men in decisions regarding the introduction of new HIV testing technologies in Australia

4 Seize the day: the era of combination prevention 27

5 GEOFF HONNOR provides a definition of combination prevention and considers what it means for the response to HIV, presenting his views on how we should best engage with it

6 Treatment as prevention – another string to our bow 29

7 SEAN SLAVIN advocates for the benefits of combination prevention

9 The use of HIV treatment for prophylaxis and rehabilitation 31

JAE CONDON outlines the use of treatment as primary and tertiary prevention, explaining how careful management of an individual's treatment regime can dramatically improve quality of life

From social marketing to social change: a day in the life of an HIV-prevention campaign 33

PAUL MARTIN tracks the controversy and support surrounding Rip & Roll, a social marketing campaign for gay men

It's time to talk top: the risk of insertive, unprotected anal intercourse 36

ERIC M GLARE argues that discussions about HIV prevention and anal sex are missing an important element

Regional Feature: Testing, treatment and prevention among gay and other men who have sex with men in Japan 40

By JANE KOERNER and SEIICHI ICHIKAWA

Web Watch 44

Book review: *Gay and Lesbian perspectives VI* 45

ABIGAIL GROVES reviews a new collection of queer histories as recounted by Australian scholars

Treatment briefs 46

HIV Australia welcomes submissions from interested authors.

To submit an article or report for consideration, email editor@afao.org.au



AUSTRALIA

Australia's stable HIV rates no cause for complacency

New data released 27 September in the Kirby Institute's *HIV, Viral Hepatitis and Sexually Transmissible Infections in Australia Annual Surveillance Report 2011*, indicates that rates in HIV in Australia continues to remain stable, at around 1,000 new infections per year. However, Rob Lake, Executive Director of the Australian Federation of AIDS Organisations (AFAO), warns this is no reason to become complacent.

'Australia's HIV infection rates have been running a little above 1,000 cases per year since 2006. Australia now needs to move beyond this plateau and decrease infection rates,' Mr Lake said.

'As a signatory to the UN Political Declaration on HIV/AIDS, Australia has committed to a goal of a 50% reduction in new HIV infections by 2015. Containing the Australian epidemic is a significant achievement, but it's time to focus on reducing infection rates. This target would mean we'd be taking our UN commitment seriously; a 50% reduction in annual diagnoses would represent the lowest ever rate of HIV infection in Australia since the beginning of the epidemic,' Mr Lake said.

New NHMRC research grants announced

\$673.7 million in new National Health and Medical Research Council (NHMRC) grants were announced by The Minister for Mental Health and Ageing, the Hon Mark Butler, on 17 October.

In total, 1,140 grants were announced to support researchers, research projects and research institutions Australia-wide.

Grant recipients included Professor John De Wit of the University of NSW, who will receive \$419,897 to determine when and why people who are HIV-positive start antiretroviral treatment (ART). The study will examine the potential public health impact of promoting the use of ART on the HIV epidemic, contributing to the better use of treatments and HIV prevention. Professor Sean Emery from UNSW was awarded \$1,016,660.00 for a randomised trial to determine the safety and efficacy of early versus deferred treatment of HIV. There were also several basic science grants for HIV, and one on liver disease among people with HIV and hepatitis B co-infection.

Reform and debate stifled at CHOGM

The Commonwealth HIV/AIDS Action Group (CHAAG) has called for the immediate release of the full Eminent Persons Group (EPG) report, *A Commonwealth of the People – Time for urgent reform*, amid concerns the report's recommendations could be stymied without a full and frank public debate. This call was made in the lead-up to the Commonwealth Heads of Government Meeting (CHOGM), that took place 28–30 October 2011, in Perth.

CHAAG's call came after two members of the EPG, Dr Emmanuel Akwetey and Sir Ronald Sanders, expressed serious concern about the report's suppression, while speaking at the opening of the Commonwealth People's Forum in Perth. As at press time, the EPG Report, had not been released.

Also missing from the formal CHOGM agenda were issues relating to HIV, and laws that impede health-based responses to the pandemic. These issues include the decriminalisation of homosexuality, sex work and injecting drug use. International pressure has been building for the Commonwealth to address this. Prior to the meeting Australian Foreign Minister Kevin Rudd stated his intent to raise the issue of decriminalisation with foreign ministers from other Commonwealth countries attending the meeting, stating

that 'Australia encourages all countries to decriminalise homosexuality by removing all laws imposing criminal penalties for homosexual conduct,' Mr Rudd said. The Australian, UK and Canadian delegations all sought to raise this issue, without success.

The CHOGM Meeting in Perth was the first chance for Commonwealth Heads and Foreign Ministers to respond on behalf of the Commonwealth to these issues following the UN High Level Meeting on HIV/AIDS in New York and the accompanying 2011 *Political Declaration on HIV/AIDS*. They comprehensively failed to do so.

The EPG report was leaked by members of the Eminent Persons Group. Its recommendations relating to HIV and law reform have been referred to a committee of the Commonwealth Secretariat. CHAAG and AFAO have little expectation that this will result in any meaningful progress in this area in the short term.

New funding for HIV cure research

The push for HIV cure research has gathered momentum, with Burnet Institute's Professor Sharon Lewin named as one of seven researchers (and the only Australian) awarded a share in a \$40 million grant from the The US National Institutes of Health (NIH). The grant will fund three group collaborations, mostly based in the US, with a view that the three large groups will work together at some stage.

Discussing the research, Burnet Institute's Centre for Virology co-head and Alfred Infectious Diseases Unit director Professor Sharon Lewin said one of the key impediments to curing HIV was determining how the virus can lie dormant in 'resting cells' for years, despite long-term anti-HIV drug treatment.

'It's all new research and it's really exciting to be part of it. Not just because of the funding, but it's an opportunity for collaboration and access to amazing sample sets and to be part of new research internationally in its earliest stages,' Professor Lewin said.

Professor Lewin is in charge of three main projects, one of which will try and find a better way to track latently infected cells in patients on anti-HIV drugs. Another will use an infected sleeping cells model, that her lab recently developed, to screen new compounds that can wake persistent virus. The third project is related to a clinical trial of a cancer drug, examining how this drug might effect persistent HIV in patients on treatment. 'This funding will, without a doubt, accelerate the path to hopefully one day finding a cure for HIV,' Professor Lewin said.

ASIA-PACIFIC

New research shows regional HIV epidemic is here

New figures released at the 10th Asia Pacific AIDS Conference, held in South Korea in August, reveal alarming statistics indicating that the predicted HIV epidemic amongst men who have sex with men (MSM) and transgender people living in South-East Asia, has arrived.

In the Philippines, 70% of new infections are in MSM; in Delhi, 20% of MSM are estimated to be HIV-positive; in Indonesia, 25% of transgender people are estimated to be HIV-positive; and in Bangkok, an estimated 30% of MSM are living with HIV – with new research also showing a 10% annual infection rate among young men under 25. In Ho Chi Minh and Djakarta, HIV prevalence has tripled since 2008.

Responding to the latest figures, AFAO Executive Director Rob Lake has urged the Australian government, and in particular AusAID, to respond. 'All these statistics released at the

conference need to be appreciated in the context of the infection rate in the general community for all of these countries being under 1% ... We need a strong, targeted approach that reaches the most affected communities with effective education and support programs,' Mr Lake said.

WHO Asia-Pacific Regional Consultation on PrEP

A regional consultation on the potential applications of pre-exposure prophylaxis (PrEP) was held in Bangkok on 11–12 October. Civil Society was asked to join clinicians and policy makers to discuss how PrEP might be useful within the context of the HIV epidemic across Asia and the Pacific.

A civil society delegation presented the perspective from people living with HIV, alongside advocates for people who use drugs, men who have sex with men and sex workers.

A series of well-informed and robust discussions resulted in recommendations in relation to advocacy, policy, clinical research, and service delivery. Discussions highlighted a number of unresolved research questions around the safety of oral PrEP and rectal microbicides, and issues around resistance. Concerns were also raised by communities at risk regarding how best to assess the feasibility of PrEP pending full implementation of Universal Access for Prevention and Treatment. Another obstacle to effective PrEP implementation raised at the consultation was the need for additional funding and resources to support the roll-out of PrEP.

Information summarising outcomes and discussions from the conference

will soon be made available on the World Health Organisation (WHO) website, with a full WHO guidance document to follow at a later date.

INTERNATIONAL

Global Fund to transfer management of Mali grants

The Global Fund to Fight AIDS, Tuberculosis and Malaria reports that it will transfer management of a \$28.77 million HIV/AIDS grant from Mali's national AIDS council, the Haut Conseil de Lutte contre le Sida (HCLNS), to a new principal recipient at the end of the year. The decision follows preliminary results from an ongoing investigation by the Global Fund's Office of the Inspector General (OIG).

The scope of the grant will be limited between now and the end of the year to funding of essential services, to ensure continuity of treatment for 25,288 people in Mali who receive antiretroviral therapy with Global Fund support. Under the arrangement, it will also be possible to start new patients on treatment. Funding of all other activities, especially those which could put Global Fund grant money at risk of misappropriation, will be suspended with immediate effect.

This is the latest in a series of actions the Global Fund has taken to restore confidence in grant management in Mali after mismanagement of funds was discovered.

Expanded treatment for discordant couples could reduce HIV epidemic

A new study has been published which uses mathematical

continued overleaf

HIV AUSTRALIA

Got something to say?

Your views are important to the success of this publication.

HIV Australia publishes letters and contributions from readers.

If you want to respond to something you have read here, or have an idea for an article, please write to us at: editor@afao.org.au

modelling to predict the potential impact of expanding treatment to discordant couples in select African countries.

In the study, *Modeling the Impact on the HIV Epidemic of Treating Discordant Couples with Antiretrovirals to Prevent Transmission*¹, the authors designed a mathematical model that was able to determine the number of infections prevented as a result of treating discordant couples. They used their model to make predictions for Ghana, Lesotho, Malawi and Rwanda. The study uses data from HPTN 052, a recent clinical study indicating that treatment of the HIV in serodiscordant couples successfully reduced HIV transmission by 96%.

‘The findings from the modelling study provide insights into what to expect at a country level of expanding such a prevention strategy,’ noted Dr El-Sadr, one of the study’s authors. ‘Getting information to countries with regards to what they can expect from scale-up of treatment for discordant couples ... is critical to their decision-making,’ Dr El-Sadr said.

Reference

- 1 El-Sadr, W., Coburn, B., Blower, S. (2011). *Modelling the impact on the HIV epidemic of treating discordant couples with antiretrovirals to prevent transmission*. *AIDS*, October 11, [Epub ahead of print].

19th International AIDS Conference theme announced

Turning the Tide: 19th International AIDS Conference (AIDS 2012), will be held in Washington DC, July 2012. The conference will focus on recent scientific advances in HIV treatment and biomedical prevention, HIV cure research and the scale-up of key interventions. The theme, ‘Turning the Tide’, encapsulates optimism around key medical advances and their potential to change the path of the epidemic.

The 2012 event marks the first time that the conference has been held in

the US since the repeal of US travel restrictions for people living with HIV. However, a declaration of a history of sex work or illicit drug use remains in place as grounds for visa ineligibility, and could prevent conference delegates from entering the country.

The conference, convened by the International AIDS Society, plays a fundamental role in shaping the global response to HIV and keeping HIV on the international political agenda. A number of delegates from Australia attend each year.

Conference registration and abstract submissions for AIDS 2012 open December 2011. Further information is available at www.aids2012.org

Clinical trial shows vaccine may help prevent anal cancer

A large, international clinical trial led by doctors at the University of California, San Francisco, indicates that Gardasil, a vaccine which has been shown to be safe and effective in preventing infection with the human papillomavirus (HPV) also reduced the rates of pre-cancerous cell changes among men who have sex with men. The study was reported in the 27 October 2011 issue of *New England Journal of Medicine*.

Although anal cancer is less common than other forms of cancer, it disproportionately affects men who have sex with men and HIV-positive people. Anal cancer is caused by HPV, primarily HPV type 16 or 18, and is preceded by high-grade anal intraepithelial neoplasia (AIN) grade 2 or 3. Gardasil was effective in reducing the occurrence of AIN grades 2 and 3 among men in the study.

As anal cancer can take decades to develop, trials demonstrating Gardasil’s effectiveness against anal cancer would need to run for many years. The vaccine’s effectiveness in reducing AIN 2 and 3 is therefore significant,

as it provides important indirect evidence suggesting a likely effect in reducing anal cancers.

The trial took place between 2006 and 2008 and involved a group of 602 men between the ages of 16–26 years from Australia, Brazil, Canada, Croatia, Germany, Spain and the United States. All trial participants were men who have sex with men with a history of between one to five sexual encounters at recruitment.

The trial raises hopes that vaccination may help prevent anal cancers. ‘Based on these data, the vaccine works well to prevent HPV infection and precancerous anal disease, and will likely prevent anal cancer in men,’ said Joel Palefsky, the trial chief investigator. ‘The ideal time to begin vaccination would be before initiation of sexual activity, but vaccination may also be useful after initiation of sexual activity.’

The Gardasil vaccine is administered free to young girls in Australia, as a preventative measure against cervical cancer. Earlier this year, CSL – the manufacturer of Gardasil – applied to the Australian Pharmaceutical Benefits Advisory Committee (PBAC) to extend the free Gardasil vaccination program to boys aged 12 to 13 years old. CSL argued that ‘a gender-neutral vaccination strategy will have the greatest impact on HPV disease and is in the best interest of public health.’ The submission was rejected by PBAC due to concerns about cost and cost-effectiveness.

CSL is reapplying to PBAC to extend the free vaccination program to boys.

Disclaimer: AFAO is currently in negotiations with CSL regarding an unrestricted education grant to produce an information resource for gay and other men who have sex with men on HPV, vaccination and anal cancer.



Australia should lead a global HIV prevention revolution

By **Bill Whittaker**

The global fight against AIDS is at a crossroads. On the one hand we have exciting new scientific evidence which could dramatically reverse the pace of the HIV epidemic and prevent millions of new cases of infection, sickness and death. On the other hand, there is weariness and complacency after 30 years of the epidemic, as well as a global financial crisis putting tremendous pressure on national budgets around the world and threatening funding essential to reverse the relentless spread of HIV.

Mind-numbing statistics speak for themselves about the scale of the HIV epidemic and the work to be done: 30 million lives lost; another 33 million people living with HIV; and 7,000 new infections occurring every day, mostly among young people.

New HIV treatments are having a tremendous impact in reducing illness and AIDS-related deaths, but the sustainability of providing HIV treatment – especially in low to middle income countries – is threatened by the reality that for every one person put on HIV treatment, another two people become infected.

Recently, the United Nations agreed to a bold new Declaration to fight AIDS which Australia played a leading role in getting all UN Member States to endorse. A centrepiece of the UN Declaration are bold new HIV prevention targets for the global community to reach by 2015. These global targets include reducing sexual transmission of HIV by 50%; reducing HIV transmissions through injecting drug use by 50%; and eliminating mother to child HIV transmissions – all by 2015.

So how would these targets be achieved under the UN Declaration? Firstly, by dramatically scaling-up prevention programs; by freeing up access to HIV testing; by increasing HIV education alongside wide availability of condoms and sterile injecting equipment; by promoting male circumcision in certain contexts; and by fully exploiting the potential of new technologies for communication and connecting people – such as social media, mobile phones and the internet.

The UN Declaration also calls for global action to ensure that HIV

prevention programs properly focus on the three populations which are universally at higher risk of exposure to HIV – specifically men who have sex with men, sex workers and their clients and people who inject drugs.

Finally, the Declaration calls for new scientific evidence about the additional prevention benefits that HIV treatment can deliver, in order to best capitalise on them. So just as HIV treatment was revolutionised 15 years ago by combining different drugs – termed ‘combination treatment’ – the Declaration heralds an era of ‘combination prevention’, where proven prevention programs and innovative methods of communication are combined with wide availability of HIV treatment to help drive down rates of new HIV infections.

So what should this mean for Australia? Our rate of new HIV infections is running at around 1000 new infections per year, mostly among gay men. But should we be satisfied with this level of new infections – the

continued overleaf

personal and community impact of this – and the something like \$AUD1 billion plus price-tag that comes with each 1000 new infections? Of course not.

It is also worrying that new research on gay men in Australia shows increasing rates of some sexually transmitted infections, a decline in levels of regular HIV testing and increased unprotected sex. This is a further wake up call for us.

Australia has endorsed the need to re-orient and re-double prevention efforts as called for in the UN Declaration. There is a global expectation that we will lead by example. The starting place for this is through our National HIV Strategy, and state/territory HIV Strategies. The current National HIV Strategy is fine on principles, but scant on actions and enhanced funding – and its implementation has been slow and a source of frustration.

Unhelpfully, this current 6th National HIV Strategy and most state/territory Strategies, also continue the lamentable drift in previous National Strategies away from setting ambitious, time-bound targets to be achieved. This contradicts the approach that we have committed to do under the 2001 and 2011 Declarations and what other countries, for example the USA, are now doing in relation to use of ambitious goals and targets for their own domestic response.

Adoption of the 2011 Declaration and reaching the mid-term point of our current National Strategy – plus the fact that a number of state/territory HIV Strategies have expired – is the opportunity for us to embrace combination prevention and set new prevention targets based on the 2011 Declaration and appropriate to our epidemic.

So, what should this revitalised Australian HIV prevention effort be comprised of?

Firstly, new information campaigns – including use of social media and the internet – are needed to update people with HIV about the emerging

evidence concerning the health benefits associated with starting treatment early, including above 500 CD4 counts, and the impact that treatment has on reducing HIV transmission.

Secondly, doing a thorough analysis of the potential for pre-exposure prophylaxis with antiretroviral drugs, including the potential for pre-exposure prophylaxis using antiretrovirals selectively in the most at risk HIV-negative people. But we do have to note the limitations in the data and concerns over the suitability of current drug regimens – and realise that the greatest prevention benefit from treatment will be achieved at this point through HIV-positive people taking up early HIV treatment.

Thirdly, widely promoting the concept of ‘combination prevention’ – where successful strategies like correct and consistent condom use are employed, together with harm reduction strategies such as safe injecting practices, as well as increasing uptake of HIV treatment among people with HIV. Promotion of these concepts should take full advantage of new modes of communication, such as social media.

Fourthly, removing the ambiguity in prescribing criteria for antiretroviral treatments for people with HIV, in particular the removal of arbitrary prescribing restrictions for HIV positive people with CD4 counts above 500, so that doctors can prescribe ARVs for patients who wish to take up early treatment.

Fifthly, rolling out HIV testing campaigns and strategies like wider health provider initiated HIV testing and rapid testing, including in community settings, as soon as possible.

Finally, we should set bold prevention targets and timelines to generate momentum and assess progress against, consistent with the 2011 UN Declaration’s targets, but adapted to the Australian context, which would include:

- Reducing sexual transmission of HIV among men who have sex with men by 80% by 2015

- Eliminating HIV transmission from injecting drug use by 2015
- Eliminating HIV transmission among sex workers and clients by 2015.

These prevention targets should be complemented by a treatment target of having 90% of people with HIV in Australia on HIV antiviral treatment by 2013. (To support this target, user friendly measures like community dispensing of HIV antivirals and lessening the burden of pharmacy item co-payments need to be reviewed.)

These are the kind of bold actions that the 2011 UN Declaration calls for and that all countries, including Australia, have pledged to implement.

Australia has shown great leadership and innovation in HIV prevention. One of the best things Australia can do to support a global HIV prevention revolution is to lead by example and champion what we are doing. We must not miss this opportunity to re-vitalise our HIV prevention strategies and to help lead global efforts to stop the spread of HIV and its devastating impact on so many millions of people around the world.

This article is based on an address given by Bill Whittaker on 29 September 2011 at the 2011 Australasian Society for HIV Medicine Conference in Canberra.

Bill Whittaker is one of the architects of Australia’s response to AIDS and has worked in HIV policy and strategy for more than 25 years. He is a former President of the Australian Federation of AIDS Organisations and CEO of the AIDS Council of NSW (ACON). He participated in the United Nations Special Sessions on HIV in 2001, 2006 and 2011. Bill is a commissioner with the UNAIDS High Level Commission on HIV Prevention. He is also a special representative of the National Association of People with HIV (Australia) and a Board member of Pacific Friends of the Global Fund to Fight AIDS, TB and Malaria.



PrEParing the way

By Dean Murphy

In a little over a year we have seen the results of several trials of different antiretroviral (ARV)-based HIV prevention strategies, most of which have shown the potential of these interventions to reduce the risk of HIV acquisition. However, concerns about the impact of pre-exposure prophylaxis (PrEP) on condom use has hampered discussion about rolling out this strategy.

Evidence and controversy

There is now a growing body of evidence indicating the potential of ARV drugs in preventing sexual transmission of HIV. This includes the recent results from a study examining the impact of ARV therapy on transmission ('treatment as prevention'), as well as several studies of pre-exposure prophylaxis and one study of a vaginal microbicide. The greatest overall efficacy was demonstrated by the HPTN 052 trial, in which early initiation of ARV treatment by the HIV-positive partner showed a 96% reduction in HIV transmission.

Although these studies provide a great deal of hope for ARV-based prevention, only one of the recent trials – a Phase III clinical trial (called iPrEx) of daily oral dosing of ARVs to prevent HIV acquisition – was conducted among men who have sex with men, and potentially has an immediate and direct impact on the Australian epidemic. In November 2010, the results of this study were released showing that *Truvada* (tenofovir plus emtricitabine) is effective in reducing sexual acquisition of

HIV by 44% among men who have sex with men. A post hoc analysis showed that among those participants in the PrEP arm of the trial who were most adherent to the daily dosing regimen, the risk of contracting HIV was even lower – 73% lower than the placebo group. All participants in the study who remain HIV-negative have been invited to take part in a rollover study called iPrEx OLE (which stands for open label extension). Everyone in this study will be receiving *Truvada* and the study will be looking at longer term efficacy and safety, adherence, drug resistance, bone mineral density and fat distribution, impact on hepatitis infection, and changes in sexual behaviour.

TIME Magazine pronounced the iPrEx study as the top medical breakthrough of 2010.¹ However, there has also been a backlash against the idea of gay men using PrEP instead of condoms to prevent HIV (see campaign by AIDS Healthcare Foundation below). Also, in Australia, the responses from the media and from HIV organisations have been very cautious; even though the iPrEx trial results show that PrEP is an intervention that reduces HIV risk, PrEP is also continually positioned as undermining prevention. While it is true that any particular prevention strategy could be undermined by other changes in the external environment, what is odd in this debate is the positioning of PrEP as likely to cause more infections. This argument hinges on three different aspects:

1. condom migration (or risk compensation)
2. assumptions about adherence and efficacy in a post-trial or 'real life' context, and
3. concerns about informal use and the extrapolation of results of a daily dosing study to intermittent or event-based dosing.

Mathematical models have been constructed to look at various scenarios, including the implementation of PrEP in Australia. This modelling has suggested that if all gay men take PrEP with an overall individual level of efficacy similar to that reported in the iPrEx trial, then there would be a 50% reduction in cumulative infections over the next 10 years.² Other scenarios with only those men at highest risk of HIV taking PrEP – even if condom use and other risk reduction strategies decrease – suggest that PrEP can still have an impact if coverage and adherence are sufficiently high. Also, these more targeted strategies may make PrEP cost effective, although this would not likely be the case if it was a broad-based intervention.

In the United States, there has been a campaign against PrEP – and more particularly against the manufacturer, Gilead – by the AIDS Healthcare Foundation, a healthcare and advocacy organisation, which has campaigned against FDA (Food and Drugs Administration) approval of this drug

continued overleaf

for HIV prevention. The organisation has taken out full-page advertisements in gay print media in the United States claiming that gay and bisexual men will act recklessly and will spread HIV if they are allowed to use PrEP.

Guidelines for PrEP use

As a result of the iPrEx study results, the Centers for Disease Control and Prevention (CDC) issued interim guidance for the use of PrEP among men who have sex with men in the United States at high risk of HIV infection. (Note: FDA only regulates the marketing of drugs in the United States – not prescribing practice – so a licensed physician may prescribe off-label use of the drug regardless of FDA approval for this purpose.) However, as there are no immediate plans to make PrEP available in Australia for this purpose, there will be no benefit to Australian gay men as a result of the first randomised controlled trial shown to reduce HIV transmissions among this group.

Potential subgroups for targeting of PrEP in Australia have been identified by Poynten et al.³ These groups – men who have unprotected anal intercourse (UAI) with a known HIV-positive partner, receptive UAI with casual partners, and report use of both oral erectile dysfunction medication and methamphetamines – account for more than 70% of seroconversions (and have an HIV incidence of greater than 2%).⁴

At the time the iPrEx study results were released, AFAO noted the appropriateness of PrEP for some individuals or groups at very high-risk of HIV infection. Such individuals have yet to be specifically identified, but the article by Poynten et al., cited above should be a starting point for such consideration. More specifically, men at high risk may be identified through clinicians – for example HIV-negative partners in serodiscordant couples where the other partner does not have suppressed viral load (and

do not consistently use condoms), and men who have used PEP on a number of occasions after unprotected receptive anal intercourse.

There has been a general tendency to frame biomedical prevention as a threat to existing 'behavioural' prevention instead of a supplement to it. Given that there are no plans to make PrEP available in Australia, FDA approval for marketing of *Truvada* as prevention in the US may lead to more informal use of PrEP in this country. Currently, use of ARVs as PrEP is very low; recent research suggests that although HIV-negative men are somewhat interested in PrEP they are still worried about taking ARVs on an ongoing basis and the possible side effects of the drugs.⁵ Given these concerns by gay men – and the likelihood that PrEP would only be accessed by a small number of men – as is the case in the US – serious attention needs to be paid to PrEP so that the only option is not an informal one.

PrEP projections

In Australia, the majority of gay men surveyed in early 2011 indicated they would be willing to take PrEP.⁶ Only about half the men believed they would never need to take it. Less than one-quarter said they are going to use it as soon as it becomes available. More analysis will need to be undertaken to examine whether those who are most enthusiastic about PrEP are those men who are also those at highest risk for HIV, but it seems likely there is not going to be a rush to replace other HIV prevention strategies with PrEP except among those who are probably not currently (or consistently) using other strategies, including condoms. A qualitative arm of the Australian study referred to above is currently interviewing gay men about the acceptability of PrEP, including issues such as the use of existing HIV treatment drugs for preventing HIV acquisition, and possible stigma associated with PrEP use, both of which may have an impact on how

PrEP is understood and taken up by gay men.

Other PrEP study results

The results of two studies were released in July 2011 demonstrating that taking ARVs as pre-exposure prophylaxis (PrEP) reduces sexual transmission of HIV among heterosexual couples. The Partners PrEP study of 4,758 men and women in serodiscordant couples in Kenya and Uganda released results early because of the overwhelming outcome. The participants in the study were couples in which one partner was HIV positive and the other was HIV negative. The HIV-negative partners were assigned to one of three groups: tenofovir; *Truvada*; or placebo. There were 47 infections in people on placebo, compared to only 18 in those taking tenofovir (a 62% reduction) and 13 in those taking *Truvada* (a 73% reduction). Women and men were equally protected. The study will now continue. All participants receiving tenofovir only or *Truvada* will remain on those medications, and those receiving placebo will start receiving tenofovir or *Truvada*.

In the other study (CDC TDF2) in Botswana, 1,219 men and women were assigned to take either *Truvada* or placebo. Nine people taking *Truvada* became infected compared to 24 taking placebo – a 63% reduction. The results from these studies are in contrast to the FEM-PrEP study of 2,000 women in Kenya, Zimbabwe, South Africa, which was stopped earlier this year because *Truvada* provided no protection for the women in this study arm. More research and analysis needs to be conducted to understand why these studies had different results. It is likely that adherence plays a major role, as already indicated by detailed analyses of the iPrEx study results. Adherence in the Partners PrEP study was reported to be 97%, which may be attributed to the fact that participants were more motivated to take the medication because they were in a known serodiscordant relationship.

STUDY NAME	RESULTS RELEASED	POPULATION	DESIGN	RESULT
Partners PrEP	July 2011	Heterosexual serodiscordant couples (Kenya, Uganda) 4,578 couples	Oral daily tenofovir vs. <i>Truvada</i> vs. placebo	Tenofovir reduced HIV risk by 62%; <i>Truvada</i> reduced risk by 73%. (No statistical difference between groups.)
CDC TDF2	July 2011	Heterosexuals (Botswana) 1,219 men and women	Oral daily <i>Truvada</i> vs. placebo	<i>Truvada</i> reduced HIV risk by 62.6%
HPTN 052	May 2011	Serodiscordant couples (Africa, Asia, Americas) 1,763 couples	Immediate or deferred antiretroviral therapy for HIV-positive partner	96% reduction in HIV transmission
FEM-PrEP	April 2011	Women (Kenya, Zimbabwe, South Africa) 2,000 women	Oral daily <i>Truvada</i> vs. placebo	<i>Truvada</i> provided no protection (Trial closed early due to futility)
iPrEx	Nov 2010	MSM (Peru, Ecuador, Brazil, USA, Thailand, South Africa) 2,499 men	Oral daily <i>Truvada</i> vs. placebo	<i>Truvada</i> reduced risk by 44%
CAPRISA 004	July 2010	Women (South Africa) 889 women	1% tenofovir gel vs. placebo	39% reduction in HIV risk

Table 1 Recent HIV biomedical prevention studies.

In September 2011, researchers from the VOICE (Vaginal and Oral Interventions to Control the Epidemic) study announced that one of the study arms would be closed. An interim analysis had found that even if it continued to its scheduled completion date, the study would not be able to show whether oral tenofovir tablets were any better than a placebo for preventing HIV in the women assigned to that study group. This study involves 5,029 women at 15 trial sites in Uganda, South Africa and Zimbabwe. The study was designed with five study groups: tenofovir gel, a placebo gel, oral tenofovir, oral *Truvada* and a placebo tablet. All the other study arms will continue to the schedule's trial completion date. VOICE is an important study because it is the only trial evaluating a daily oral pre-exposure prophylaxis and a vaginal gel in the same study. This design will determine how each product works compared to its control (placebo gel or placebo tablet) and which approach women prefer.

Conclusion

These results from several trials of antiretroviral-based HIV prevention strategies show that pre-exposure

prophylaxis is efficacious among gay men and heterosexual couples. Concerns about cost-effectiveness and the impact of pre-exposure prophylaxis (PrEP) on condom use have hampered discussion about implementing PrEP in Australia. Even though the iPrEx trial results show that PrEP is an intervention that reduces HIV risk, PrEP is also continually positioned as undermining prevention. Recent research suggests that although the majority of gay men are open to the concept of PrEP, most do not believe that they would ever need to use it and most also indicate they would be unlikely to give up condoms even if they were using an ARV-based prevention strategy. However, for the minority of men who are at high risk of HIV infection and are willing to use ARVs, PrEP may be an important intervention.

For more information: <http://www.avac.org/ht/display/ReleaseDetails/i/35455/pid/212>

References

- 1 Park, A. (2010, 9 December). AIDS drugs lower the risk of HIV infection. Available at: http://www.time.com/time/specials/packages/article/0,28804,2035319_2034529_2034513,00.html (Accessed 4 October 2011).

- 2 Gray, R., Prestage, G., Down, I. et al. (2011, September). *HIV Pre-exposure prophylaxis for Australian gay men is effective but too expensive*. Paper presented at 23rd Australasian HIV/AIDS Conference, Canberra. Paper no. 466.
- 3 Poynten, I., Jin, F., Prestage, G. et al. (2010). Defining High HIV Incidence Subgroups of Australian Homosexual Men: Implications for Conducting HIV Prevention Trials in Low HIV Prevalence Settings. *HIV Medicine*, 11: 635–641.
- 4 Ibid.
- 5 Murphy, D., Holt, M., Callander, D. et al. (2011, September). *Measuring attitudes towards HIV pre-exposure prophylaxis (PrEP): findings from the PrEPARE Project*. Paper presented at 23rd Australasian HIV/AIDS Conference, Canberra. Paper no. 304.
6. Ibid.

Dean Murphy works at AFAO in the areas of HIV education and biomedical prevention.



Are we prepared for biomedical HIV prevention? The case of pre-exposure prophylaxis

By **Martin Holt**, **Jeanne Ellard** and **John de Wit**

In the last two years a number of landmark results have been announced from international trials of biomedical HIV prevention technologies. A trial of an HIV vaccine candidate in Thailand found a reduction in HIV infection of 26%.¹ A vaginal microbicide gel containing tenofovir, an antiretroviral drug, showed a 39% reduction in HIV infection among the women who used the gel.² Three trials of pre-exposure prophylaxis or PrEP (HIV-negative people taking a daily dose of tenofovir, or tenofovir and emtricitabine) have found efficacy levels of 44–73% in preventing HIV infection^{3,4,5} and

the HPTN 052 study has confirmed what many had already suspected: early and sustained HIV treatment reduces the transmission of HIV by 96% between serodiscordant partners⁶. These findings have stimulated a great deal of interest and international debate. While the findings from the vaccine and microbicide trials indicate more work needs to be done to make these technologies useful ‘in the field’, the success of antiretroviral treatment in preventing transmission between serodiscordant partners has renewed discussion about treatment access and initiation guidelines. The PrEP trial

results also appear compelling enough to make PrEP available in some settings. For example, the Centers for Disease Control and Prevention have issued interim guidelines for the prescription and monitoring of PrEP use in the United States.⁷

As yet there appear to be no plans to make PrEP available in Australia, although clinicians, policymakers, educators and researchers will be considering the issue over the coming months. What is clear is that the prevention landscape is changing, and that this requires thought, planning and careful monitoring of the impact

on the epidemic. The promise of new prevention options is welcome, but there are risks as well as opportunities.

One of the primary considerations is the effect of new prevention options on existing (and effective) practices such as condom use. The perception that new technologies may make HIV more difficult to get (or easier to manage) can lead to what is referred to as 'risk compensation'; a decreased likelihood to use condoms in general and particularly with partners whose HIV status is different or unknown to you.⁸ The concern here is not so much the likelihood of risk compensation among people using the new technology (who will be protected to some degree from HIV) but the likelihood of risk compensation among the broader community, in which a decline in condom use might lead to an increase in HIV infections. This effect has been seen before when combination antiretroviral treatments became widely available. It was found that optimism about HIV treatments was associated with subtle but significant increases in the rates of unprotected sex among gay men in Australia, and an increased likelihood of HIV seroconversion in some countries, although this pattern is far from clear internationally.^{9,10,11,12}

Social science research has an important role to play in planning for, adapting to and monitoring the effects of biomedical HIV prevention. This role is not just to identify which people are willing to use new technologies or how best to implement them (although that is undoubtedly important). Social scientists, like many of their biomedical peers, are also interested in how trial efficacy translates into real world effectiveness, the unintended and unforeseen consequences of new technologies, and the impact of technological innovation on social networks, cultures and perceptions of risk.¹³ The social, biomedical and technological are not separate domains, but intertwine and mutually affect each other.¹⁴ We therefore need to

attend to the ways in which biomedical technologies are taken up, used in line with or against clinical guidelines or educational recommendations, and the flow-on effects that these combinations of people, technologies and knowledge about HIV have on existing cultures of safety and risk. For example, how would PrEP use be viewed by the majority of gay men who currently use condoms? How would this play out in sexual situations in which one partner is using PrEP while another expects to use condoms? What are these actors' expectations of appropriate sexual conduct, safety and risk?

We have begun to explore some of these issues in a pilot study of Australian gay and bisexual men's attitudes to and expectations of PrEP (the PrEPARE Project). In collaboration with colleagues at the University of New South Wales, the Australian Federations of AIDS Organisations and Goldsmiths College, London, we completed a national, online survey of gay and bisexual men earlier this year and are currently conducting follow-up, qualitative interviews in Sydney. The survey revealed that most HIV-negative and untested men surveyed were interested in PrEP, with nearly 8 out of 10 saying they would be willing to take PrEP to prevent getting HIV. Nearly half said they would take PrEP even if it wasn't 100% effective and half said they were prepared to pay for PrEP. However,

there was also caution about PrEP; only a quarter thought that PrEP would be effective in preventing HIV and over half were worried about taking it on an ongoing basis. Two-thirds were concerned about potential side effects.

We have conducted additional analyses to identify which HIV-negative and untested men are most interested in using PrEP and the likelihood of decreased condom use among men willing to take PrEP. Of note is the finding that men who engage in unprotected anal intercourse with casual partners and who perceive themselves to be at risk of HIV are particularly likely to be interested in PrEP. These men are also quite likely to report problems in using condoms. This suggests that there is a specific group of men who are interested in using PrEP and who would benefit from it (or other prevention options). It may be that PrEP is simply too expensive to offer through the public health system in Australia. However, our findings suggest that PrEP, if judged to be sufficiently effective, could be targeted to those most at risk of HIV infection in Australia, rather than made widely available.

PrEP and other technologies in development require careful analysis and monitoring by social researchers.

continued overleaf

It was found that optimism about HIV treatments was associated with subtle but significant increases in the rates of unprotected sex among gay men in Australia, and an increased likelihood of HIV seroconversion in some countries, although this pattern is far from clear internationally.

When new prevention options become available, we have an investment in them being implemented in the most effective ways. That means paying close attention to the expectations of affected communities, the likely ways new prevention technologies will be used, and the potential impacts on existing sexual cultures. In our opinion, it does not matter whether PrEP becomes formally available in Australia in the near future (although that conversation is already underway). In the Melbourne and Sydney Gay Community Periodic Surveys (conducted in early 2011) 1.5% of gay men reported the use of antiretroviral drugs as non-prescribed PrEP.^{15,16} This is the first reported use of PrEP in Australia, despite it being not officially available. This confirms our previous experience that gay men in particular will react to developments within the field, adapting their sexual practices and meanings of risk in reference to trial results, new technologies and other forms of biomedical knowledge.¹⁷ This process may be subtle, and its effects difficult to ascertain. However, that does not mean we should avoid engaging with these developments. Indeed, it is essential that we do.

References

- 1 Rerks-Ngarm, S., Pitisuttithum, P., Nitayaphan, S., Kaewkungwal, J., Chiu, J., Paris, R., et al. (2009). Vaccination with ALVAC and AIDSVAX to prevent HIV-1 infection in Thailand. *New England Journal of Medicine*, 361(23), 2209–2220.
- 2 Karim, Q., Karim, S., Frohlich, J., Grobler, A., Baxter, C., Mansoor, L., et al. (2010). Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*, 329(5996), 1168–1174.
- 3 Baeten, J. (2011). *Antiretroviral pre-exposure prophylaxis for HIV-1 prevention among heterosexual African men and women: the Partners PrEP study*. Paper presented at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rome.
- 4 Grant, R., Lama, J., Anderson, P., McMahan, V., Liu, A., Vargas, L., et al. (2010). Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *The New England Journal of Medicine*, 363, 2587–2599.
- 5 Thigpen, M., Kebaabetswe, P., Smith, D., Segolodi, T., Soud, F., Chillag, K., et al. (2011). *Daily oral antiretroviral use for the prevention of HIV infection in heterosexually active young adults in Botswana: results from the TDF2 study*. Paper presented at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rome.
- 6 Cohen, M., Chen, Y., McCauley, M., Gamble, T., Hosseinipour, M., Kumarasamy, N., et al. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*, 365(6), 493–505.
- 7 Centers for Disease Control and Prevention. (2011). Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men. *Morbidity and Mortality Weekly Report*, 60(3), 65–68.
- 8 Eaton, L., and Kalichman, S. (2007). Risk compensation in HIV prevention: implications for vaccines, microbicides, and other biomedical HIV prevention technologies. *Current HIV/AIDS Reports*, 4, 165–172.
- 9 Elford, J. (2006). Changing patterns of sexual behaviour in the era of highly active antiretroviral therapy. *Current Opinion in Infectious Diseases*, 19(1), 26–32.
- 10 Stolte, I., Dukers, N., Geskus, R., Coutinho, R., & de Wit, J.. (2004). Homosexual men change to risky sex when perceiving less HIV/AIDS threat since availability of highly active antiretroviral therapy: a longitudinal study. *AIDS*, 18, 303–309.
- 11 Van de Ven, P., Rawstorne, P., Nakamura, T., Crawford, J., Kippax, S. (2002). HIV treatments optimism is associated with unprotected anal intercourse with regular and casual partners among Australian gay and homosexually active men. *International Journal of STD & AIDS*, 13, 181–183.
- 12 Van der Snoek, E., De Wit, J., Mulder, P., Van der Meijden, W. (2005). Incidence of sexually transmitted diseases and HIV infection related to perceived HIV/AIDS threat since highly active antiretroviral therapy availability in men who have sex with men. *Sexually Transmitted Diseases*, 32(3), 170–175.
- 13 Imrie, J., Elford, J., Kippax, S., & Hart, G. J. (2007). Biomedical HIV prevention—and social science. *The Lancet*, 370(9581), 10–11.
- 14 Rosengarten, M., Michael, M., Mykhalovsky, E., Imrie, J. (2008). The challenges of technological innovation in HIV. *The Lancet*, 372(9636), 357–358.
- 15 Hull, P., Holt, M., Mao, L., Kao, C., Prestage, G., Zablotska, I., et al. (2011). *Gay Community Periodic Survey: Sydney, February 2011*. National Centre in HIV Social Research, The University of New South Wales, Sydney.
- 16 Lee, E., Holt, M., Mao, L., McKenzie, T., Batrouney, C., Kennedy, M., et al. (2011). *Gay Community Periodic Survey: Melbourne 2011*. National Centre in HIV Social Research, The University of New South Wales, Sydney.
- 17 Kippax, S., Race, K. (2003). Sustaining safe practice: twenty years on. *Social Science & Medicine*, 57(1), 1–12.

This confirms our previous experience that gay men in particular will react to developments within the field, adapting their sexual practices and meanings of risk in reference to trial results, new technologies and other forms of biomedical knowledge.

Dr Martin Holt, Dr Jeanne Ellard and Professor John de Wit work at the National Centre in HIV Social Research (NCHSR), based at the University of New South Wales. A version of this article appeared in the NCHSR's Annual Report of Trends in Behaviour 2011.

The policy pendulum: can testing policy increase testing rates and reduce HIV transmission in Australia?

By **Levinia Crooks**

Australia first introduced a formal HIV testing policy in 1998 and revised it in 2006. In approaching the 2011 revision, the Expert Reference Committee asked itself a major question: at this point in time – and looking forward – is there any need for a National HIV Testing Policy?

We believe that there is a clear need for a national policy. A number of issues – including the introduction and treatment of new testing technology – require advice and guidance that a new HIV testing policy can deliver. More importantly, as our understanding of HIV and its management changes, so too does the role of HIV testing. Although the number of new HIV infections across Australia remains fairly stable, it is our hope that an effective testing policy will make it possible to reduce rates of new HIV infection.

For people living with HIV, the earliest possible diagnosis contributes to both better clinical outcomes as well as reduction in onward transmission¹; the new HIV testing policy facilitates more effective ways of achieving this. From my perspective, it was also vital to create a testing policy resource which was easily accessible to both practitioners and those seeking testing. The review of the testing policy presented an opportunity to put the new policy into an interactive web-based format, in order to effectively promulgate the most up-to-date information to the sector. The web format allows us to provide additional support, so that medical practitioners conveying results can easily access the resources necessary to best assist them, and share these resources with their patients.

Following are a range of considerations and implications relevant to the development of the new testing policy.

Overcoming hurdles to the introduction of point of care (PoC) testing

Traditional pathology tests are those where a sample is taken from the patient and then sent to the laboratory for testing and interpretation, while PoC tests are interpreted on the spot with the patient.

The previous testing policy recommended against the use of PoC testing in Australia, despite them being widely used in many other countries.² This presented a major barrier to the introduction of PoC testing in Australia because without a policy that was at least supportive of evaluating their use in the Australian environment, the Therapeutic Goods Administration (TGA) had no mandate to start accessing the efficacy of PoC tests and producers of the tests had no incentive to lodge applications.

The 2011 National HIV Testing Policy now gives the green light to PoC tests undergoing evaluation. Having this hurdle removed means that producers of PoC tests will not see the policy as hostile and a barrier to their applications. But that still means there is quite a way to go before PoC tests are licensed in Australia. Accommodating PoC tests into the testing process will take some time, as the evaluation process is rigorous and the steps involved getting an approved test into use can take many months.

New concepts

The new policy also introduces some new concepts; the concept of ‘informed consent’ in place of pre-test discussion (formerly pre-test counseling) and ‘conveying a test result’ in place of post-test counseling. Informed consent is what we have always been trying to achieve before

initiating a test. These new concepts make this goal explicit. The new policy also allows the concept to span testing for a number of conditions in addition to HIV. We aim to standardise this language across testing for a number of conditions, including HIV, hepatitis C and B and other sexually transmitted infections (STIs).

Educational tools for doctors and patients

In the past we have expected practitioners to be fully up to date with matters relating to HIV at the point they were requesting HIV tests. At the same time data tells us that doctors are only very infrequently called upon to use this knowledge. This is not an effective use of resources, doctors who may have received some training in HIV years ago cannot always rely on their recall. What they need is access to current information relevant to their setting and to be able to talk to a more experienced practitioner if necessary. The new policy approach and our offering of support to new diagnoses can provide this.

We know from existing testing patterns that most practitioners performing HIV testing have little experience of conveying a positive test result. When ASHM reviewed data from a number of jurisdictions we found that many doctors had only conveyed one HIV-positive result in the previous five to eight year period.³ It is not realistic to expect health practitioners to remember training which has never been put into use, so having an accessible and useable policy, and relevant attachments and resources, available online seems a much more rational approach. The

continued overleaf

provision of online resources will assist in delivering a positive test result by making a range of procedural guidance and information easily available – for both the practitioner and the patient.

The 2011 policy aims to have results conveyed in a clinical setting and to use any result as an opportunity for education. It also recognises that a one-off positive result can require a very tailored response and that people need to be able to readily access accurate information.

A positive HIV test result may be the result the patient expected or it may come as a complete surprise. Whatever the circumstance, it is a difficult situation for both the patient and the person providing the result. In the past, few people would have reached for the HIV testing policy for practical advice, patient fact sheets, referral information or general advice. With the testing policy being presented as a website with lots of linked resources, we hope that practitioners will reach for the website as a first point of call.

Limitations

Whether any of the above features will reduce HIV transmissions remains the important, but unresolved, question.

We know a number of newly diagnosed infections are being identified in people who acquired their infection outside Australia.⁴ This new policy is likely to have little impact on those numbers. At best it will perhaps allow us to make the HIV diagnosis sooner. Different arms of government look to substantive policy such as this to help them arrange their services. It is particularly important that refugees get access to timely health assessment. This policy, in recognising and stating the benefits of early detection and treatment of HIV, assists in facilitating the timely assessment and management of HIV among refugees and humanitarian entrants.

In the event that a PoC test is evaluated and licensed for use in Australia, we will need to make absolutely sure that

those using such a test are aware of its limitations. The tests currently in production (though not licensed for use as PoC tests in the community) cannot detect HIV infection as early as those tests which are performed in the laboratory. So it will be important that those doing the tests and the patients being tested are aware of this.

The future

We know that many people contract HIV from people who have only recently become infected themselves, and thus may be totally unaware of their own positive status; we have seen this data from a range of sources. For instance, data from a Melbourne study by Alisa Pedrana and colleagues indicated that 20% of gay men who tested HIV-positive held an incorrect belief about their HIV-negative status.⁵ We have also seen this from serological studies undertaken by Doris Chibo and Chris Birch who have identified clusters of related recent HIV infections.⁶ How often this occurs is hard to determine because of the lag time between infection and diagnosis. Along with studies looking at PoC testing, I think it would be timely to look more closely at people recently identified as contracting HIV. The more we can find out about these events the better we might be able to assist in driving down new infections.

The testing pendulum has swung from: don't test there is nothing you can do about it, to test and seek prophylaxis for opportunistic infections, and then access ARV treatment. Frequent testing will identify new infections earlier. Adoption of protective behaviours following infection will stop onward transmission. But no amount of testing will prevent a new infection from occurring when a person is exposed to HIV. The risk of contracting HIV from such an exposure will largely be contingent on the source patient's HIV viral load; we know this is highest during seroconversion and in early infection. We hope that the new HIV testing policy will help us to more

effectively intervene at this crucial early stage.

Please take the time to review the new HIV testing portal <http://testingportal.ashm.org.au>. We appreciate your feedback.

References

- 1 Marks, G., Crepaz, N., Senterfitt, J., and Janssen, R (2005). Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: Implications for HIV prevention programs. *Journal of Acquired Immune Deficiency Syndromes*, 39(4), 446–453.
- 2 Pedrana, A., Guy, R., Bowring, A., Hellard, M. and Stoové, M. (2011). *Community models of HIV testing for men who have sex with men (MSM): Systematic Review 2011*. Report commissioned by ACON.
- 3 McGuigan, D., Wheeler, E., Bowden, V. (2010). *One Year On: Interim Findings from the 'GP Mentoring at the Time of HIV Diagnosis' Project*. Paper presented at the 2010 Australasian HIV/AIDS Conference, Sydney, 20–22 October 2010.
- 4 The Kirby Institute. (2011). *HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2011*. The Kirby Institute, the University of New South Wales, Sydney.
- 5 Pedrana A, Hellard M, Wilson K, Guy R and Stoové M. (2011) [in press]. High rates of undiagnosed HIV infections in a community sample of gay men in Melbourne, Australia. *JAIDS* – accepted 22/09/2011.
- 6 Chibo, D., Kaye, M. and Birch, C. (2011). HIV Transmissions During Seroconversion Contribute Significantly to New Infections in Men Who Have Sex with Men in Australia. *AIDS Res Hum Retroviruses*, Sept. 21 [Epub ahead of print]. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21806486> (accessed 11 October 2011).

Levinia Crooks is the Chief Executive Officer of ASHM, the professional organisation which provides support to the health workforce in HIV, viral hepatitis and sexually transmissible infections. Levinia has worked in the HIV and related diseases area for 25 years and has recently co-chaired the Expert Reference Committee overseeing the development of Australia National Testing Policy.



Rapid HIV Testing in Australia: what are the next steps?

By Phillip Keen

The revised National HIV Testing Policy was launched at the 2011 ASHM Conference by Levinia Crooks, ASHM CEO, and Co-Chair of the Expert Reference Committee responsible for developing the new policy (see page 15 for an article by Levinia Crooks describing key features of this policy). The revised policy supports the use of rapid HIV testing in some circumstances. Phillip Keen discusses some next steps, now that the policy support for rapid HIV testing is in place.

Introduction

Policy support for use of rapid HIV testing kits at the point of care has been welcomed by AFAO and our member organisations as a significant achievement towards the roll-out of rapid testing technology in Australia. However, there are still no rapid tests licensed by the Therapeutic Goods Administration (TGA) for use at the point of care in this country. AFAO understands that at least one rapid test kit has been submitted for licensing to the TGA, but it is not clear how long the TGA assessment process will take. While we await the outcome of this process, there are other important tasks that require our attention. The next steps should involve planning for the introduction of rapid testing services in Australia; this should include the involvement of policymakers, community-based organisations, educators, researchers and clinical staff.

This article, while not intending to be too proscriptive, suggests some key areas of work relevant to these various groups.

Policymakers

Although support for rapid testing in the National HIV Testing Policy and TGA licensing of rapid test kits are both major steps forward, a significant barrier to the uptake of rapid testing will remain unless payment for their use is provided under Medicare. Without Medicare support, a GP offering rapid tests would have to absorb the cost of the test kits, or else pass the cost on to their patients. Similarly, if rapid tests were offered by a publicly funded sexual health clinic service providing testing services free to patients, equipment costs would have to be covered by the clinic's funding; any new community-based testing services run by non-government organisations would face

an additional funding hurdle while unable to recoup costs from Medicare.

The Sixth National HIV Strategy has identified priority actions in HIV testing, including:

Increase the number of people in priority populations who voluntarily seek HIV testing and increase the rate of testing among people at higher risk of exposure to HIV infection to decrease the burden of undiagnosed HIV in the community.¹

More than half of gay men in a recent study indicated that they would test, or test more often if rapid HIV testing were available free at a community organisation.² Additionally, there is strong evidence many countries that offering rapid HIV testing services and community based testing to gay and other men who have sex with men has

continued overleaf

increased testing volumes, achieved outstanding results in the ratio of positive tests to total tests, and attracted a high proportion of men who have never previously tested.³ Although there have been no cost-effectiveness studies in relation to rapid HIV testing undertaken in Australia to date, it is likely that rapid testing will be very cost effective as the National HIV Testing Policy has a number of mechanisms in place which will limit the use of rapid HIV tests to people at increased risk of HIV infection.⁴

In order to achieve the benefits that are likely to accrue from rapid HIV testing and community-based testing, policymakers should consider funding trials, and (subsequent to TGA licensing) targeted clinical and community-based testing services. Under the National HIV Testing Policy, community organisations providing rapid HIV testing services will require endorsement from state and territory health departments. Health officers and community organisations should commence dialogue regarding the appropriateness of community-based testing services in their jurisdictions and the necessary planning and resourcing needed to build any new services.

Community-based HIV organisations

AIDS Councils and related community-based organisations should be working now to identify and engage with public and private clinical services that are well placed to introduce rapid HIV testing. Commencing dialogue now to identify barriers and necessary preparatory work will expedite the delivery of rapid testing following TGA licensing.

Another area for action is in relation to developing models for community-based testing. Although the Western Australian AIDS Council has built successful community-based HIV and STI testing services, participating in or managing testing services

Rapid HIV Testing Background

Until very recently Australia's National HIV Testing Policy has not supported the use of rapid HIV testing at the point of care. Rapid HIV tests are routinely used in many developed and developing countries. Their use is supported by the World Health Organisation, UNAIDS, and permitted by regulators of medical devices in many countries. Many rapid HIV testing and community-based testing services have achieved outstanding results in providing convenient and popular testing services, with strong public health outcomes in increasing testing among people most at risk of HIV infection, and reducing undiagnosed HIV (see Alisa Pedrana's article on page 20, describing the outcomes of a systematic review of the published literature on rapid HIV testing and community-based testing among gay men and other men who have sex with men).

AFAO has been advocating that Australia should incorporate rapid HIV tests into existing clinical services, and develop new community-based HIV testing services (for more background about AFAO's position on rapid testing, see the *AFAO Policy Briefing Paper on Rapid HIV Testing*, 2010).

The new 2011 National HIV Testing Policy now supports rapid HIV testing for use as screening tests at the point of care (PoCT):

PoC testing may be considered for community-based testing interventions for high-risk (gay men) or hard-to-reach populations and individuals (who are resistant to conventional testing). It may also be appropriate for people who might be otherwise reticent to access conventional testing and/or return for test results.

would be new areas of work for most community-based HIV organisations. Community organisations will need to consider the mix of testing services currently available in their area, as well as what new services should be put in place to make testing more accessible and acceptable to their constituents. Where community organisations develop new partnerships with existing clinical services, or new community-based testing services, they will need to carefully assess their current competencies and plan how to build new competencies. The mix of clinical and peer-based experience in staffing models for new community based services will need attention, and issues of medical indemnity will require investigation.

HIV Educators

HIV educators will need to plan for the arrival of rapid HIV testing by preparing information resources and community awareness campaigns. Rapid HIV tests have specific limitations and benefits. The limitations of rapid tests include a longer window period following exposure to HIV to detect an infection, compared to the best currently available laboratory

tests (approximately one to two weeks longer, depending on the rapid test) and that reactive results on rapid tests require further testing to confirm an HIV diagnosis. The benefits of rapid tests include a less invasive method for collecting the specimen (usually blood from a finger-prick or an oral sample), and a rapid result; rapid HIV tests take between one minute and approximately twenty minutes to process the specimen. Building community knowledge and informed, realistic expectations among gay men regarding rapid tests will be crucial to achieving successes from their introduction.

Clinical staff

Introducing rapid HIV testing into clinical settings will require the development of new skills, clinical guidelines and quality control protocols and processes. Administering rapid tests at the point of care requires careful set-up, specific equipment and careful attention to specific processes performed at precise intervals, which are particular to the test kit being used. Staff involved in administering and interpreting rapid tests will require specific training, and periodic assessment and skills updates (AFAO

understands that ASHM is currently developing a curriculum for a training program for health workers who will administer rapid HIV tests). Guidelines for providing information to clients regarding some of the limitations of rapid tests will need to be developed.

There are currently two trials of rapid HIV testing already underway in Australia, and a third about to commence. In the absence of TGA licensed rapid tests being available, clinical trials are the only way to legally provide rapid HIV tests. Trials also offer valuable opportunities for developing and documenting local experience in delivering rapid HIV testing, to guide future practice. Trials have commenced at the Melbourne Sexual Health Centre, and a trial in Brisbane is being conducted through the Brisbane Sexual Health Clinic and AIDS Medical Unit. A third trial will commence in October 2011 in Sydney; four sexual health clinics will participate. All the current trials are targeted to gay and other men who have sex with men. These three trials have a range of objectives, and

between them will produce valuable knowledge in relation to assessing test performance, the acceptability of rapid testing to clinical staff and testing clients, and the impact of rapid testing on gay men's testing frequency.

A gap exists in relation to trials in private General Practice settings. HIV testing in GP settings is a critical component of HIV testing in Australia, so developing appropriate models for providing rapid testing within them requires urgent attention. As stated earlier in this article, the current lack of Medicare funding for rapid HIV tests presents an additional barrier to the introduction of rapid testing in private settings.

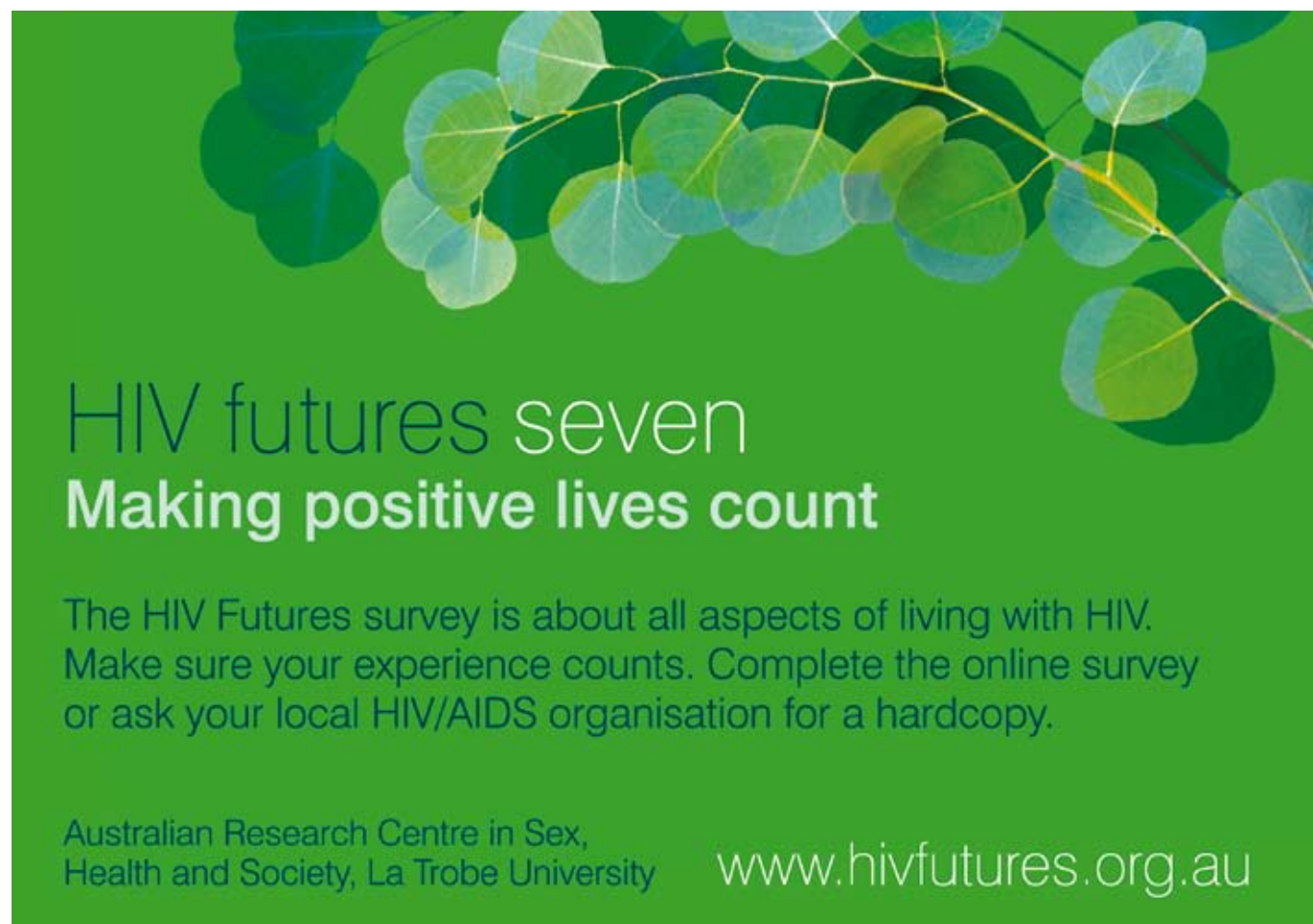
Researchers

Australian researchers have generated valuable knowledge regarding gay men's attitudes to HIV testing, barriers to testing and the acceptability of rapid testing. As we move towards a context where rapid testing is routinely offered, researchers will need to consider how to understand the impact of rapid testing on gay men's testing behaviour and risk practices.

References

- 1 Department of Health and Ageing [DoHA]. (2010). *Sixth National HIV Strategy 2010–2013*. DoHA, Canberra.
- 2 Prestage, G., McCann, P., Hurley, M., Bradley, J., Down, I., Brown, G. (2010). *Pleasure and Sexual Health: The PASH Study, 2009*. Monograph. National Centre in HIV Epidemiology and Clinical Research, University of NSW, Sydney.
- 3 Pedrana, A., Guy, R., Bowring, A., Hellard, M., Stoové, M. (2011). *Community models of HIV testing for men who have sex with men (MSM): Systematic Review 2011*. Report commissioned by ACON.
- 4 Department of Health and Ageing [DoHA]. (2011). National HIV Testing Policy. DoHA, Canberra. Available online at: <http://testingportal.ashm.org.au/hiv> (accessed 11 October 2011).

Phillip Keen is an AFAO HIV Health Promotion Officer in the AFAO-NAPWA Education Team. Phillip has led AFAO's recent advocacy work in relation to ensuring that rapid HIV testing at the point of care can be made available in Australia. He is a member of the Expert Reference Committee overseeing the revision of Australia's National HIV Testing Policy.



HIV futures seven
Making positive lives count

The HIV Futures survey is about all aspects of living with HIV. Make sure your experience counts. Complete the online survey or ask your local HIV/AIDS organisation for a hardcopy.

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

www.hivfutures.org.au



The future of HIV testing: exploring new strategies to improve access to testing through community-based testing

By **Alisa Pedrana** and **Mark Stoové**

In Australia, men who have sex with men (MSM) account for more than 65% of newly diagnosed and 85% of newly acquired cases of HIV each year.¹ Despite high self-reported annual testing rates (around 60%)² and a reduction in viral loads among those on antiretroviral therapy (ART)³, Australia has witnessed substantial increases in newly diagnosed HIV infections over the past decade⁴. This rise has been attributed to factors including moderate increases in sexual risk behaviours among gay men and dramatic increases in other sexually transmitted infections (STIs) including syphilis, gonorrhoea and chlamydia^{5,6,7,8}, which are known to increase HIV transmission risk.^{9,10,11}

Regular HIV testing is one of the key HIV prevention strategies for gay and homosexually active men in Australia. Frequent testing decreases the number of people who are unaware of their

HIV status and reduces cases of late diagnoses. Timely diagnosis of HIV provides opportunities for optimal commencement of treatment, which in turn suppresses viral load, thereby reducing transmission risk and enhancing long-term health outcomes for individuals^{12,13}. Frequent testing and timely diagnosis also provides opportunities for risk assessment and allows for discussion of risk reduction strategies and behaviour modification to reduce the risk of onward transmission.¹⁴

HIV testing patterns among men who have sex with men in Australia

Although annual Australian HIV testing rates among MSM are generally considered to be high, national behavioural data and a recent national online survey of 3,457 MSM paint a different picture: only about 20% of

men deemed to be in the 'high-risk' category tested regularly for HIV; 20% of the men surveyed reported two or more HIV tests per year; while between 6–24% said that they had never been tested.^{15,16,17} Non-adherence to the recommended HIV testing guidelines among many gay and other MSM is also concerning. A recent study assessing compliance with recommended HIV testing frequency guidelines among MSM attending primary care clinics in Melbourne reported re-testing rates as low as 35% in one year, indicating that self-reported annual testing rates among MSM could be over-estimated.¹⁸

So why, despite extensive health promotion activities designed to highlight the importance of HIV testing¹⁹, are so many men not testing as frequently as recommended?

Structural barriers to HIV testing

Structural, personal and policy barriers to frequent HIV testing are commonly reported.^{20,21,22} These include not knowing where to get tested, difficulties in getting an appointment, difficulties finding a gay-friendly doctor and the need to return for a test result. A number of study findings indicate that many MSM prefer HIV testing options that provide more timely results and greater convenience.²³ These men report not having enough time to get tested, citing inconveniences such as the return visit required to receive results when being tested at GP clinics and sexual health services (where the majority of HIV testing is conducted).²⁴ Current testing guidelines recommend annual testing for sexually active gay men and more frequent testing (3–6 monthly) for men at ‘high risk’.²⁵

Current models of HIV testing in Australia

In Australia, HIV testing involves conventional testing of venous blood samples using enzyme-linked immunoassay (EIA) followed by confirmatory Western blot at a laboratory. Test results usually take a few days (but sometimes a week) because testing is often batched. Conventional HIV testing requires a return visit to the testing site to receive results and post-test counselling. Thus, the process from testing to receipt of results can be 1–2 weeks and multiple appointments per test means that ‘high risk’ men, may need 4–8 clinic appointments per year.

Technical advances in rapid HIV testing have resulted in test performance comparable to conventional testing. Rapid HIV tests therefore provide a potentially valuable alternative to current testing models. Advantages of rapid testing include specimen collection processes that are less invasive, results are available within 30 minutes and provided back to clients in the same visit, testing can be conducted almost anywhere including by non-clinically trained staff in community-based settings, and

individuals are only required to return for another visit if their rapid test is ‘preliminary positive’ or indeterminate, which accounts for a small proportion of tests.²⁶

Review of community-based models of HIV testing

Community models of HIV testing for MSM, often using HIV rapid tests, have been used widely in the United States^{27,28,29} and throughout Europe^{30,31} for over 10 years, and more recently in New Zealand³². The primary goal of community based HIV testing models is to increase opportunities for people at risk of HIV to get tested. The Centers for Disease Control and Prevention (CDC) in the United States recommend that community-based organisations test all at-risk clients³³; while the European Centre for Disease Prevention and Control recommends offering HIV testing in medical and non-medical settings, in cooperation with non-governmental organisations to facilitate access and uptake³⁴. However, to date there has been limited uptake of community-based HIV testing models in Australia and current HIV testing policies and other regulatory restrictions in Australia preclude the use of rapid tests, except under very restricted circumstances.³⁵ In response, ACON recently commissioned the Burnet Institute to undertake a systematic review of published literature in relation to community-based testing and rapid HIV testing for MSM.³⁶ This review examined 32 published papers between

2000 and 2010 that described 44 community-based HIV testing services accessed by MSM (mostly located in the US (n=28) and Europe (n=11)).

HIV testing outcomes

The review demonstrated that on average a third of MSM who were tested at services had never been tested previously for HIV. In addition, services were generally successful in attracting men who were at high risk; most services identified a high number of new HIV infections, with the median HIV positivity of 3.9% among services that catered for MSM only. The highest positivity rates were reported at community-based organisations/ community clinics. These data suggest that rapid testing services, particularly those based in community sites, are providing an alternative HIV testing option for populations at risk of HIV who may not routinely access other HIV testing services.

Uptake of rapid HIV tests

Rapid testing at the services was common, with three quarters of services included in the review offering rapid testing for HIV antibodies (24 finger-prick, 10 oral-fluid). Where rapid testing was provided onsite, clients received the results of their rapid test on the same day, usually in the same session, at the point-of-care. In most services, only ‘preliminary’ positives and

continued overleaf

These data suggest that rapid testing services, particularly those based in community sites, are providing an alternative HIV testing option for populations at risk of HIV who may not routinely access other HIV testing services.

indeterminate results were confirmed by conventional confirmatory testing. Provision of more timely HIV results by these services could potentially reduce onward HIV transmission rates because clients are immediately aware of their HIV status and receive post-test counselling. Rapid tests also enable testing to be conducted by non-medically trained staff, without the need for the space and privacy needed for traditional blood draw procedures; 65% of these services were therefore able to provide outreach rapid testing services.

Rapid HIV tests

Test results at these services were provided to clients within 15–60 minutes of the specimen being collected. In most services (30 out of 34), a single rapid test algorithm was used followed by whole blood collection for confirmatory testing if the rapid test was reactive or indeterminate. Clients were usually offered the opportunity to return to the test site in person to receive their confirmatory test results or given alternative options such as attending a local partnering community-based organisation or sexual health clinic. Most reports in the review did not aim to formally evaluate test performance. However from the information reported, often based on a small number of positive tests, the rapid HIV tests showed very high positive-predictive values, meaning that when a rapid HIV test

was positive it was extremely likely to indicate a true infection.

Testing Protocols, Testing Outcomes and Communicating Results

Universal pre- and post-test counselling was provided at all the community-based services. Pre-test counselling for rapid testing included additional information regarding the meaning of a rapid test result. In many outreach services and community-based organisations, one agency provided the testing services and another agency provided care and treatment for referred positives, highlighting the importance of developing prompt and durable linkages to ongoing medical care. Location, operating hours and procedures for accessing testing at community-based testing services were considered key to reducing barriers to HIV testing among MSM, and to have implications for the cost and feasibility of various staffing models. Most of the 44 services reviewed (33 out of the 44 services reviewed) offered a walk-in HIV testing service, five offered both walk-in and by appointment services, and three by appointment only. The majority of services (63%) offered testing at no cost to clients.

Staffing models and staff training

Involvement of a wide range of staff (e.g. peer/outreach workers, nurses, physicians, social workers, phlebotomists, volunteers) was reported by the services reviewed, with staffing

profiles varying by service type, size and by region. Most services utilised non-medically trained staff to undertake rapid HIV testing, including pre/post-test discussions, risk assessment and referral. A number of studies in the review demonstrated the feasibility and reliability of non-medically trained staff in conducting HIV counselling and testing when specific rapid testing training and quality assurance processes were in place. The use of non-medically trained staff also provided a substantial reduction in costs compared to physician-led testing services. The studies reporting on acceptability also highlighted the importance of providing client-friendly services and the key role of peer and welfare oriented testing staff in achieving this outcome. Ongoing staff training and supervision were considered important, particularly to increase acceptability and effectiveness of rapid testing within community-based services.

Community-based testing (with and without the provision of rapid testing) has been shown to be feasible and to provide a model of HIV testing that attracts a significant proportion of MSM who have never tested before, and men who are at high risk of HIV. With the rest of the world making progress in further reducing barriers to testing and providing greater access to health services, can Australia afford to be left behind?

References

- 1 National Centre in HIV Epidemiology and Clinical Research. (2010). *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2010*. National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales, Sydney.
- 2 Holt, M., Mao, L., Prestage, G., Zablotska, I., de Wit, J. (2010). *Gay Community Periodic Surveys National Report 2010*. National Centre in HIV Social Research, National Centre in HIV Epidemiology and Clinical Research. The University of New South Wales, Sydney.
- 3 Law, M., Woolley, I., Templeton, D., Roth, N., Chuah, J., Mulhall, B., et al. (2011).

Rapid tests also enable testing to be conducted by non-medically trained staff, without the need for the space and privacy needed for traditional blood draw procedures; 65% of these services were therefore able to provide outreach rapid testing services.

- Trends in detectable viral load by calendar year in the Australian HIV observational database. *J Int AIDS Soc*, 14, 10.
- 4 National Centre in HIV Epidemiology and Clinical Research op. cit. 2010.
 - 5 Middleton, M., Grulich, A., McDonald, A., Donovan, B., Hocking, J., Kaldor, J. (2008). Could sexually transmissible infections be contributing to the increase in HIV infections among men who have sex with men in Australia? *Sex Health*, 5(2), 131–140.
 - 6 National Centre in HIV Epidemiology and Clinical Research. (2009). *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2008*. National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales, Sydney.
 - 7 National Centre in HIV Epidemiology and Clinical Research op. cit. 2010.
 - 8 Teague, R., Mijch, A., Fairley, C. K., Sidat, M., Watson, K., Boyd, K., et al. (2008). Testing rates for sexually transmitted infections among HIV-infected men who have sex with men attending two different HIV services. *Int J STD AIDS*, 19(3), 200–202.
 - 9 Buchacz, K., Patel, P., Taylor, M., Kerndt, P., Byers, R., Holmberg, S., et al. (2004). Syphilis increases HIV viral load and decreases CD4 cell counts in HIV-infected patients with new syphilis infections. *AIDS*, 18(15), 2075–2079.
 - 10 Wasserheit, J. (1992). Epidemiological synergy. Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. *Sex Transm Dis*, 19(2), 61–77.
 - 11 Wilson, D., Hoare, A., Regan, D., Law, M. (2009). Importance of promoting HIV testing for preventing secondary transmissions: modelling the Australian HIV epidemic among men who have sex with men. *Sex Health*, 6(1), 19–33.
 - 12 Attia, S., Egger, M., Muller, M., Zwahlen, M., Low, N. (2009). Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. *AIDS*, 23(11), 1397–1404.
 - 13 Cohen, M., Chen, Y., McCauley, M., Gamble, T., Hosseinipour, M., Kumarasamy, N., et al. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 365(6), 493–505.
 - 14 Marks, G., Crepaz, N., Senterfitt, J., Janssen, R. (2005). Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: Implications for HIV prevention programs. *Journal of Acquired Immune Deficiency Syndromes*, 39(4), 446–453.
 - 15 Holt et. al. op. cit.
 - 16 Rawstorne, P., Holt, M., Kippax, S., Worth, H., Wilkinson, J., and Bittman, M. (2009). *E-male survey 2008: key findings from a national online survey of men who have sex with men in Australia*. National Centre in HIV Social Research, The University of NSW, Sydney.
 - 17 Zablotska, I., Imrie, J., Bourne, C., Grulich, A., Frankland, A., Prestage, G. (2008). Improvements in sexual health testing among gay men in Sydney, Australia, 2003–2007. *Int J STD AIDS*, 19(11), 758–760.
 - 18 Guy, R., Goller, J., Spelman, T., El-Hayek, C., Gold, J., Lim, M., et al. (2010). Does the frequency of HIV and STI testing among MSM in primary care adhere with Australian guidelines? *Sex Transm Infect.*
 - 19 Guy, R., Goller, J., Leslie, D., Thorpe, R., Grierson, J., Batrouney, C., et al. (2009). No increase in HIV or sexually transmissible infection testing following a social marketing campaign among men who have sex with men. *J Epidemiol Community Health*, 63(5), 391–396.
 - 20 Chen, M., Bilardi, J., Lee, D., Cummings, R., Bush, M., Fairley, C. (2010). Australian men who have sex with men prefer rapid oral HIV testing over conventional blood testing for HIV. *Int J STD AIDS*, 21(6), 428–430.
 - 21 Pedrana, A., Hellard, M., Guy, R., Wilson, K., Stoové, M. (2011). High rates of undiagnosed HIV infections in a community sample of gay men in Melbourne, Australia. (accepted). *JAIDS Journal of Acquired Immune Deficiency Syndromes*.
 - 22 Prestage, G., McCann, P., Hurley, M., Bradley, J., Down, I., Brown, G. (2009). *Pleasure and Sexual Health: The PASH Study*, National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales, Sydney.
 - 23 Chen et al. op. cit.
 - 24 Prestage et al. op. cit.
 - 25 STIGMA (2010). *Sexually Transmitted Infection Testing Guidelines For Men Who Have Sex With Men 2010*. Sydney Australasian Chapter of Sexual Health Medicine/Royal Australasian College of Physicians, Royal Australian College of General Practitioners, Australasian Society of Infectious Diseases and the Australasian Society for HIV Medicine.
 - 26 Bennett, A. (2009, June 22, 2009). Point of care rapid HIV testing: considerations for service provision. *HIV Nursing*.
 - 27 Aguirre, D., Mares-DelGrasso, A., Emerson, C., Tsang, J., Pincus, J., Calhoun, C., et al. (2007). Rapid HIV testing in outreach and other community settings – United States, 2004–2006. (Table). *Morbidity and Mortality Weekly Report*, 56(47), 1233(1235).
 - 28 Bogart, L., Howerton, D., Lange, J., Becker, K., Setodji, C., Asch, S. (2008). Scope of Rapid HIV Testing in Private Nonprofit Urban Community Health Settings in the United States. *Am J Public Health*, 98(4), 736–742.
 - 29 Bowles, K., Clark, H., Tai, E., Sullivan, P., Song, B., Tsang, J., et al. (2008). Implementing rapid HIV testing in outreach and community settings: results from an advancing HIV prevention demonstration project conducted in seven U.S. cities. *Public Health Rep*, 123 Suppl 3, 78–85.
 - 30 De La Fuente, L., Delgado, J., Hoyos, J., Belza, M., Alvarez, J., Gutierrez, J., et al. (2009). Increasing early diagnosis of HIV through rapid testing in a street outreach program in Spain. *AIDS Patient Care and STDs*, 23 (8), 625–629.
 - 31 Koevoets, W., van Loon, S. (2004). *Rapid HIV testing in a one-hour procedure motivates MSM in the Netherlands to take the test*. Paper presented at the Access for All: 15th International AIDS Conference.
 - 32 Smythe, E. (2007). *Evaluation of 3 month Auckland based rapid test pilot*. Auckland: New Zealand AIDS Foundation.
 - 33 Branson, B., Handsfield, H., Lampe, M., Janssen, R., Taylor, A., Lyss, S., et al. (2006). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *Morbidity & Mortality Weekly Report Recommendations & Reports*, 55(RR-14), 1–17; quiz CE11–14.
 - 34 European Centre for Disease Prevention and Control [ECDC]. (2010). *HIV testing: increasing uptake and effectiveness in the European Union*. ECDC, Stockholm.
 - 35 Australia Government Department of Health and Ageing. (2006). 2006 National HIV Testing Policy. Retrieved from http://www.health.gov.au/internet/main/publishing.nsf/content/health-pubhlth-strateg-hiv_hepc-hiv-index.htm#strategy.
 - 36 Pedrana, A., Guy, R., Bowring, A., Hellard, M., Stoové, M. (2011). *Community models of HIV testing for men who have sex with men (MSM): Systematic Review 2011*. Burnet Institute, Melbourne.

Alisa Pedrana is a PhD candidate and research assistant at the Centre for Population Health, Burnet Institute. Mark Stoové is head of the HIV/STI Research Group at the Centre for Population Health, Burnet Institute.



Who's calling the shots on gay men's health?

By **Andrew Burry** and **David Mills**

In this opinion piece, Andrew Burry and David Mills argue that Australia's gay community should play a central role in determining the services and support appropriate for their needs. If some gay men prefer to self-administer their HIV tests in privacy, they ask, who are we to question their right to do so?

Australia demonstrates an occasional reluctance to embrace innovations successfully employed in other countries including from those with similar HIV epidemics. Testing is an example, even though this has been given special prominence in our HIV response. Discussion around rapid testing and increased use of community settings with peer support has been robust, but potential for self-administered testing is a discussion without an audience. The Australian response has been world leading, but are we blocking further success by over protecting what we have already achieved?

It is widely accepted that individuals make decisions that we may not agree with, but we support informed choices

and build capacity to reduce risk and harm. We understand the reality that men who have sex with men will not always use condoms with casual partners, and we accept a critical role in reducing risk, even though we don't fully know how best to do so. We have a long-standing model for HIV testing, but this model may be precluding vulnerable groups of men from *actually* testing, and it must now be time to question some of the underlying assumptions to what may no longer be fully effective.

Over time, competing and complementary policy questions have built up around HIV testing in Australia: consent, client benefit, maintaining epidemiological quality,

clinical standards, contact tracing and prevention of transmission.¹ The consequence of these policy tensions and other concerns have seen testing controlled predominantly within clinical settings with limited influence from the community side of the HIV partnership. The testing model is largely one-size fits all, and arguably perhaps, metropolis-centric.

One-size rarely fits all and new approaches are needed to increase the number of men who have (anal) sex with men who have ever tested for HIV and their frequency of testing. Despite promotion by AIDS Councils and clinicians, 40% of men recruited through gay community periodic surveys had not received an HIV test

in the last 12 months.² Mathematical modelling suggests that 9–13% of men who have sex with men living with HIV are undiagnosed, contributing to 31% of new HIV infections.³

For a long time we have had significant insights into barriers to testing for men who have sex with men⁴ and we understand how this contributes to the rate of transmission. We have not been ignoring this evidence: sexual health clinics have been adjusting their practice to reduce some of these barriers but other changes are needed to make further improvement.

We suggest there are three main groups of reasons that fuel a resistance to self-administered testing and particularly home based approaches.

Firstly, there is a notion of clinical control, or ‘doctor knows best’. The history of medicine in Australia is one where a doctor figure is relatively unquestioned in diagnosis, prognosis and prescription. And yet, paradoxically, the history of our HIV epidemic is one where the early and crucial success came substantially in the absence of the medical establishment. Gay men worked out that they needed to take control of an issue that threatened their entire community and collective action from within turned the tide. Since then gay men have had a diminishing control over their own health.

Secondly, we have institutionalised homophobia. A suggestion that homophobia in the HIV sector is influencing gay men’s health is unlikely to be a welcome one. Nonetheless, we believe that the current denial of internationally proven testing approaches meets the criteria. This plays out through a belief that gay men are fundamentally irresponsible and cannot be trusted to always act in a *socially responsible* way. Resources made available to gay men are routinely censored to avoid any risk that a proportion, no matter how small, will use them inappropriately. For example, within the sector we are reluctant to discuss with gay men that in the absence of condoms, better to

be a top than a bottom, better to have unprotected sex with an HIV negative partner than a positive one, better not to let someone come inside your arse and so on. Ironically, gay men have long known these things we hesitate to discuss.

Thus, testing and providing results must only occur in highly controlled settings, so that a person can be managed irrespective of their own capacity for self-management.

The third set of reasons is epidemiological. Australia has probably the best epidemiological data around HIV diagnoses in the world and our surveillance system is highly evolved. One of the reasons for this success is that testing of men who have sex with men is highly managed and controlled and we collect a considerable amount of information. In terms of managing the response and assisting prevention efforts, this data is important in allowing modelling and insights into some dynamics of transmission. Should testing bypass this established system, less data might be available and therefore surveillance quality would decline.

For self-administered testing to be considered as a future strategy, we suggest that all three sets of barriers have to be addressed to the satisfaction of stakeholders; although here we would argue that the health and wellbeing of men who have sex with men should be preminent within the context of overall public health policy.

The epidemiological considerations are straightforward. We need only be confident that a self-administered positive result would in all probability result in a confirmatory test via the established system, and equivalent data would still be obtained as it is now. Contact tracing requirements would be achieved. Some who get a positive result may take no follow up action, but would this number be significantly greater than the numbers who don’t return for a positive result now?

Balancing this is that properly targeted and managed, self-administered testing could raise the total testing rate/frequency and would offer a significant benefit for those living away from convenient, anonymous testing locations and who are now not screened at all.

It won’t be easy to encourage clinicians and social scientists to relax their level of control over the Australian HIV response, largely because there is an appropriate pride in the contribution they have made. But like all of us that seek to minimise the personal and social impacts, and the transmission of HIV, we can’t overlook the fact that we are servants of those we seek to serve. Just as we have to some extent placed people living with HIV at the centre of our response, we must similarly find a more central role for a gay community

continued overleaf

In other words, if you are a man that has sex with men, we want you to test at least once per year. If some gay men prefer to self-administer their test and to do so in privacy, who are we to question their right to do so?

in determining the services and support appropriate for their needs. With or without rapid testing, the process itself can be a burden on gay men simply for being gay. In other words, if you are a man that has sex with men, we want you to test at least once per year. If some gay men prefer to self-administer their test and to do so in privacy, who are we to question their right to do so?

This leads us to the more difficult issue of homophobia and judgements made on how gay men *might* behave if they were able to assume more control over their own health. One set of arguments are around an idea that gay men will choose to use a negative result as permission to avoid safer sex measures. This is surely an unsustainable argument in the face of no supporting evidence. Why would a self-administered test be likely to influence behaviour any more than a traditional test? In any event, we might suggest that more frequent testing for someone who is highly sexually active will reduce their risk of knowingly passing on the virus and this can't be said for someone who has no information of their status.

Another set of arguments are based around the physical and mental wellbeing of a person who tests privately and gets a positive result; false or true. Again there is no evidence that there would be an increase in self-harm following a positive result from a

self-administered test. On the contrary, the *New England Journal of Medicine* in 2006 said that expanded screening resulted in no reported increase in the rate of suicide, and this after 175,000 people purchased kits.⁵

These assumptions about what gay men might do are homophobic and embedded in the institutions we count on to support health and wellbeing. We should no longer justify denying the rights of gay men to the best technology based only on speculation about what a few might do. Discussion now must be firmly focussed on enabling the introduction of self-administered testing, rather than either denying its existence or vilifying its use.

If our consideration of self-administered testing took the positive perspective of seeking to answer how it could be introduced and how it could further support our HIV response, our conversation would be different. We would identify for whom a self-administered HIV test at home would be most suited. For example, a person who had some level of risk, had ever previously had an HIV test and who might not now test. Or, a person for whom, for any reason, alternative testing modality was difficult. We might also consider a variety of models under which self-administered testing could be introduced. For example, physician prescribed, or with

a regulated supply of kits that met appropriate quality standards or with an education commitment that makes the use of a kit an informed and supported choice.

Denying the many for what a few *might* do is choosing a lowest common denominator approach that should be unacceptable. That we are accepting it means weakening our claim to a future best practice HIV response.

References

- 1 Department of Health and Ageing (DoHA). (2006). *National HIV Testing Policy 2006*. Commonwealth of Australia, DoHA, Canberra. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-hiv-testing-policy> (accessed 27 September 2011).
- 2 Holt, M. et al. (2011). *Gay Community Periodic Surveys: National Report 2010*. National Centre in HIV Social Research, University of New South Wales, Sydney. Available at: http://nchsr.arts.unsw.edu.au/media/File/GCPS_2010_National_report.pdf (accessed 27 September 2011).
- 3 Wilson, D. et al. (2008) *Mathematical models to investigate recent trends in HIV notifications among men who have sex with men in Australia*. National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, Sydney. Available at: [http://www.med.unsw.edu.au/NCHECRweb.nsf/resources/HIV-Mod_FINAL-Rep/\\$file/Final+NCHECR+Modelling+Report.pdf](http://www.med.unsw.edu.au/NCHECRweb.nsf/resources/HIV-Mod_FINAL-Rep/$file/Final+NCHECR+Modelling+Report.pdf) (accessed 27 September 2011).
- 4 Koelmeyer, R., Grierson, J., and Pitts, M. (2011) *Motivations for and barriers to HIV testing in Australia: Information to support the revision of the National HIV Testing Policy 2006*. The Australian Research Centre in Sex, Health and Society, Melbourne. Available at: http://www.ashm.org.au/images/arv_guidelines/arcs_his_motivations_for_and_barriers_to_hiv_testing_report.pdf (accessed 27 September 2011).
- 5 Alexi, A., Wright, M., Ingrid T., Katz, M. (2006, February). Home Testing for HIV, *The New England Journal of Medicine*. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMp058302> (accessed 27 September 2011).

Andrew Burry is General Manager at the AIDS Action Council of the ACT. David Mills was Community Development Manager at the AIDS Action Council, and has since taken up a position with the AIDS Committee of Ottawa, Canada.

These assumptions about what gay men might do are homophobic and embedded in the institutions we count on to support health and wellbeing. We should no longer justify denying the rights of gay men to the best technology based only on speculation about what a few might do.



Seize the day: the era of combination prevention

By Geoff Honnor

If there were there any residual doubts about the increasing centrality of antiretroviral therapy (ART) to the prevention of HIV transmission, they've been well and truly dispelled by a series of recent research findings which prove conclusively that our understanding of best-practice HIV prevention must now be inclusive of an increasing range of methodologies and approaches.

Welcome to the era of combination prevention (also referred to as 'intensive combination prevention' – ICP) in which biomedical and behavioural approaches will mesh in an increasingly synergistic framing – a framing that poses some significant challenges for Australian prevention policy and funding.

Further research findings are awaited – particularly in respect to the efficacy of episodic pre-exposure prophylaxis (PrEP) dosing and studies of the role of treatments in serodiscordant gay couples. What all this means practically, in terms of specific application to the Australian response, is yet to be determined. However, I think the question is no longer whether we need to engage with the treatment as prevention paradigm, it's now about how we do this. Where does our emphasis have to be placed? Who will we target and under what circumstances? What does it mean in terms of current guidelines and practice and – crucially – who leads the debate, sets the timeframe and ultimately, delivers implementation?

The 6th National HIV Strategy provides some support – and limited guidance:

New technological developments should be considered for their relevance and value to the Australian HIV response.

Areas of current interest include:

- *communication and biomedical technologies relevant to specific prevention and health promotion interventions*
- *prevention agents such as microbicides and vaccines.*

Over the life of this strategy the expertise and analysis available across these fields will be monitored to ensure a coordinated, considered and evidence-based approach to potential implementation.¹

'Monitoring' feels a little passive in the light of what's emerged since – and it's not clear as to who will monitor, or indeed, the process by which any action or outcomes might be initiated as a result. This wording could be construed as an illustration of how swiftly the frontier has moved since the initial draft of the current strategy was crafted in 2009, although I acknowledge this observation is made with the benefit of hindsight.

On the evidence available from the extraordinarily long lead-up to introduction of point-of care rapid HIV testing in Australia (supported for the first time in the 2011 redraft of the National HIV Testing Policy), swift resolution of all of this might not be easily attainable.

I wonder if a tendency to well-intentioned procrastination might be emerging as an artefact of Australia's comparative success in HIV epidemic containment, characterised by institutional reluctance to consider and embrace the case for alternative approaches and thinking around prevention. This is particularly the case (and in purely pragmatic terms,

understandably so) where existing policy, regulatory and funding frameworks are essential 'agent of change' ingredients. Stakeholders are rightfully proud of – and invested in – what's been accomplished to date and the body of evidence accumulated in support of the effectiveness of the Australian approach is compelling. The reluctance to embrace rapid, point-of-care HIV testing (RHT) in Australia until very recently (despite the fact that comparable international jurisdictions had almost universally done so while demonstrating increased testing efficacy and target demographic acceptability) seems to illustrate this.

Community advocacy around RHT frequently seemed to be heard as an assault on the integrity of the Australian investment in sophisticated testing infrastructure and a disregard of the comparatively high testing rates in priority populations – particularly gay men. In fact, the case proposed was much more about building on success via an enhancement to existing prevention capacity that had the added benefit of going directly to what gay men, in particular, were telling researchers about their testing methodology preferences: cheap, convenient, accessible and offering swift turnaround on results.

Similarly, recognition of the role of antiretrovirals (ARV) in HIV prevention and the possibilities offered should not be read as a rejection of – and a replacement for – the behavioural approaches that have underpinned our success to date. To frame the discussion

continued overleaf

as a choice between binary opposites is to surely miss the point.

At the outset, it's useful to restate a fundamental principle: the primary purpose of HIV ART is to constrain disease progression in people living with HIV and it follows that people living with HIV have a right to decide how and when they engage with it. This may appear to be self-evidently the case but given that earlier initiation of treatment has emerged as one of the preferred new approaches elsewhere, it bears repeating.

I don't think that principle and approach have to be in any way mutually exclusive here. It does follow, however, that if we're to consider earlier initiation of treatment as an option – and I think we should – there should be a shared understanding of underpinning principles.

It's also the case that consideration of earlier initiation of treatment will require engaging with prevalent perceptions about treatment among affected communities in Australia.

To a significant extent, the public discourse about treatment is still framed in late 90s perceptions of massive pill burden, corrosive side effects and a fragile yet toxic therapeutic impact in desperate contest with virulent disease progression. Without overlooking the very real treatment challenges that some of us do still face, it's crucial to be able to point to the remarkable advances that have been made over the last 15 years and to publicly articulate the health benefits – at individual and population level – accruing from them.

My sense is that for many of those more recently diagnosed, the eventual requirement to engage with ART is seen as an unwelcome milestone – hopefully, a long way off – of the life-changing point where pre-treatment 'natural' wellness finally evaporates and a decline into pharmaceutical reliance can no longer be avoided. The clinical evidence suggests otherwise of course – disease progression is constant, albeit individually variable – but the narrative

is powerful. This is understandable in a historical context but it's less clear as to why the narrative prevails, unchallenged, in the present.

This aversion to medication is even more powerfully wrought in those not living with HIV. Attitudinal surveys of Sydney gay men in relation to the acceptability of pre-exposure prophylaxis (PrEP) reveal a decided wariness about using antiretrovirals in this context, and a strong desire to know much more about it before considering it as a prevention agent.

This may give some heart to those who perceive affected communities to be worryingly prone to seduction by the latest research findings. The release of the Swiss Consensus Statement in early 2008 was accompanied by a remarkable outpouring of Australian clinical/research sector concern about the Statement's flow-on potential for invoking a collapse of serodiscordant condom culture and reckless abandonment of behavioural norms. The community sector's rather more nuanced response seemed to get buried in the noise.

The reality was – and is – that the Body Positive lives with a finely-honed sense of the balance between research findings, media reporting, translation into practice and real life application and is possibly the last group to be easily enticed by the siren call of the new.

In terms of solutions, I think that a practical first step begins to shape in an HIV sector forum specifically convened to engage with the future of HIV prevention. The aim would be to identify appropriate clinical, strategic, operational and policy responses and to initiate the development of an implementation plan with accountabilities, milestones and goals clearly indicated. It will come as no surprise that I think it should happen sooner rather than later.

My position isn't based on a sense of any magic bullets in the offing, nor is it sourced in a rejection of the safe sex culture invented and enacted by gay

men 30 years ago – and remarkably and admirably sustained today – albeit in evolving circumstances that are far more reflective of the informed and adaptive ingenuity of gay men than they are of the 'complacency' frequently used to describe what's going on.

In February, I was invited to Ottawa to participate in a Health Canada International HIV Prevention Policy Dialogue. The closing words of my presentation – specifically about gay men's prevention – to that meeting seem appropriate here:

Finally, I share the view that HIV is now endemic – rather than epidemic – in communities of gay men throughout the developed world. This means that we're unlikely to bring HIV to an end simply by scaling up our current programmatic approaches. We need to continue supporting gay men to sustain the condom culture that has been so central to ensuring that the overwhelming majority of gay men remain free from infection but we also need to recognise and respond to the risk management diversification inherent in the adaptive journey that gay men are on. We need to be realistic and pragmatic in doing this and we need to utilise the partnership approach that has served us well. We also need to be innovative and creative and not afraid to embrace the possibilities of change and we need to do that now. As a great Australian once observed – it's time.

References

- 1 Commonwealth Department of Health and Ageing [DoHA]. (2010). *The Sixth National HIV Strategy: 2010–2013*. DoHA, Canberra. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies-2010> (accessed 27 September 2011).

Geoff Honnor is an HIV positive gay man who is currently employed as Director, Community Health at ACON. The views expressed are his personal reflections and should not be read or understood as ACON's position on any of the matters discussed.



Treatment as prevention – another string to our bow

By Sean Slavin

The relationship between HIV treatments, viral load and infectiousness has been a topic of much debate during the past three years. However, since combination antiretroviral therapy (cART) and viral load testing became widely available in the mid-1990s, clinicians and people living with HIV have postulated that a lower viral load implies lower infectivity.

From the late 1990s, behavioural monitoring of gay men's sexual practices in Australia began to note an increase in the rate of unprotected sex between partners with different or unknown HIV statuses.¹ Further investigation revealed that, for some HIV-positive gay men, viral load was a factor in decisions not to use condoms.² In other words, these men were interpreting an undetectable viral load as an indicator of a decreased risk of passing on HIV to their sexual partners.

The implications of these changes in sexual practice were widely debated, with much disquiet expressed about the safety of the approach. Then in 2008, just prior to the International AIDS Conference in Mexico, the Swiss Federal AIDS Commission published a controversial statement that concluded

that an undetectable viral load meant the virus could not be transmitted in the context of heterosexual sex.³ This year, the 'Swiss Statement' seems to have been vindicated by results from the large-scale HTPN 052 clinical trial showing that early commencement of antiretroviral (ARV) therapy lowers the relative risk of HIV transmission by 96%.⁴

While there is certainly debate about the relative risks of adopting this approach among gay men, the news this year that treatment 'is' prevention has had the very beneficial effect of enabling HIV-positive people to feel less infectious and thus less anxious about transmitting the virus to sexual partners.

We know that for many HIV-positive people, sexuality is a significant site of anxiety; the *HIV Futures 5* survey reported that 25% of gay men and 50% of women and heterosexual men surveyed did not currently have sex.⁵ Treatment as prevention measures lower transmission risks and support a positive attitude to sexuality, an important element of wellbeing, and should be encouraged for these reasons.

For some HIV-positive people the link between undetectable viral load and reduced infectiousness may lead to more unprotected sex. However, for most, it is likely to be regarded as an additional supporting element in a personal prevention strategy that includes other measures such as condom use. In thinking about these possibilities – biomedical prevention and behavioural prevention – it is important not to see them as mutually exclusive alternatives but rather as complementary aspects of a new approach some have called combination prevention.^{6,7}

While this 'combination approach' may be new, it is not accurate to argue that treatment as prevention is entirely new. HIV treatments have been used as post-exposure prophylaxis (PEP) for over a decade in Australia, particularly among gay men, and PEP is probably responsible for preventing many new infections. Ongoing research into pre-exposure prophylaxis and microbicides are also examples of using treatments as prevention.

continued overleaf

It is now recommended that people commence treatment earlier and this, together with an increase in effective and tolerable treatment options, has greatly improved the prognosis for people with HIV. In making decisions as to when and how to treat based on the best clinical advice, people living with HIV are experiencing enhanced wellbeing that manifests in various ways, including an increased confidence that they will not pass on the virus to their sexual partners. We need further research to explore the relative risk associated with an undetectable viral load and sex without condoms among gay men, but the fact that treatment as prevention works so well among heterosexual couples is encouraging.

The preventative effects of treatments should not be regarded as a threat to the broader prevention effort. Effective treatment of HIV infection leads to

much improved outcomes for HIV-positive people. Healthier people are likely to be more empowered participants in the matrix of prevention activities.

Approaches to prevention should include all the strategies we currently have available. We should embrace the era of combination prevention with confidence that a greater number of strategies means a greater number of opportunities to more effectively prevent new infections. This will also assist people with HIV in the very important area of relationships and sexual wellbeing.

References

- 1 Van de Ven, P., Rawstone, P., Crawford, J., Kippax, S. (2002). Increasing proportions of Australian gay and homosexually active men engage in unprotected anal intercourse with regular and with casual partners. *AIDS Care*, 14(3). 335–341.
- 2 Van de Ven, P., Mao, L., Fogarty, A. et al. (2005). Undetectable viral load is associated with sexual risk taking in HIV

serodiscordant gay couples in Sydney. *AIDS*, 19(2), 179–184.

- 3 Vernazza, P., Hirschel, B., Bernasconi, E., Flepp, M. (2008). Les personnes séropositives ne souffrant d'aucune autre MST et suivant un traitement antirétroviral efficace ne transmettent pas le VIH par voie sexuelle. *Bulletin des médecins suisses*, 89(5).
- 4 Cohen, M., Chen, Y., McCauley M. (2011). Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *The New England Journal of Medicine*, 10,1056.
- 5 Grierson, J., Thorpe, R., Pitts, M. (2006). *HIV Futures 5: Life as we know it*, La Trobe University, Melbourne.
- 6 Merson, M., Padian, N., Coates, T. et al. (2008). Combination HIV Prevention. *Lancet*, 372.1805–06.
- 7 Padian, N., McCoy, S., Karim, S. (2011). HIV Prevention transformed: the new prevention research agenda. *Lancet*, 378, 269–278.

Sean Slavin is Assistant Director and Manager of Research Programs at NAPWA.

INTERNATIONAL MICROBICIDES CONFERENCE
SYDNEY AUSTRALIA 15-18 APRIL 2012

From discovery to delivery

www.microbicides2012.org

Scholarship and Abstracts 17 November 2011 | Early Bird Registration 31 January 2012 | Accommodation 9 March 2012 | Registration 30 March 2012



The use of HIV treatment for prophylaxis and rehabilitation

By Jae Condon

'The highest possible quality of life, for the longest possible length of time'

— Dr Sandy Beveridge

The most recent years of the HIV epidemic have been characterised by much discussion about the optimal time to start HIV treatment and health issues relating to living longer with HIV.

During a recent meeting of the Australasian Society of HIV Medicine (ASHM) GP Study Group, Dr Sandy Beveridge, Gerontologist gave a presentation on HIV and ageing. Dr Beveridge began the presentation by stating that he previously worked as an s100 Prescriber in General Practice and now works in Gerontology.

Dr Beveridge shared the philosophy of his clinical practice as being to 'maintain an individual's *'highest possible quality of life, for the longest possible length of time'*'. This statement, although perhaps considered 'a given' when providing health care, resonates more profoundly when considered in the context of the current phase of the HIV epidemic, as health issues relating to HIV and ageing have come to the fore.

'HIV and ageing' is a term used to collectively describe a number of health issues that are presenting earlier among people living with HIV than among the general population. Synergies between the ageing process, the virus, certain HIV treatments, as well as lifestyle choices are believed to contribute.¹

In the absence of a cure for HIV, or the ability to enforce lifestyle changes, improving an individual's treatment combination may be an easily implemented strategy that can help treat and prevent adverse health effects to promote a person's *'highest possible quality of life, for the longest possible length of time'*.

Treatment as primary prevention

Pre-exposure prophylaxis (PrEP) and prevention of HIV transmission

Pre-exposure prophylaxis, or PrEP, uses HIV treatment to reduce the risk of HIV infection during sex between serodiscordant couples. The iPrEx trial² evaluated the safety and effectiveness of PrEP using *Truvada*, a once daily tablet containing two medications (tenofovir/emtricitabine) and known to be effective in providing post-exposure prophylaxis, or PEP.

The trial showed that tenofovir/emtricitabine reduced risk of HIV infection by approximately 44 percent among gay men, men who have sex with men (MSM) and transgender women among whom the most common sexual behaviour was anal sex.

The FEM-PrEP³ trial among heterosexual women in sub-Saharan Africa also tested the use of once-daily *Truvada*. This trial was discontinued when an independent review found equal numbers of HIV transmission

in both the treatment and the placebo arm, suggesting that the study intervention was ineffective in preventing HIV transmission.

Treatment to reduce the risk of HIV transmission

The much anticipated 'Opposites Attract' study⁴, to be conducted by the Kirby Institute in NSW, is expected to commence soon. This observational study will be observing couples where the positive partner is *not* on treatment and couples where the positive partner *is* on treatment. The study will observe clinical, behavioural and qualitative information, with the object of study being the effect of detectable or undetectable viral load on HIV transmission.

Because of the observational nature of the study a number of related issues will be able to be researched, including semen vs blood viral load, sexual behaviour, how viral load is used to negotiate sex and condom use, knowledge of partner's viral load and the impact of receiving HIV treatment on sexual decision-making and behaviour.

The results of this work will help inform directions for treatment as primary prevention into the future.

continued overleaf

Treatments as tertiary prevention

Commencing treatment

Tertiary prevention generally describes the prevention of disease progression after the diagnosis of a health issue. Effective disease management (through antiretroviral therapy) can prevent the onset of HIV related morbidity and mortality.

The optimal goal of any HIV treatment strategy is to reduce HIV RNA viral load to the lowest level possible (i.e., 'undetectable', depending on which treatment combination and laboratory test is used), so as to restore and preserve immune function and reduce the risk of HIV-associated health issues and illness. With the increasing number of improved treatments, and with improvements in side effects, people living with HIV are more easily able to take treatments, and more easily make the decision to commence treatment. However, opinions differ regarding the optimal time to do so.

Many agree that starting treatment before an individual's CD4 count reaches 350, compared with the previous standard of 200. The results of the CASCADE study⁵ suggest few benefits of starting HIV treatment at CD4 counts of over 500, compared with CD4 counts of between 350 and 500.

Recent results of the START study⁶ show some possible advantages of commencing treatment at a CD4 count of over 650. Some even advocate for commencing treatment at the time of diagnosis, to mitigate the effects of seroconversion illness, preserve immunity and health of people living with HIV in the long term and perhaps even reduce the incidence of forward transmission.

Many also take into consideration HIV associated neuropathic disorder (HAND) when recommending the commencement or review of treatment. This specialised area of HIV medicine continues to attract great interest.⁷ Current and future research is anticipated to offer further evidence to assist with all of these treatment-related decisions.

Treatment and rehabilitation

Ongoing improvements in treatment and care have resulted in people living with HIV reporting improvements in energy, mood, mental state, sleep, cognition, digestion and health of the heart, bones, liver, kidney function, skin conditions, vitamin status and self image. These improvements are often attributed to the modification of HIV treatment combinations to address side effects and related health issues.

The ability to modify treatment combinations to improve quality of life, as well as federally funded treatment of HIV related facial lipoatrophy, have given many people the opportunity and choice to return to work, study, volunteering and relationships.

As one person recently stated:

*'Since my doctor and I changed my meds, I can go out now to for shopping for the first time in ages without feeling tired or worrying that I might s**t myself in public. I don't have to plan my day around my medication, or know where the nearest toilet is when I leave the house. My doctor says that if I exercise and lose weight I may even be able to reduce my diabetic and heart tablets. I have a family history of diabetes, and my doctor explained how my old meds increased my risk of diabetes and heart disease. It was only when I told my doctor [about my side effects] that we were able to do anything [about them]. I am really happy that I said something. You think that because you are undetectable that everything is OK, but my doctor told me that lots of things have changed, and now so has my life.'*

Conclusion: changing treatments to optimise health

The increasing numbers of HIV treatment options, including proven existing treatments, increase options for HIV specialist medical professionals and people living with HIV. In this time of expanding treatment options, are an undetectable viral load and 'healthy' CD4 count the only benchmarks by which to measure the success of HIV treatment?

People living longer with HIV are at higher risk of developing issues normally associated with ageing much earlier than expected in the general population. Because we know that some HIV treatments contribute to the development and/or progression of these health issues, regular review of HIV treatment combinations should become an integral component of HIV monitoring and care, as part of a range of strategies to promote the 'highest possible quality of life, for the longest possible length of time.'

References

- 1 For further discussions on the relationship between HIV, ageing and antiretroviral treatments, see *HIV Australia*, Volume 8, Number 3. Available at: <http://www.afao.org.au/library/hiv-australia/volume-8/number-3> (accessed 24 October 2011).
- 2 Timing of HAART Initiation and Clinical Outcomes in Human Immunodeficiency Virus Type 1 Seroconverters. (2011). Funk, M., Fusco, J., Cole, S. et. al. (the Writing Committee for the CASCADE Collaboration). 2011. *Arch Intern Med*, 171(17), 1560–1569. doi:10.1001/archinternmed.2011.401
- 3 AIDS MEDS. (2011, July 6). CD4s Above 500: HIV Treatment Need Still Unclear. Available at: http://www.aidsmeds.com/articles/hiv_australia_start_1667_20736.shtml (accessed 21 October 2011).
- 4 For an overview and related reading regarding the impact of HAART on the ageing process and HIV-cognitive impairment, including HAND, see Brew, B. (2010). HAART and mind: HIV-cognitive impairment, antiretroviral therapy and ageing. *HIV Australia*, Volume 8, Number 3. Available at: <http://www.afao.org.au/library/hiv-australia/volume-8/number-3/hiv-cognitive-impairment-HAART-and-ageing> (accessed 24 October 2011).
- 5 <http://www.iprexole.com/>
- 6 Hendrix, C. et al. MTN-001: A Phase 2 cross-over study of daily oral and vaginal TFV in healthy, sexually active women results in significantly different product acceptability and vaginal tissue drug concentrations. Eighteenth Conference on Retroviruses and Opportunistic Infections, Boston, abstract 35LB, 2011
- 7 The study will be led by The Kirby Institute's Ben Bavinton.

Jae Condon is the Treatments and Client Support Officer of the HIV Wellness Program at ACON.

From social marketing to social change: a day in the life of an HIV-prevention campaign

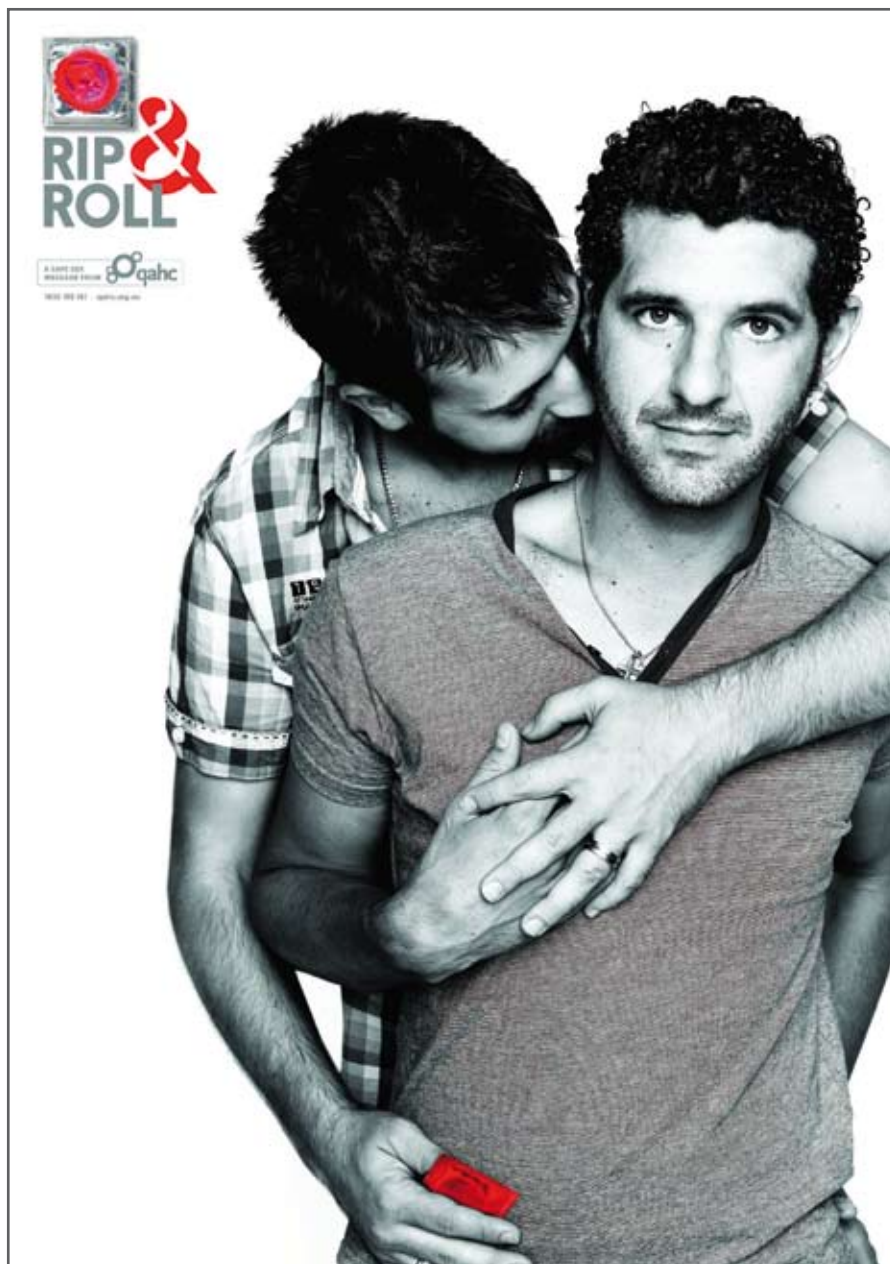
By Paul Martin

Condom social marketing has been a mainstay of gay men's HIV prevention for over two decades. However, this form of health promotion still has the potential to cause controversy, as we saw earlier this year when gay men, sex, same-sex relationships and the Christian right all converged to create the perfect media storm around Rip & Roll, a safe-sex campaign produced by Healthy Communities. Ultimately, community support from across the country and successful engagement with social media meant that Healthy Communities came through these events stronger than ever.

Background

Rip & Roll is a basic condom reinforcement campaign, promoting condom use as a community norm among gay men. Originally launched in 2010, the campaign includes press and outdoor advertisements featuring men, usually shirtless, holding an open condom wrapper and the slogan 'Rip & Roll – a safe sex message from Healthy Communities', accompanied by a picture of a condom in its wrapper. The campaign is supplemented with promotional giveaways and an online presence. The initial campaign featured on billboards and bus stops throughout Brisbane and some regional areas of Queensland. Overall feedback from the campaign was positive and we elected to run it again the following year.

In 2011 new models, including a gay couple, were selected to feature in the adverts. All models were volunteers sourced from the local gay community and the selection attempted to represent a cross-section of men of diverse age and ethnicity. This year as part of the campaign, we introduced an old-style photo booth that was taken to gay events, allowing people to create personalised strips of photos with Rip & Roll branding displayed on one of the frames. Electronic versions of the photos were uploaded to the Rip &



Roll Facebook page, allowing people to tag the images and share them with friends. Rip & Roll also featured on the cover of an edition of Time Off magazine, a prize which Healthy Communities won in an online charity auction.

The Controversy

The image of a gay male couple (pictured above) was selected for outdoor posters displayed at bus shelters and on billboards. The couple

were fully clothed and embracing each other, with one man holding a condom packet. Within 24 hours, complaints were received by all parties responsible for the campaign's outdoor visibility (Adshel, Goa Billboards, the Advertising Standards Bureau (ASB) and Healthy Communities). The following day Adshel removed the bus shelter ads. Healthy Communities was not notified directly about this removal,

continued overleaf

but found out because a number of concerned community members contacted us to ask why the campaign had been taken down.

On reviewing the complaints received by the ASB, it became clear to us that the majority of submissions shared a similar wording, including one attributed to Wendy Francis, the State Director of the Australian Christian Lobby (ACL) in Queensland. ACL's website confirmed that this connection was likely – they already issued a media release welcoming the removal of the campaign, citing a groundswell of community concern.

After verifying that Adshel had received around 40 public complaints and were in the process of removing the posters from bus shelter, Healthy Communities requested that the campaign be reinstated on the grounds that we were not breaking any laws or contravening advertising standards, along with our suspicions that the complaints seemed to have been orchestrated by a single body (the ACL).

Initially Adshel refused to reinstate the posters, prompting us to issue a media release stating that they had caved in to homophobic pressure and calling on them to put the posters back up. We also altered our contacts through Healthy Communities' email and Facebook contacts, and let the

two guys in the advert know what was happening. Michael, one of the models, then set up a Facebook event page calling for the reinstatement of the campaign and shared the message amongst his networks.

Community Response

By the next morning, over 20,000 people had indicated they were 'attending' the Facebook event page, and this figure grew to 95,000 people within two days. Healthy Communities fielded media inquiries from within Australia and from overseas for most of the day. Several other Facebook pages were set up by community members in support of the campaign and supportive emails and phone calls flooded in, along with a few complaints. A rally was rapidly arranged by Facebook users, who congregated outside Adshel's offices and the protest received extensive media coverage. Adshel offices around Australia were inundated with emails and phone calls demanding that posters be put back up.

Following an admission by Wendy Francis on ABC local radio that she was involved in the campaign to get the adverts removed, Adshel reversed its decision and reinstated the advertisements. The company claimed that they were not aware that the complaints had been orchestrated or that they had been the target of a

coordinated ACL campaign. Within 30 hours of the ads being pulled, they were back up, and Adshel gave Healthy Communities an additional two-weeks advertising at no cost.

Spin-offs

While Adshel's decision to reinstate the campaign was welcomed, many in the community still felt anger about Adshel's actions and how they were so easily influenced by a small group of Christian fundamentalists. Many of the complaints Adshel received went beyond claims that the discussion of sex should not occur in the public space (lest children see it and ask questions), but rather objected to depictions of homosexuality as normal. Some complainants even questioned the right of the guys in the picture to wear a Christian cross and wedding rings (which are actually engagement rings). The community became galvanised around the broader issue of homophobia.

Rip & Roll featured prominently in the Pride rally and march in Brisbane that was held just two weeks after the controversy exploded. Several speakers spoke about Rip & Roll at the rally and many people marched carrying the Rip & Roll couple's poster.

Goa Billboards, who did not give in to pressure to remove the Rip & Roll adverts from their billboards, joined together with other advertising companies in Brisbane in response to the level of homophobia they observed or received in connection with the campaign. In consultation with Healthy Communities, the billboard company launched the 'Embrace Acceptance' campaign, which aimed to turn the negativity against Rip & Roll into a positive. Couples and families were invited to submit pictures of themselves in the Rip & Roll embrace, and a number of these images were selected to be displayed on electronic billboards throughout Brisbane, promoting diversity in relationships and families. The campaign was delivered free of charge.

The company claimed that they were not aware that the complaints had been orchestrated or that they had been the target of a coordinated ACL campaign. Within 30 hours of the ads being pulled, they were back up, and Adshel gave Healthy Communities an additional two-weeks advertising at no cost.

Media attention on Healthy Communities led to more traffic to our website and increased donations. Around this time we also launched our 'Equality in Health' campaign promoting our work to ensure equal access to health services and health outcomes for LGBT people in Queensland, thereby building on the theme of Rip & Roll.

The ASB decision on the Rip & Roll campaign has implications for other gay men's HIV prevention advertising. The ASB found that the advertisement *'is very subtle in handling the issue of safe sex'* and that *'the overall tone of the advertisement is clearly that of a medical issue and not of a sexual issue'*. They went on to state that that 'the Board is strongly in favour of the important health message this advertisement portrays and considered that whilst some members of the community would prefer not to see this issue advertised, the public health message overrides any social sensitivity'.

Lessons Learnt

The first lesson we learnt was the speed and volume of media inquiries in response to a controversy. While we did not plan for the campaign to be controversial, we did prepare for that eventuality. Even so, fielding radio, TV and print interviews was very labour-intensive, especially while also monitoring and responding to social media and following progress of the debate in a fast-moving environment and adapting our media messages accordingly.

The real change from previous controversies (e.g. 'Bubble Boy' in 1994¹) was social media. Facebook and Twitter allowed the message of Rip & Roll to spread far and wide. It allowed people to shift from being passive consumers of a story to being active participants. Just the act of 'liking' or 'attending' a page/event helps people to feel a part of the action. Many people contributed their own comments; it was clear that supporters came from all

walks of life. We were able to use the comments from community members in our media responses.

Much of the social media activity was beyond our control. Healthy Communities didn't set up the Facebook support pages - members of the community did. The conversations about Rip & Roll and related issues weren't moderated by us, but by the online community. While it was challenging for us to keep up with the conversations across multiple media platforms, we learnt that the online community was generally self-regulating. If an extreme negative comment was posted, it would be responded to by 20 other people. Our role was to intervene with the facts, and let the community carry the debate. The community ownership that developed was a large part of the campaign's success.

The controversy surrounding Rip & Roll - which began as a simple condom reinforcement campaign - illustrated that people will become active when they see an injustice, and that social media helps to mobilise the community to action. The use of community members as models and the ability of real people to contribute their comments gave the campaign a human element and turned it from a social-marketing campaign into a social-change campaign.

Worried that the safe sex message of the campaign may have become lost in the controversy, we surveyed over 200 people several weeks later. 94% of people recognised the main message of the campaign as condom use, followed by 69% associating the message with HIV and STI prevention.

Work has begun on Rip & Roll 3.

References

- 1 'Bubble Boy was a health promotion campaign produced by the Queensland AIDS Council in 1995, designed to promote discussion of sex sex and safe injecting practices in gay hotels and nightclubs. The campaign was banned by Queensland and Commonwealth authorities for because of fears that it 'promoted' homosexuality using pornographic imagery in a 'swap card' format that would appeal to minors. See Kennedy, M. (1995). 'Bubble Boy Banned', *HIV/AIDS Legal Link*, Vol. 6, No. 1.

Paul Martin is the Executive Director of Healthy Communities.

The controversy surrounding Rip & Roll - which began as a simple condom reinforcement campaign - illustrated that people will become active when they see an injustice, and that social media helps to mobilise the community to action.

It's time to talk top: the risk of insertive, unprotected anal intercourse

By Eric M Glare

This article describes the biological role of anal mucus and its association with the gastrointestinal immune system, which harbours a persistent reservoir of HIV that potentially leads to infectious anal mucus. Eric Glare argues that all HIV prevention discussions should highlight the role anal mucus plays in HIV transmission.

Strategic positioning, where an HIV-negative man takes the insertive role in unprotected anal intercourse with an HIV-positive partner in order to reduce his risk of infection, has been associated with an intermediate incidence of HIV in cohorts of Sydney men who have sex with men (MSM).¹ Circumcision of the insertive partner and an undetectable blood plasma viral load in the receptive partner are two factors often cited as contributing to risk reduction in strategic positioning practices, despite there being a paucity of data on HIV transmission by anal intercourse in men who take the insertive role in male-to-male sex.²

Men who practise strategic positioning are attempting to take perceived risks into account to form personalised boundaries around anal intercourse but, until recently, a comprehensive understanding of HIV transmission through insertive unprotected anal intercourse has not been widely canvassed in research literature. A 2008 study of risk factors associated with HIV seroconversion in gay men in England identified that some men taking the insertive role in anal intercourse contracted HIV because they did not perceive that they were at risk of infection.³ GMFA, a gay men's health charity based in the UK, responded with a campaign called Arse Facts that identified anal mucus as a body fluid containing HIV at potentially infectious levels.⁴

Anal mucus is increasingly being mentioned in Australian campaigns as the infectious body fluid potentially infecting the insertive partner during unprotected anal intercourse.^{5,6,7} At times, the explanation of the role that anal mucus plays in transmitting HIV to the insertive partner has been

relegated to in-depth discussions of topics such as risk reduction, but is frequently left out of more introductory information about HIV transmission (e.g. Whereversexhappens.com⁸), and some campaigns discuss the risk of insertive anal intercourse without mentioning any body fluids involved⁹.

Some campaigns warn that even if an HIV-positive person has an undetectable blood plasma viral load they might have higher viral load in anal mucus, particularly if they also have another STI.^{10,11} However, it should also be noted that a recent study, looking at men who have sex with men, found that plasma and rectal viral load were correlated, and that STI in the rectum did not increase the likelihood of detecting HIV in anal mucus, including those that had low or undetectable levels of HIV in their blood.¹² This study suggests that a lower HIV viral load in blood plasma would also mean a lower viral load in anal mucus.

The role of anal and gastrointestinal mucus

Anal mucus¹³ and, more generally, gastrointestinal mucus found throughout the length of the gut are the body fluids that protect the delicate inner lining of our gastrointestinal tract. Mucus lubricates, prevents drying and protects the mucous membranes that line our nose, mouth, lungs, eyes, inner ears, our urinary-genital organs and our gut. Mucus in the gastrointestinal tract forms a defensive divide between the fragile epithelial cells that absorb nutrients and the digesting slurry of acids, enzymes, food and commensal bacteria that transit our gut.

Studies in rats have shown that the mucus in the gastrointestinal tract consists of two constantly renewed

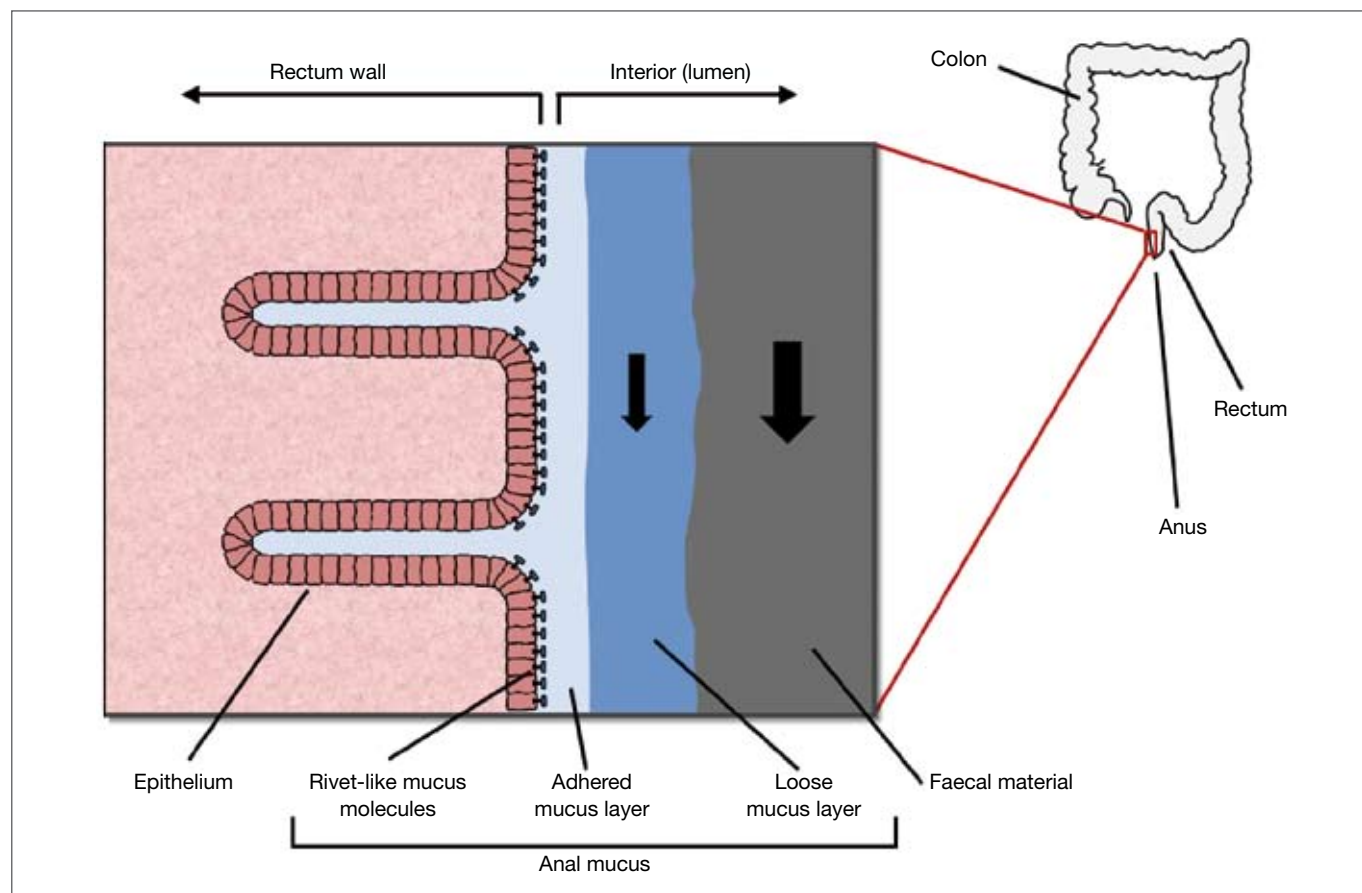
layers that in the colon total 0.15mm thick.¹⁴ The outer layer that is most exposed is loose and moves with faecal material lubricating its passage down the gut (see Figure 1). The inner mucus layer is firmly pinned to the gut wall rather like pieces of paper on a noticeboard. The adherence of the inner mucus layer allows the outer mucus layer to slide over the inner layer as material moves down the gut. This ensures that the gastrointestinal wall from oesophagus to anus is always covered and protected by a layer of mucus.

Whilst the outer layer functions in lubricating, the firmly adhered mucus layer functions more as a protective barrier from corrosive stomach acids and bacteria creating a stable microenvironment at the mucosal surface.^{15,16} The gastrointestinal tract is home to ten times more bacteria than human gut cells; these bacteria are essential for healthy nutrition but are detrimental to our health if they get into other areas of the body. Bacteria are found in the outer mucus layer but not in the inner layer of mucus which forms a tight net-like structure lining the gut epithelium. The sub-microscopic molecular pores of the mucus 'net' allow nutrients to cross to the epithelium, and viruses to varying extents, but not bacteria (Figure 1).¹⁷

Anal mucus and HIV

From the early days of the epidemic, receptive anal sex with ejaculation has been known to carry the highest risk of sexual transmission of HIV, and this is dependent on HIV penetrating the mucus layers of the rectum. What has not been widely appreciated is that mucus in the rectum of infected people also contains infectious HIV¹⁹ – virus that has moved in the opposite direction from the gut wall into the mucus²⁰.

Figure 1 Schematic diagram of the mucus layers in the anus and rectum. Rivet-like mucus molecules pin the adhered mucus layer to the epithelium¹⁸ so that the wall of the rectum is always protected. The loose mucus layer moves with faecal material (indicated by arrows) lubricating the passage of faeces by sliding over the adhered layer of mucus.



HIV viral load in anal mucus is difficult to measure, but it is typically higher than in blood plasma or semen taken from the same person, even for those on highly active antiretroviral therapy (HAART).²¹ HIV replication in the gastrointestinal tract is responsive to HAART and blood plasma viral load reflects the overall amount of active viral replication in the body. In men who had undetectable viral load in blood plasma, HIV viral particles were rarely detected (2%) in rectal samples but plenty of HIV infected cells were still found in the mucosa.²²

In a study measuring HIV shedding into the rectum, the presence of HIV-infected cells and local inflammation were the principle determinants of rectal HIV levels amongst individuals with a low plasma HIV viral load of less than 10,000 copies/mL, suggesting that the HIV was locally produced.²³ When HIV-infected cells were present in the rectal wall, increased blood plasma HIV viral load did not increase the risk of shedding of HIV into the anal-rectal canal but

inflammation from other STI – such as human papilloma virus (HPV) – did increase the amount of virus released. Although the act of taking samples could have stimulated release of HIV particles from the rectal wall or from the circulation by micro-bleeding, the trauma was likely to have been considerably less than that associated with anal intercourse.²⁴

The gastrointestinal tract is the largest immune organ in the body.²⁵ Approximately 70% of the immune system is found in the gastrointestinal tract in what is called gut-associated lymphoid tissue (GALT). The tonsils and adenoids at the back of the throat as well as a diffuse network of immune cells throughout the length of the gut are all part of the GALT.^{26,27} The major sites of HIV replication in the body are the lymph nodes and the GALT of the gastrointestinal tract; relatively little HIV is produced in the blood.²⁸

While mucus provides a physical barrier of protection, GALT harbours immune cells that can specifically target

any microorganisms that penetrate the gut mucus. In healthy people, CD4 lymphocytes are found in their largest numbers in the gut and, due to their active surveillance role, they are often mature and activated bearing co-receptors such as CCR5, preferred for HIV infection.²⁹ These CD4 cells are important both as the primary target of HIV infection following unprotected receptive anal sex and as the main source of HIV in rectal mucus that might infect subsequent insertive partners.³⁰ The role of the mucus bilayer as the bi-directional frontier of the immune defence of the gut emphasises the importance of anal and rectal mucus in HIV transmission, whether through receptive or insertive anal intercourse.

CD4 counts in blood plasma drop over the months and years following infection, but CD4 cells in the gastrointestinal tract are depleted rapidly in the acute phase of HIV infection. In a group of 32 newly

continued overleaf

infected men (mean = 37 days from infection), CD4 cells in the gastrointestinal wall were greatly reduced within the first few weeks of infection.³¹ Impressively, the study included six men first sampled within 19 days of infection. The study found that gastrointestinal CD4 cells remained depleted at more than 50% of normal levels, even in people who had a relatively normal blood CD4 count due to long-term HAART.³²

The enduring depletion of gastrointestinal CD4 cells indicates a failure of immune reconstitution of GALT in the gut despite active recruitment of effector and naive CD4 cells.³³ This is currently an active area of research; it has been found that some of the CD4 cells are – as expected – killed by cycles of HIV infection, but other uninfected CD4 cells are killed by inflammation as bystanders to the primary fight against HIV.³⁴

From the earliest stages of infection of the many CD4 cells in the gastrointestinal mucosa, HIV causes a breakdown in the delicate balance protecting the gut wall from bacteria and their toxins. Epithelial cells struggle to maintain and repair junctions between cells, leading to impaired barrier function and increased permeability of the epithelium.³⁵ This damage allows toxins and microbes to invade the gut wall and the circulation close-by. Bacterial products can be found in the bloodstream of people with HIV. Known as microbial translocation, this process triggers systemic immune activation.³⁶ The immune response increases HIV replication increases activation of CD4 cells and their susceptibility to HIV infection, and induces immune cell death in the gastrointestinal tract. Essentially, the immune response against microbial translocation amplifies the damage caused by HIV in the gut, preventing effective immune reconstitution in many people.

It is not known what happens to the mucus bilayer during microbial translocation but it is likely that it is disorganised and not efficient at protecting the gut wall.

The implication of the failed immune reconstitution in the gastrointestinal tract is that the gut is a major reservoir of HIV persistence – even in people receiving HAART.³⁷ This, in turn, suggests that anal mucus might be the body fluid most capable of returning to infectious levels of HIV, albeit momentarily, in people on well-maintained HAART.

Interestingly, a Sydney study of men who have sex with men conducted from 2001 to 2007 found that the per-contact probability of HIV transmission due to unprotected anal intercourse, both insertive and receptive, was similar to estimates from developed countries in the pre-HAART era.³⁸ This was despite the more recent cohort having a high proportion of HIV-infected men who were on HAART and had an undetectable blood plasma viral load.

The immunobiology of the anus and rectum strongly implicates anal mucus in HIV transmission; it is not known to what extent blood contributes to transmission, although micro-bleeding is thought to occur during anal intercourse. In the absence of a major bleed from conditions such as haemorrhoids, fissures, tears and trauma, the predominant body fluid by volume is likely to be mucus, although this has not yet been confirmed by specific data.

Implications for HIV education

From an educational point of view, talking about anal mucus makes sense. Anal mucus is macroscopic, it is visible particularly with diarrhoea or after douching, and people can feel its moistness; microscopic invisible blood has none of these associations. Anal mucus is well known to people who practise fisting, where keeping individualised aliquots of lubricant from cross-contamination with body fluids is central to play-etiquette.³⁹ Anal mucus can vary in appearance from clear to white, or brown. Because people can see and feel mucus, they can understand the role it plays in HIV transmission through their own personal association with the body fluid. Mucus provides a more powerful,

less mysterious mechanism for transmission than microscopic blood.

Vaginal mucus is directly analogous to anal mucus in HIV transmission and whilst blood is likely to be a factor and a plausible mechanism of vaginal-penile transmission, in prevention education vaginal mucus is said to be the infectious body fluid. The rectum is much more susceptible to trauma than the vagina, as the rectal wall is very thin compared to the vagina and more easily damaged, and there is a much bigger stigma against anal intercourse that jointly might account for the comparative lack of anal mucus in many explanations of transmission.

In both vaginal and anal intercourse, blood resulting from rough sex, binge sex, large toys and fisting is seen as an amplifier of the risk of transmission (e.g. see *Wherever sex happens*⁴⁰). Talking about anal mucus counters stigma that says anal sex is not natural and causes tissue damage which facilitates transmission. This conversation makes HIV transmission seem a more normal biological process because it does not rely solely on the explanation of damage to the rectum to facilitate transmission; HIV is present in mucus in the rectum, not just further away in the circulation.

During anal sex, HIV can be transmitted to the insertive partner when a bodily fluid containing HIV from the receptive partner, such as anal mucus, enters the body of the insertive partner. This can occur through the foreskin and surrounding areas, the eye of the penis to the urethra (also a mucous membrane), or through tiny (often invisible) breaks in the skin of the penis.

HIV prevention discussions that neglect to explain how the insertive partner in anal sex is infected leave a hole in the discourse as well as a gap in the understanding of how HIV is transmitted during anal sex. Explaining the potential roles of both anal mucus and blood is a direct rebuttal to the taboo of talking about the specifics of anal sex. This must be good for prevention.

References

- 1 Jin, F., Crawford, J., Prestage, G., et al. (2009). HIV risk reduction behaviours in gay men: Unprotected anal intercourse, risk reduction behaviours, and subsequent HIV infection in a cohort of homosexual men. *AIDS*, 23(2), 243–252. doi:10.1097/QAD.0b013e32831fb51a
- 2 Jin, F., Jansson, J., Law, M., Prestage, G., et al. (2010). Per-contact probability of HIV transmission in homosexual men in Sydney in the era of HAART. *AIDS*, 24(6), 907–913. doi:10.1097/QAD.0b013e3283372d90 Link: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2768371/>
- 3 INSIGHT case-control study findings: Elam G., Macdonald, N., Hickson, F., et al. (2008). Risky sexual behaviour in context: qualitative results from an investigation into risk factors for seroconversion among gay men who test for HIV. *Sex Transm Infect*, 84(6), 473–7. doi:10.1136/sti.2008.031468 See also: Macdonald, N., et al. (2008). Factors associated with HIV seroconversion in gay men in England at the start of the 21st century. *Sex Transm Infect*, 84(1), 8–13.
- 4 GMFA – the gay men's health charity. (2008). *Arse Facts*. Available at: <http://www.gmfa.org.uk/londonservices/adcampaigns/arse-facts/arse-facts-info> (accessed 5 October 2011).
- 5 ACON. (2007). *HIV & AIDS – The Basics: A safe sex guide for gay men*. Available at: www.acon.org.au/sites/default/files/Safe-Sex-Basics_0.pdf (accessed 29 September 2011).
- 6 Australian Federation of AIDS Organisations (AFAO). (2002). *HIV+ Gay Sex: A booklet about being gay, having HIV and sex*. AFAO, Sydney. Available at: http://www.afao.org.au/_data/assets/pdf_file/0017/4706/HIV_gaysex.pdf (accessed 29 September 2011).
- 7 Australian Federation of AIDS Organisations (AFAO). 2008. *The Drama Downunder*. [Online] (See specifically: Introduction/STIs and HIV transmission HIV/How do you get it?) Available at: <http://thedramadownunder.info>. (accessed 29 September 2011).
- 8 Victorian AIDS Council/Gay Mens Health Centre (VAC/GMHC). *Wherever sex happens*. (see specifically: risk reduction: tops and bottoms) [Online] Available at: <http://whereversexhappens.com/> (accessed 5 October 2011).
- 9 Victorian AIDS Council/Gay Men's Health Centre (VAC/GMHC). (2010). *Staying Negative*. [Online]. (See specifically: HIV/AIDS and safe sex: bottom or passive partner). Available at: [www.stayingnegative.net.au](http://stayingnegative.net.au) (accessed 5 October 2011).
- 10 AFAO 2008, op. cit. (See specifically: Introduction/STIs and HIV transmission/ HIV-positive men and STIs).
- 11 VAC/GMHC *Wherever sex happens*, op. cit. (See specifically: risk reduction: sections 'undetectable viral load' and 'tops and bottoms').
- 12 Kelley C. F., Haaland R. E., Patel P., Evans-Strickfaden T., Farshy C., Hanson D., et al. (2011) HIV-1 RNA rectal shedding is reduced in men with low plasma HIV-1 RNA viral loads and is not enhanced by sexually transmitted infections in the rectum. *J Infect Dis.*, 205(5), 761–67. doi:10.1093/infdis/jir400
- 13 Mucus (noun) is the secretion produced by mucous (adjective) membranes. Anal mucus is used elsewhere and here for simplicity, particularly for people who do not have English as their first language. Much of the research refers to rectal mucus because that is where the fluid was sampled; also referred to as mucosal secretions or rectal secretions. Anorectal mucus is probably the most accurate name for the body fluids involved in HIV transmission but this has not been confirmed by specific data to date.
- 14 Atuma, C., Strugala, V., Allen, A., and Holm, L. (2001). The adherent gastrointestinal mucus gel layer: thickness and physical state in vivo. *Am J Physiol Gastrointest Liver Physiol*, 280(5), G922–9. Available at: <http://ajpgi.physiology.org/content/280/5/G922.long>
- 15 ibid.
- 16 Phillipson, M., Johansson, M., Henriksnäs, J., et al. (2008). The gastric mucus layers: constituents and regulation of accumulation. *Am J Physiol Gastrointest Liver Physiol*, 295(4), G806–12. doi: 10.1152/ajpgi.90252.2008 Link: <http://ajpgi.physiology.org/content/295/4/G806.long>
- 17 Johansson, M., Phillipson, M., Petersson, J., et al. (2008). The inner of the two Muc2 mucin-dependent mucus layers in colon is devoid of bacteria. *Proc Natl Acad Sci USA*, 105(39), 15064–9. doi:10.1073/pnas.0803124105
- 18 ibid.
- 19 Zuckerman, R., Whittington, W., Celum, C., et al. (2004). Higher Concentration of HIV RNA in Rectal Mucosa Secretions than in Blood and Seminal Plasma, among Men Who Have Sex with Men, Independent of Antiretroviral Therapy. *The Journal of Infectious Diseases*, 190(1), 156–61. doi: 10.1086/421246
- 20 Kiviat N., Critchlow C., Hawes S., et al. (1998). Determinants of Human Immunodeficiency Virus DNA and RNA Shedding in the Anal-Rectal Canal of Homosexual Men. *The Journal of Infectious Diseases*, 177(3), 571–8. doi:10.1086/514239 Link: <http://jid.oxfordjournals.org/content/177/3/571.long>
- 21 Zuckerman, R. et al., op. cit.
- 22 The mucosa is the mucous membrane layers forming the inner surface of organs such as the gastrointestinal tract; includes the epithelium and aggregates of immune cells in GALT follicles. In: Lampinen, T. M., Critchlow, C. W., Kuypers, J., et al. (2000). Association of antiretroviral therapy with detection of HIV-1 RNA and DNA in the anorectal mucosa of homosexual men. *AIDS*, 14(5), F69–75. Available at: http://journals.lww.com/aidsonline/Fulltext/2000/03310/Association_
- of_antiretroviral_therapy_with.1.aspx (accessed 4 October 2011).
- 23 Kiviat, N. B., et al., op. cit.
- 24 ibid.
- 25 Janeway, C., Travers, P., Walport, M., and Shlomchik, M. (2001). *Mucosal Immunity*. In: Janeway, C., Travers, P., Walport, M., and Shlomchik, M. J. (eds.), *Immunobiology, 5th Edition: The immune system in health and disease*. Garland Science, New York, 10.13–10.20. Available at www.ncbi.nlm.nih.gov/books/NBK27169/ (accessed 4 October 2011).
- 26 ibid.
- 27 Spahn, T. and Kucharzik, T. (2004). Modulating the intestinal immune system: the role of lymphotoxin and GALT organs. *Gut*, 53(3), 456–65. doi:10.1136/gut.2003.023671
- 28 Mehndru, S., Poles, M., Tenner-Racz, K., et al. (2007). Mechanisms of gastrointestinal CD4+ T-cell depletion during acute and early human immunodeficiency virus type 1 infection. *J Virol*, 81(2), 599–612. doi:10.1128/JVI.01739-06
- 29 Brenchley, J., Schacker, T., Ruff, L., et al. (2004). CD4+ T cell depletion during all stages of HIV disease occurs predominantly in the gastrointestinal tract. *J Exp Med*, 200(6), 749–59. doi:10.1084/jem.20040874
- 30 Kiviat, N. et al. op. cit.
- 31 Mehndru, S. et al. (2007). op. cit.
- 32 Mehndru, S., Poles, M., Tenner-Racz, K., et al. (2006). Lack of mucosal immune reconstitution during prolonged treatment of acute and early HIV-1 infection. *PLoS Med*, 3(12), e484. doi:10.1371/journal.pmed.0030484
- 33 Hofer, U., and Speck, R. (2009). Disturbance of the gut-associated lymphoid tissue is associated with disease progression in chronic HIV infection. *Semin Immunopathol*, 31(2), 257–66. doi:10.1007/s00281-009-0158-3
- 34 ibid.
- 35 Shacklett, B. and Anton, P. (2010). HIV infection and gut mucosal immune function: Updates on pathogenesis with implications for management and intervention. *Curr Infect Dis Rep.*, 12(1), 19–27. doi:10.1007/s11908-009-0072-9
- 36 Hofer, U. and Speck, R. op. cit.
- 37 Shacklett, B. and Anton, P. op. cit.
- 38 Jin, F. et al. (2010), op. cit.
- 39 Herman, B. (1991). *Trust the hand book: A guide to the sensual and spiritual art of handballing*. Alamo Square Press, San Francisco.
- 40 VAC/GMHC *Wherever sex happens*, op. cit. (see specifically: Drug use/decreased physical awareness and Risk reduction/ tops and bottoms/there are other risk factors/point 5)

Eric Glare (PhD) is a PLHIV speaker and educator with the Positive Speakers Bureau, People Living With HIV/AIDS Victoria. He did his PhD studies on PCR technology and the gene expression of CD4 cells in asthma and allergy and is now retired as a biomedical researcher.



Regional Feature: Testing, treatment and prevention among gay and other men who have sex with men in Japan – an update

By **Jane Koerner** and **Seiichi Ichikawa**

Japan is a country with low HIV prevalence by international standards. In 2009, less than 0.1% of the total population were estimated to be living with HIV.¹ Despite this, the yearly number of cases of HIV in Japan has been steadily rising, with dramatic increases observed among men who have sex with men since 2000.²

At the end of 2010, there were a total of 18,342 cumulative reports of people with HIV and or AIDS in Japan; this cumulative figure consists of 11,573 people with HIV and 5,330 people with AIDS. Additionally, there were 1,439 reports of people becoming infected through blood products prior to 1986.³

In 2010, 68% of new cases of HIV were acquired through male-to-male sexual transmission, while heterosexual transmission accounted for 18% of cases.⁴ Gay men and other men who

have sex with men are therefore deemed a priority population in terms of HIV prevention in Japan.⁵ Continued increases in Japan's HIV rates, along with disproportionate rates of HIV among men who have sex with men have led gay community-based groups, through funding by the Japan's Ministry of Health, Labour and Welfare (MHLW), to focus on capacity development activities around testing and treatment, and to support the development of awareness campaigns targeting gay men and other men who have sex with men.

Japan's response to HIV is based around the provision of education, voluntary HIV counseling and testing, and access to high quality HIV treatments.⁶ While gay men and other men who have sex with men are designated as a priority group in relation to HIV policy, efforts

to date have not slowed the steady increase in cases of HIV among this group. This article summarises recent HIV testing, treatment and prevention initiatives in Japan, particularly those that target priority populations of gay men and other men who have sex with men, and makes recommendations for future directions.

HIV testing

Japan's HIV testing policy is based on the provision of free and anonymous testing at public health centres, but the majority of these centres only provide HIV testing for a two to three hour period one day per week.⁷ A few local governments have contracted volunteer based non-government organisations (NGOs) to provide rapid HIV testing services in the evenings and on weekends and non-anonymous HIV

tests are also available at hospitals and clinics, but the cost is not fully covered by health insurance.

While there has been little research into the accessibility of HIV testing services, a survey conducted among men who have sex with men attending a community-organised HIV testing event in Nagoya found that 66.5% of respondents reported that HIV testing at public health centers is difficult to access due to limited available times for HIV testing is and lack of information on where to go for testing.⁸

In 2006, the MHLW provided funding through the Japan Foundation for AIDS Prevention for a five-year strategic research project that aimed to increase HIV testing rates and reduce AIDS diagnoses among the general population and men who have sex with men in the Tokyo and Osaka areas.⁹ One of the project's aims was to increase gay and bisexual men's awareness of gay-friendly HIV counseling and support services, using gay community campaigns produced by NGOs. This was accompanied by workshops for public health centre staff to increase their capacity to address the needs of gay and bisexual men. Community campaigns promoting HIV testing and the merits of early diagnosis were also conducted in 2010.

While the final results of all this work are yet to be published, the project has fostered a range of collaborations between local government and NGOs that work with gay and HIV-positive people. The project has also successfully collated a range of information on HIV testing, counseling and support services for men who have sex with men. Furthermore, the NGOs involved with the project were able to extend their outreach to previously unreached groups piloting new information tools, and support HIV testing projects.

A future priority is to increase the availability and capacity of gay-friendly HIV testing services around the country, which at this time remain variable in their capacity to provide non-judgmental HIV testing and counseling. We believe that improving the accessibility and sensitivity of public health centre HIV testing would

benefit not only gay, bisexual and other men who have sex with men, but also other groups using HIV testing services, including sex workers, young people, foreigners and people who use drugs.

Treatment

The standard of medical treatment for HIV available in Japan is high, with new antiretroviral drugs rapidly included into treatment regimen guidelines and made available at a minimal basic cost through health insurance. While health insurance is available to all Japanese residents, access requires legal residence status and is dependent on the payment of monthly health insurance premiums; people with low incomes and illegal foreign workers are precluded from accessing health insurance, and are therefore also unable to access subsidised HIV treatments.¹⁰

People living with HIV and AIDS also face high levels of social stigma and many people have concerns about employers and others finding out about their HIV status.^{11,12} There have been a number of recent studies conducted regarding social isolation¹³, work-related issues¹⁴, and treatment issues¹⁵ faced by people living with HIV. In relation to HIV-positive gay and bisexual men, research regarding attitudes and behaviours relating to safe sex practices indicates the need for more targeted programs to reduce stigma and increase condom usage among these groups.¹⁶

A recent internet survey of people living with HIV investigated respondents' experiences of receiving a positive HIV test. Of the 239 respondents, 49.8% stated that sex and sexuality-related issues were not adequately addressed by the medical professional providing the test result; only 48.5% were given follow-up information at the time of diagnosis (such as how to prevent HIV transmission; whether it was okay for them to have sex; how to prevent HIV transmission; whether it was necessary to disclose their status to sexual partners etc.).¹⁷ These results indicate a reluctance among health workers to discuss sex and sexuality related-issues with HIV-positive people. This highlights the need for more post-diagnosis support and counseling services for gay and bisexual men – and more training for health practitioners, particularly in regional areas as HIV counseling and support services are concentrated in the largest cities of Tokyo and Osaka.

Prevention

The first baseline behavioural study – providing data on gay and bisexual men's HIV knowledge, HIV testing rates and condom use – was undertaken

continued overleaf

People living with HIV and AIDS also face high levels of social stigma and many people have concerns about employers and others finding out about their HIV status. There have been a number of recent studies conducted regarding social isolation, work-related issues, and treatment issues faced by people living with HIV.

Survey location and sample	Tokyo Gay Club Survey					Osaka Gay Club Survey								Osaka Gay Bar Survey		
Survey year	2001 ^a	2003 ^a	2005 ^a	2007 ^a	2009 ^a	1999 ^b	2002 ^c	2003 ^c	2004 ^c	2006 ^c	2008 ^c	2010 ^c	2005 ^d	2007 ^d	2009 ^d	
Number of participants	n=539	n=529	n=934	n=1039	n=942	n=498	n=403	n=596	n=592	n=687	n=856	n=943	n=496	n=912	n=1315	
Experience of HIV testing																
Past year	25.1	25.4	36.0	37.0	47.3	19.5	34.3	31.4	35.7	38.0	41.1	46.1	27.2	29.5	26.8	
Lifetime	—	—	—	—	—	34.1*	—	—	—	—	—	—	—	54.2	51.8	
Rate of condom use during anal sex with men in past six months																
100% use with casual partners	49.4	66.1	63.1	63.1	55.7	56.5	56.5	59.2	62.1	66.6	71.3	71.8	44.9	54.8	54.0	
100% use with regular partners	42.8	54.9	56.6	55.4	54.4	45.9	45.9	46.2	51.4	61.2	63.6	62.4	34.1	39.2	42.6	
HIV NGO program recognition																
Knowledge of gay community centre		21.0	42.3	—	—	—	—	26.2	44.4	33.6	48.7	52.0	30.0	39.8	59.3	
Knowledge of gay community paper		—	—	—	—	—	—	38.2	52.0	33.4	40.2	48.2	73.4	64.4	70.6	

Table 1 HIV testing, condom use and HIV NGO knowledge among men who have sex with men in Japan

- Kimura, H., et al., *Osaka sex behaviour survey – Findings from the 2010 Osaka Club Survey, in Study Group on the Development and Implementation of Community-based HIV Prevention Interventions for MSM Heisei 22 Research Report*, S. Ichikawa, Editor. 2011, Ministry of Health Labour and Welfare: Tokyo. p. 168–179.
- Ichikawa, S., (2003.) Prevention Intervention among MSM (men who have sex with men) – Project MASH Osaka. *Japanese Journal of AIDS Research*, 5(3): 174–18.
- Kimura, H., et al., (2010). *Evaluation of HIV prevention interventions in Osaka – Findings of the 2009 Club Survey in Study Group on the Development and Implementation of Community-based HIV Prevention Interventions for MSM, Heisei 22 Research Report*, S. Ichikawa, Editor. Ministry of Health Labour and Welfare: Tokyo. 171–180.
- Shiono, S., et al., (2010.) Evaluation of Osaka's HIV Interventions and of the factors related to HIV preventive behaviors: Findings from the 2009 Bar survey, in *Study Group on the Development and Implementation of Community-based HIV Prevention Interventions for MSM Heisei 20 Research Report*, S. Ichikawa, Editor. Ministry of Health Labour and Welfare: Tokyo. 195–243.

* Past five years

in Osaka in 1999, following a successful partnership between gay men, researchers and a local government health official. The results obtained were instrumental in informing HIV prevention activities in Osaka, and this model was repeated in other regions, funded through research grants from the MHLW. However, it was not until 2003 that the first specifically targeted prevention programs for men who have sex with men were funded through the provision of grants to fund community centres.

The first centres were established in Tokyo and Osaka in 2003, and there are now six centres operating in Nagoya (since 2004), Fukuoka (2006), and Sendai and Naha in Okinawa in 2009.

The establishment of community centres operated by NGOs and located in districts containing gay bars has been instrumental in facilitating networking between HIV prevention and support NGOs, gay commercial venues, community event organisers and individuals, but efforts were hampered by the lack of staff as most of the centers were only funded for one part time position (or less) per centre. In March 2011, the MHLW announced a new policy initiative to fund HIV programs for men who have sex with men in six cities, including Tokyo, Osaka, Nagoya, Sendai, Fukuoka, and Okinawa. This funding will be used to conduct information outreach delivering condoms and publications

to gay commercial venues, and conduct other prevention and support activities. While this is an encouraging new step, NGO capacity remains rather weak, with small numbers of staff (currently nine positions nationally).

To date, HIV prevention activities have been evaluated through surveys conducted at gay clubs and gay bars, and mobile phone RDS surveys; survey findings indicate some success in increasing condom use, HIV testing, and NGO activities (see Table 1). Behavioural surveys indicate that prevention activities need to be extended to older gay and bisexual men, and that school-based HIV and sex education is needed for young gay and bisexual men.

While a few local governments have included men who have sex with men in their HIV testing and prevention policies and plans, the vast majority do not have any targeted HIV testing and prevention programs or plans. In order to extend prevention activities nationally, it is critical that NGO capacities are scaled-up and that local governments implement initiatives that include men who have sex with men in developing local HIV policies. Furthermore, a national coordinating body needs to be established, which includes representatives from national and local government to coordinate and direct the response in relation to gay and bisexual men. HIV policy is currently under review by the MHLW, with outcomes of the review expected in the next months.

Future challenges

This article has outlined initiatives which have attracted recent funding from the Ministry of Health, Labour and Welfare. There has been no commitment to maintain or scale up activities, and in view of the huge levels of government support needed for rebuilding efforts following the Northern Kanto tsunami and Fukushima nuclear reactor meltdown, there is a concern that resources will be diverted. In view of the continued increase in HIV infections among men who have sex with men in Japan, improved coordination and funding to increase gay friendly HIV testing, to support gay community HIV prevention efforts and to support people with HIV, must be continued.

References

- 1 UNAIDS. (2010). *Report on the global AIDS Epidemic*. Available at: UNAIDS Report on the global AIDS epidemic 2010 www.unaids.org/globalreport/Global_report.htm (accessed 25 October 2011).
- 2 National AIDS Surveillance Committee. (2010). *UNGASS Country Progress Report: Japan (Report to UNAIDS – HIV/AIDS Trends in Japan December 2009)*. Available at: http://www.unaids.org/en/dataanalysis/monitoringcountryprogress/2010progressreportsubmittedbycountries/japan_2010_country_progress_report_en.pdf (accessed 21 October 2011).

- 3 National AIDS Surveillance Committee, *HIV/AIDS in Japan, 2010*. (2011). AIDS Prevention Information Network. Available at: <http://api-net.jfap.or.jp/status/2010/10nenpo/gaiyou.pdf> (accessed 26 October 2011) (in Japanese).
- 4 *ibid.*
- 5 Akino, K. (2008). Various policies for HIV/AIDS control after the revision of AIDS Prevention Guideline. in M. Kashiwazaki, (ed.). *Challenging practices on HIV/AIDS in Japan, 2008*, Japanese Foundation for AIDS Prevention, Tokyo. Available at: http://www.jfap.or.jp/english/booklet/2008/data/1/003_akino.pdf (accessed 21 August 2011).
- 6 *op. cit.* (Akino, K 2008).
- 7 See HIV test search homepage www.kensa.com (in Japanese).
- 8 Kaneko, N., Utsumi M., and Ichikawa S. (2007). HIV testing behaviour and HIV preventive behaviour among gay and bisexual men in Tokai area. *Japanese Journal of Nursing Research*. 30(4): 194–43 (in Japanese).
- 9 See Strategic Research Homepage http://www.jfap.or.jp/strategic_study/index.html (in Japanese).
- 10 Tarui, M., Sawada, T., and Castro-Vazquez, G. (2004). *Issues Concerning Human Rights and HIV/AIDS of Non-Japanese Workers, in Expert Meeting on HIV/AIDS and Human Rights in Asia-Pacific*. Bangkok. Available at http://www.aidslex.org/site_documents/I010E.pdf (accessed 21 August 2011).
- 11 Yajima, T., Hasegawa, H., Ikushima, Y., and Inoue, Y. (2008). *Future and Long Life Series: Connected to society connected to people: Treatments, Work, Love, Future*. PLACE Tokyo, Japan Network of People living with HIV/AIDS. Available at: <http://www.ptokyo.com/publications/booklets.php> (in Japanese) (accessed 21 August 2011).
- 12 Ikushima, Y. and Wakabayashi C. (2009). People living with HIV/AIDS: Work, life, and community. In Y. Ikushima, Editor. *Study group on the support for HIV-positive people and others in regional areas*. PLACE Tokyo, Japan Network of People living with HIV/AIDS. Available at: http://www.chiiki-shien.jp/resource.html#a_tool [in Japanese] (accessed 21 August 2011).
- 13 Yajima, T. et al. *op. cit.*
- 14 Ikushima, Y. et al. *op. cit.*
- 15 Ikushima, Y., Takaku Y., Nagano K., Hasegawa H., Yajima T., and Inoue Y. (2009). *Future & Long Life Series: Thinking about treatments in the era of long-term HIV treatment*. PLACE Tokyo, Japan Network of People living with HIV/AIDS. <http://www.ptokyo.com/publications/booklets.php> [in Japanese].
- 16 Inoue, Y., Yamazaki Y., Kihara M., Wakabayashi C., Seki Y., and Ichikawa S. (2006). The intent and practice of condom use among HIV-positive men who have sex with men in Japan. *AIDS Patient Care and STDs*, 20(11), 792–802.
- 17 Yajima, T., Takaku Y., Nagano K., Hasegawa H., Ikushima Y., and Inoue Y. (2011). *The experience of 239 people with HIV about the experience of being informed about their HIV status*, PLACE Tokyo, Japan Network of People Living with HIV/AIDS. <http://www.ptokyo.com/publications/booklets.php> (in Japanese).

Jane Koerner is a Research Associate in the Study Group on HIV Prevention Interventions among Men who have sex with Men, which is funded by the Ministry of Health, Labour and Welfare, and located at Nagoya City University. Jane has been working on HIV related issues in Japan for more than a decade. Professor Seiichi Ichikawa is Head of the Study Group on HIV Prevention Interventions among Men who have sex with Men, and has been working with gay NGOs in conducting HIV prevention, support and research since 1998.

There has been no commitment to maintain or scale up activities, and in view of the huge levels of government support needed for rebuilding efforts following the Northern Kanto tsunami and Fukushima nuclear reactor meltdown, there is a concern that resources will be diverted.



WEB WATCH:

The redevelopment of www.afao.org.au

On September 22, the Australian Federation of AIDS Organisations (AFAO) launched our new look website. Initially established in 1998, the site was last restructured at the end of 2004.

The development of the new website was a consultative process involving staff, AFAO members, external stakeholders and an Australian web development company.

The major goals of the redevelopment were to improve navigational function and to better promote work and resources produced by AFAO, our members, and other relevant organisations. The redeveloped site aims to be a leading Australian portal to HIV/AIDS information, news and resources.

Key strategies to achieve these goals are: a restructured home page, a revised site structure, banner ads, featured links, related articles listings and a searchable Library, all of which add up to multiple entry points to information throughout the site.

Because currency of information is vital, all pages on the new site have been revised and updated. Older resources and policy documents have been retained for historical interest, but flagged as 'Archived'.

Look, feel and accessibility

Throughout the redevelopment process, we were mindful that the site conformed to the World Wide

Web Consortium's Web Content Accessibility (W3CAG) Guidelines standards as much as possible. We also used large heading fonts throughout and included a link to accessibility tips on every page. The design avoids the use of flash-based animations and uses only one scrolling banner per page.

The new design makes greater use of visual communication. In February we coordinated a photo shoot to obtain images that would enhance and represent site content. Use of images add a human face, keeping the site more warm, engaging and personal than if we had to rely on generic stock images. Colourful promotional banners set against the textured charcoal background complement the images and invite the user to further explore the site.

Finding your way around

In recognition that there are different audiences using the site, the homepage has been restructured to feature prominent entry points related to our most common search queries and priority audiences. The heading 'I WANT TO...' on the left hand side of the page, links to information on common 'tasks' users wish to fulfil: getting an HIV test, finding an appropriate HIV service, migrating to Australia, and making donations to HIV organisations.

The second grouping, 'INFO FOR ...' at right, links to gateway pages with information for key site users: people with HIV, people who think they may have been exposed to HIV, family and friends, gay men, students, journalists, and policy advocates.

The home page also features a 'Latest News' section highlighting news and new resources from Australia and abroad. At time of going to press this section featured news from CHOGM, a promotion for the survey HIV Futures Seven, and information related to findings from the recent GP Workforce project. Users can subscribe to an RSS feed for latest news.

The site navigation menu has also been restructured to better reflect user interests and needs rather than AFAO's organisational structure. A 'breadcrumb' trail above the content on every page helps users track their location within the site's structure.

Lists of 'Related Articles' links appear prominently on every page and thumbnail images and banners promote pages, resources, events and research programs relevant to the page.

What else is new?

The most significant new feature is the 'Library' section, which stores all AFAO's policy documents and health promotion resources. The library is available from the top-level menu on the home page and includes: discussion and briefing papers, fact sheets, literature reviews, posters, reports, submissions, training kits and of course, *HIV Australia*. The Library is searchable by keywords and topic, making it easier for users to find relevant information when they don't know the exact name of documents they are searching for.

Our revised Links section now includes links to online campaigns and resources produced by AFAO and our members.

A new section on research links to latest HIV-related prevention, treatments and social research findings and provides information about participating in research.

We have also made our jobs and events pages more interactive, enabling users to post their own jobs and events (subject to moderation).

What do you think?

Participants involved with initial user-testing during the site development are positive about the final result, however there is still further user-testing to be done to fine-tune the live site. We also invite you to give us your feedback using the feedback forms now on the bottom of most pages on the site, or by emailing web@afao.org.au

BY JILL SERGEANT, WEBSITE OFFICER AND FINN O'KEEFE, COMMUNICATIONS OFFICER AT AFAO.
JILL AND FINN WORKED TOGETHER ON THE AFAO WEBSITE REDEVELOPMENT PROJECT.



BOOK REVIEW:
'OUT HERE: GAY AND LESBIAN PERSPECTIVES VI'
 Edited by Yorick Smaal, Graham Willett. Published by Monash University publishing

Yorick Smaal and Graham Willett's 'Gay and Lesbian Perspectives VI' (2011) is the latest in the series of collections drawn from the annual conference on Australia's Homosexual Histories'. As such, it aims to provide, in the editors' words, 'an accessible collection of some of the latest scholarship on lesbian, gay and queer histories' (p. xii).

The first thing to notice about this collection is that it's very much more gay than it is lesbian. The editors note that the chapters are organised around 'politics, medicine, HIV/AIDS, lesbianism, and finally, the gay male world' (p. xii). They neglect to mention that the chapters on politics relate to law reform as it applies to gay men, medical perspectives on male homosexuality, and HIV/AIDS among gay men. As a result, only two of the thirteen chapters are about women, which seems likely to disappoint any lesbians who get as far as buying the book.

That aside, each of the essays in this collection adds to the mosaic of Australia's gay and lesbian history – uncovering people and episodes that are so easily erased or simply forgotten. Yorick Smaal's own essay on gay men's social networks in Queensland during World War Two, for example, is quite fascinating. Taken from police records, Smaal builds a picture of gay life in wartime Brisbane, and explores the methods that homosexual men used to find each other and build

social networks and relationships at a time when public discourse about homosexuality was virtually non-existent. Similarly, Peter Di Scascio rehabilitates Australia's lesbian artists, against the backdrop of an art world and a society that have consistently erased both women artists and lesbian sexuality.

Unfortunately many of these articles are disappointing, in terms of the analysis they offer – perhaps because the same issues of marginalisation and invisibility keep recurring in gay and lesbian history. For example, Roberta Foster glibly dismisses the significance of historical gender non-conformity, saying that, 'for these people, the drag act existed as a challenging gesture disconnected from identity politics' (Why? Who says? And what is 'identity politics' anyway?). By contrast the drag kings of Melbourne's King Vic Hotel 'deconstruct' gender in a 'potent arena where hegemonic arrangements of gaze and spectatorship are challenged' (p. 162) and 'subjectivity, bodies, space and spectatorship are radically reinscribed' (p. 165). Through all this postmodern gobbledygook, Foster's analysis seems to be a straightforward re-hash of Judith Butler's (1990) influential argument that drag, through its caricatures of gender norms, has the capacity to highlight the socially constructed nature of gender in general.

Similarly, Emily Wilson argues that the medicalised discourse of homosexuality influenced early responses to HIV/AIDS in Australia. No surprises there. But a more interesting line of inquiry (and to be fair, one which is probably outside the parameters of Wilson's research) would be to explore the ways in which medical discourses of HIV continue to construct gay men's lives and behaviour in medical terms.

In this respect, Robert Hurley makes what to my mind is the most interesting argument, in his piece about the current state of the HIV epidemic – a current situation which is intimately bound up with recent history. Hurley argues HIV is now



endemic among gay men but more importantly, that the meaning of the virus has changed now that it has become de-coupled from 'AIDS' and all that that term implies. To expect a continually falling rate of new HIV infections is, he believes, no longer realistic in this context. To suggest that HIV is not as scary as it once was is not particularly original, but Hurley goes beyond this to explore the implications of this for HIV educators and policy-makers. How can HIV prevention and education remain relevant in a situation where gay men are fully aware of the virus and yet choose to take risks? Situating these men as problematic or even pathological is not tenable, let alone effective. Hurley says that he takes the 'long view' (p. 131) on the epidemic, noting that it took 600 years to overthrow feudalism. Let's hope that the history of HIV/AIDS and, indeed, of the marginalisation of gays and lesbians, is much shorter than that.

Free ebook version available at:
<http://books.publishing.monash.edu/apps/bookworm/download/epub/Out+Here%3A+Gay+and+Lesbian+Perspectives+VI/126/>



TREATMENT BRIEFS

US PANEL UPDATES ANTIRETROVIRAL TREATMENT GUIDELINES

On 14 October the US Department of Health and Human Services (DHHS) issued updated guidelines for the use of antiretroviral therapy (ART) in adults and adolescents, coinciding with the release of revised European AIDS Clinical Society (EACS) guidelines at the 13th European AIDS Conference, held October 12–15 in Belgrade.

The key changes in these new US guidelines relate to which drugs to start in a first-line regimen for treatment-naïve patients. The Australasian Society for HIV Medicine website provides a commentary on the DHHS guidelines.

DETECTABLE VIRAL LOAD ASSOCIATED WITH POOR CONTROL OF CO-MORBID CONDITIONS

Recent US research suggests that poor control of HIV is associated with suboptimal management of other serious health conditions.¹ The study involved patients receiving antiretroviral therapy, who also had diabetes and/or hypertension (high blood pressure). A detectable viral load was associated with poorer control of the co-morbid conditions. A total of 70 patients with diabetes and 291 individuals with hypertension were included in the study.

‘This is the first study to demonstrate that poor control of HIV-1 RNA is directly correlated with poor control of diabetes and hypertension, two comorbidities of increasing importance in the management of patients with HIV infection,’ comment the investigators. Traditional risk factors,

the inflammatory effects of untreated HIV, and the side-effects of some antiretroviral drugs may all be causing these co-morbid conditions.

HIV therapy demands high levels of treatment adherence, as does control of diabetes and hypertension. The study authors state that poor adherence is likely to account for their findings. ‘Our findings demonstrate that poor HIV control is related to poor control of diabetes and hypertension, and we suspect that poor adherence to therapy for HIV is correlated with poor adherence to other conditions,’ write the authors.

‘Research on how patients prioritise medications for their comorbidities in relation to their HIV medications could shape treatment adherence programs,’ the investigators conclude, stating that ‘the most successful adherence programs combine several interventions...our results argue that the scope of these programs should be expanded to include both antiretroviral agents and agents for other comorbidities.’

Reference

- 1 Monroe, A. et al. (2011). Control of medical comorbidities in individuals with HIV. *J Acquir Immune Defic Syndr*, online edition. doi:10.1097/QAI.0b013e31823801c4.

HIV TREATMENT AT 500 CD4 LEVEL WOULD PUT 50% OF PATIENTS IN NEED OF ART WITHIN A YEAR OF SEROCONVERSION

Raising the CD4 cell threshold for the initiation of antiretroviral therapy to 500 cells/mm³ would mean that almost 50% of patients would need to start HIV treatment within a year of their infection with HIV, investigators from an international study of seroconverters report in the 15 October edition of *Clinical Infectious Diseases*.¹

A threshold of 350 cells/mm³ would result in approximately a third of patients starting therapy within a year of infection with the virus. Large numbers of patients with HIV are

diagnosed late and the investigators comment: ‘Our findings provide strong support for public health campaigns to encourage early HIV infection diagnosis and testing.’

The earlier initiation of HIV therapy appears to have several advantages. For instance, the results of observational studies suggest that it reduces the risk of both HIV-related and non-HIV-related illnesses. Moreover, prompt therapy may also have public health benefits, significantly reducing the risk of onward HIV transmission.

Raising the CD4 cell threshold for the initiation of therapy will have cost implications for health systems, many of which are already struggling. Investigators from the CASCADE (Using Concerted Action on AIDS and Death In Europe) study analysed the medical records of 18,495 individuals with a known date of HIV seroconversion, to predict the amount of time between infection with the virus and a fall in CD4 cell count to below 500, 350 and 200 cells/mm³. They also calculated the proportion of patients who would reach these CD4 cell count thresholds one, two and five years after infection with HIV.

‘These data signify a substantial increase in the number of individuals who require treatment within the first five years after becoming infected following the recent changes in [US and WHO] guidelines,’ write the authors. ‘These estimates...will be essential to health care planners estimating the additional costs of increasing the CD4 cell count threshold for cART (combination antiretroviral therapy) initiation.’

Reference

- 1 Lodi, S. et al. (2011). Time from human immunodeficiency virus seroconversion to reaching CD4+ cell count threshold <200, <350, and <500 cells/mm³: assessment of need following changes in treatment guidelines. *Clin Infect Dis*, 53(8), 17–25.

Michael Carter, *Aidsmap*

● Subscribe to *HIV Australia*

If you're not already receiving a copy of *HIV Australia* but would like to, please complete your details below and return to *HIV Australia*, PO Box 51, Newtown NSW 2042 Australia or fax to (+61 2) 9557 9867

Name
Organisation
Address
Country
Email
Telephone

● November

28–2 December

6th SAHARA Conference

Port Elizabeth, South Africa

<http://www.sahara.org.za/chairman-message/conference-chair-message>

29–2 December

2011 International Conference on Family Planning

Dakar, Senegal

<https://www.conftool.com/fpconference2011>

● December

1–3

BIT's 2nd Annual World AIDS Day (HIV-2011)

Beijing, China

www.bitlifesciences.com/HIV2011

4–8

16th International Conference on AIDS and STIs in Africa (ICASA)

<http://www.icasa2011addis.org>

6–9

5th International Workshop on HIV Persistence: The Reference Workshop on HIV Reservoirs

St Martin, West Indies

<http://www.informedhorizons.com/persistence2011>

2012

● January

9–10

2nd International Workshop on HIV and Women

Bethesda MD, United States

<http://www.virology-education.com>

18–20

15th Bangkok International Symposium on HIV Medicine

Bangkok, Thailand

www.hivnat.org/symposium/sb15th

● February

20–21

Surveillance and/in Everyday Life: Monitoring Pasts, Presents and Futures

Sydney, Australia

<http://surveillanceandeveryday.com>

20–22

International Science Symposium on HIV and Infectious Diseases

Chennai, India

<http://hivscience.yrgcare.org>

13–15

10th Biennial AIDS Impact Meeting

<http://www.aidsimpact.com/2011>

● March

21–23

10th European Meeting on HIV and Hepatitis: Treatment Strategies and Antiviral Drug Resistance

Barcelona, Spain

<http://www.virology-education.com>

● April

12–13

Silence & Articulation: 12th Social Research Conference on HIV, Hepatitis C and Related Diseases

Sydney, Australia

<http://nchsrconference2012.arts.unsw.edu.au>



KEEP EVERYTHING
HAPPY
DOWNUNDER!

GET TESTED,
GET TREATED
NO DRAMA!

WWW.THEDRAMADOWNUNDER.INFO

